DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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| D2094 | 493.841(e) ROUTINE CHEMISTRY<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.<br>(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investation of ungraded alkaline phosphatase (ALP) PT results for the 3rd event of 2014. Findings include:<br><br>a. The laboratory was enrolled with the College of American Pathologists (CAP) PT program for ALP for the 3rd event 2014.<br><br>b. The CAP results showed that five of five samples (CHM-06 through CHM-10) were ungraded with a code [20].<br><br>c. There was no documenation that the ungraded ALP results had been investigated.<br><br>d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results.<br><br>e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or | D2094 | D2094<br>The lab has investigated this ungraded PT event for ALP and has documented its investigation and conclusions.<br><br>The new lab director has approved enhanced procedures for proficiency testing, which reinforce the lab's systems for the investigation of ungraded PT results. The lab's technical supervisors will be responsible for ensuring that these procedures are implemented and followed.<br><br>The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action for ungraded proficiency tests with outcomes of less than 100%. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures. | 2/12/16 |

| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|---|---|---|
| Kingshuk Das Digitally signed by Kingshuk Das Date: 2016.02.12 10:18:05 -08'00' | Lab Director | 2/12/16 |

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| D2094 | Continued From page 1<br>documented. | D2094 | | |
| D2128 | 493.851(e) HEMATOLOGY<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.<br>(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investigation of ungraded blood cell identification PT results and failed to investigate and document the investigation of an unsatisfactory blood cell identification PT result for the 2nd event of 2014.<br>Findings include:<br><br>a. The laboratory was enrolled with the American Proficiency Institute (API) PT program for blood cell identification for the 2nd event 2014.<br><br>b. The API results showed that two of five samples (BCI-13, BCI-14) were ungraded.<br><br>c. The API results showed that BCI-11 was graded as "unacceptable."<br><br>d. There was no documenation that the | D2128 | D2128<br>Two out of two challenges for "Blood Cell ID (Educational)" were "Not Graded" for the second API event of 2014. The lab has investigated this ungraded PT event and documented its investigation and conclusions.<br><br>Four out of five challenges for "Blood Cell Identification" were acceptable for the second API event of 2014, meaning that the PT event received a passing grade. The lab has investigated the one unacceptable challenge and documented its investigation and conclusions.<br><br>The new lab director has approved enhanced procedures for proficiency testing, which reinforce the lab's systems for investigation of ungraded PT results and any challenges that receive an unacceptable grade. The lab's technical supervisors are responsible for ensuring that these procedures are implemented and followed.<br><br>The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action | 2/12/16 |

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| D2128 | Continued From page 2<br>ungraded and unsatisfactory results had been investigated.<br><br>e. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results.<br><br>f. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or documented. | D2128 | D2128 (continued)<br>for proficiency tests with outcomes of less than 100% or challenges that are ungraded. In addition, the lab will monitor compliance through its improved occurrence management and audit procedures. | |
| D5024 | 493.1215 HEMATOLOGY<br><br>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1269, and §§493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met. The laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403); document CBC calibrations (see D5437); include two QC materials with differing white blood cell (WBC) patterns each day of testing (see D5447); verify stated values of commercially assayed CBC controls (see D5469); ensure QC for PT/INR was acceptable prior to reporting patient test results (see D5481); follow corrective action policies and procedures as necessary to maintain the laboratory operation for testing patient CBC specimens in a manner that ensured accurate | D5024 | D5024<br>The laboratory has completed assessments to identify any patients affected or having the potential to be affected by the issues identified in this observation, and has taken corrective and preventative action. Among other things, the lab has hired a new lab director and established improved quality systems and procedures addressing the issues identified in this observation. (D5403, D5437, D5447, D5469, D5481, D5779, D5801). | 2/12/16 |

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| D5024 | Continued From page 3<br>and reliable patient test results and reports (see D5779); have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's CBC processes and [redacted] corrective actions taken to resolve problems (see D5779); and ensure that the calculated International Normalized Ratio (INR) results were accurate prior to reporting final patient results (see D5801). | D5024 | | |
| D5217 | 493.1236(c)(1) EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing records and interview with the General Supervisor, the laboratory failed to investigate and document an investigation of ungraded troponin proficiency testing (PT) results from the 2nd event 2014. Findings include:<br><br>a. The laboratory was enrolled in proficiency testing for troponin with the American Proficiency Institute (API) for the 2nd event 2014.<br><br>b. Troponin results for five of five specimens (CM-06 through CM-10) were ungraded by API.<br><br>c. There was no documentation that the ungraded results had been investigared or reviewed by the laboratory personnel.<br><br>d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results. | D5217 | D5217<br>Troponin I results for the second event of 2014 were "Not Graded" due to "No Consensus" for all challenges. The lab has investigated this ungraded PT event and documented its investigation and conclusions.<br><br>The new lab director has approved enhanced procedures for proficiency testing, which reinforce the lab's systems for investigation of ungraded PT results. The lab's technical supervisors are responsible for ensuring that these procedures are implemented and followed.<br><br>The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action for ungraded proficiency tests. In addition, the lab will monitor compliance through its improved | 2/12/16 |

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| D5217 | Continued From page 4<br>e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or documented. | D5217 | D5217 (continued)<br>occurrence management and audit procedures. | |
| D5311<br>110H<br>120H<br>140H<br>210B<br>220B<br>310B<br>320M<br>330B<br>340B<br>400B<br>510M | 493.1242(a) SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable:<br>(1) Patient preparation.<br>(2) Specimen collection.<br>(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.<br>(4) Specimen storage and preservation.<br>(5) Conditions for specimen transportation.<br>(6) Specimen processing.<br>(7) Specimen acceptability and rejection.<br>(8) Specimen referral.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and pre-analytic policies and procedures record review on September 23, 2015, the laboratory failed to establish written policies and procedures for patient specimen labeling. Findings included:<br><br>a. It was the practice of the laboratory to require that all patient specimens received be labeled with laboratory generated bar codes that were issued at the point of specimen collection.<br><br>b. The laboratory maintained no written policies and procedures detailing this patient specimen labeling policy and procedure.<br><br>c. According to laboratory records, the laboratory performed approximately [redacted] patient tests annually. | D5311 | D5311<br>As noted in the findings, it was the practice of the lab to label all patient specimens with lab-generated bar codes issued at the point of collection. Those bar codes and related software properly tracked patient specimens.<br><br>The new lab director has approved written policies and procedures addressing patient specimen labeling. The lab's supervisors, quality systems director, and lab director will be responsible for ensuring that these procedures are implemented and followed.<br><br>The lab will provide oversight of accessioning through monthly QA meetings. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures, both of which address preanalytic activities. | 2/12/16 |

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| D5391<br>110H<br>120H<br>140H<br>210B<br>220B<br>310B<br>320M<br>330B<br>340B<br>400B<br>510M | 493.1249(a) PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br><br>1. Based on laboratory personnel interviews and pre-analytic remedial action record review on September 23, 2015, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems when received patient specimens did not meet the laboratory's criteria for acceptability. Findings included:<br><br>a. According to laboratory personnel, during the accessioning of patient specimens, if a patient specimen was received that did not meet the laboratory's criteria for acceptability, a description as to why the specimen did not meet the laboratory's criteria for acceptability would be electronically noted, applicable laboratory personnel would be notified, appropriate corrective actions would be taken and electronically noted, and the incident would be captured for quality assessment review.<br><br>b. The laboratory maintained no written policies and procedures detailing this quality assessment process.<br><br>c. According to laboratory records, the laboratory performed approximately [redacted] | D5391 | D5391 #1<br>As noted in the findings, if a patient specimen did not meet the lab's acceptance criteria, the lab's practice was to describe the issue in its electronic system, to notify relevant lab personnel, and to take, and electronically note, appropriate corrective action. Patient specimens that did not meet the lab's acceptance criteria were not used for testing.<br><br>The new lab director has approved enhanced specimen rejection procedures, which require the relevant lab personnel to further monitor and assess received patient specimens and to correct problems as needed. These procedures also require a supervisor to review and approve daily a list of requested redraws. The lab has conducted training on these procedures.<br><br>During monthly QA meetings, the lab will review, among other things, specimen rejection rates and any associated issues. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures, both of which address preanalytic activities.<br><br>The new lab director is responsible for | 2/12/16 |

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| D5391 | Continued From page 6<br>patient tests annually.<br><br>2. Based on laboratory personnel interviews and patient specimen referral policies and procedures record review on September 23, 2015, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems for patient specimens referred to other laboratories for testing. Findings included:<br><br>a. According to laboratory personnel, a log of patient specimens referred to other laboratories for testing was reviewed daily to ensure the timely receipt and reporting of the test results performed by the other laboratories.<br><br>b. The laboratory maintained no written policies and procedures detailing this quality assessment process. | D5391 | D5391 #1 (continued)<br>the lab's QA program, and has also appointed a Quality Director who will provide additional oversight.<br><br>D5391 #2<br>As noted in the findings, the lab's practice was to review its log of patient specimens referred to other labs to ensure the timely receipt and reporting of the test results performed by the other labs.<br><br>The new lab director has approved enhanced procedures for referral testing, which require, among other things, the lab to document its review of pending orders and results for referral tests, including the lab's log of patient specimens referred to other labs.<br><br>The lab's management, including the lab director and quality systems director, is responsible for monitoring and assessing compliance with these procedures, and ensuring that corrective action is taken as needed. The lab also requires monitoring of turnaround times for reference labs and related issues during monthly QA meetings, through regular audits, and through its improved occurrence management. | 2/12/16 |
| D5393<br>110H<br>120H<br>140H<br>210B<br>220B<br>310B<br>320M<br>330B<br>340B<br>400B<br>510M | 493.1249(b)(c) PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and patient specimen referral policies and procedures record review on September 23, 2015, the | D5393 | | |

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| D5391 | Continued From page 6<br>patient tests annually.<br><br>2. Based on laboratory personnel interviews and patient specimen referral policies and procedures record review on September 23, 2015, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems for patient specimens referred to other laboratories for testing. Findings included:<br><br>a. According to laboratory personnel, a log of patient specimens referred to other laboratories for testing was reviewed daily to ensure the timely receipt and reporting of the test results performed by the other laboratories.<br><br>b. The laboratory maintained no written policies and procedures detailing this quality assessment process. | D5391 | (Continued) | |
| D5393<br><br>110H<br>120H<br>140H<br>210B<br>220B<br>310B<br>320M<br>330B<br>340B<br>400B<br>510M | 493.1249(b)(c) PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and patient specimen referral policies and procedures record review on September 23, 2015, the | D5393 | D5393<br>As noted in the findings, the lab's practice was to review its log of patient specimens referred to other labs to ensure the timely receipt and reporting of the test results performed by other labs.<br><br>The new lab director has approved enhanced procedures for referral testing, which require, among other things, that review of referral testing logs will be documented. | 2/12/16 |

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| D5393 | Continued From page 7<br>laboratory failed to document all preanalytic systems quality assessment activities, specifically for patient specimens referred to other laboratories for testing. Findings included:<br><br>a. According to laboratory personnel, a log of patient specimens referred to other laboratories for testing was reviewed daily to ensure the timely receipt and reporting of the test results performed by the other laboratories.<br><br>b. The laboratory maintained no documentation indicating that the patient specimen referral log was reviewed daily. | D5393 | D5393 (continued)<br>The lab's management, including the lab director and quality systems director, is responsible for overseeing compliance with these procedures. The lab also requires monitoring of turnaround times for reference labs and related issues during monthly QA meetings, through regular audits, and through its improved occurrence management. | |
| D5400 | 493.1250 ANALYTIC SYSTEMS<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to have a procedure manual that included corrective action for chemistry quality control (QC) (see D5403); failed to have procedures signed, dated, and approved by the laboratory director prior to use (see D5407); failed to have freezer temperature consistent with manufacturer | D5400 | D5400<br>The laboratory has completed assessments to identify any patients affected or having the potential to be affected by the issues identified in this observation, and has taken corrective and preventative action. Among other things, the lab has hired a new lab director and established improved quality systems and procedures addressing the issues identified in this observation. (D5403, D5407, D5413, D5421, D5423, D5429, D5437, D5447, D5449, D5469, D5477, D5481, D5775, D5779, D5787, D5791, D5793). | 2/12/16 |

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| D5400 | Continued From page 8<br>requirements (see D5413); failed to verify performance specifications on the Advia XPT (see D5421); failed to establish performance specification when the alkaline phosphatase test system was modified (see D5423); failed to perform weekly maintenance on the Evolis (see D5429); failed to document hematology calibration (see D5437); failed to include two quality control materials at least once each day WBC differentials were performed (see D5447); failed to include positive quality control materials each day patient specimens were assayed (see D5449); failed to verify the criteria for acceptability of quality control materials for hematology and chemistry (see D5469); failed to check blood agar plates for its ability to support growth (see D5477); failed to ensure that QC test results met the laboratory's criteria for acceptability for Prothrombin Time/International Normalized Ratio and the [redacted] prior to reporting patient test results (see D5481); failed to have a system that twice per year evaluated and defined the relationship for WBC differentials and the [redacted] (see D5775); failed to follow hematology corrective action policies and procedures (see D5779); failed to have a record system that documented the lot number of media used to test patient bacteriology specimens (see D5787); failed to follow quality assessment (QA) policies and procedures (see D5791); and failed to monitor the effectiveness of corrective actions and revise policies and procedures to prevent recurrence of problems (see D5793). | D5400 | | |
| D5403<br><br>400M | 493.1251(b) PROCEDURE MANUAL<br><br>The procedure manual must include the following when applicable to the test procedure: | D5403 | D5403 #1:<br>The laboratory proactively paused testing on the Advia 2120i during the survey. The lab has completed an | 2/12/16 |

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| D5403 | Continued From page 9<br>(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.<br>(2) Microscopic examination, including the detection of inadequately prepared slides.<br>(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.<br>(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.<br>(5) Calibration and calibration verification procedures.<br>(6) The reportable range for test results for the test system as established or verified in §493.1253.<br>(7) Control procedures.<br>(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.<br>(9) Limitations in the test methodology, including interfering substances.<br>(10) Reference intervals (normal values).<br>(11) Imminently life-threatening test results, or panic or alert values.<br>(12) Pertinent literature references.<br>(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.<br>(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and the laboratory's hematology Advia 2120i | D5403 | D5403 #1 (continued)<br>assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures that address the corrective actions to take when QC fails to meet the lab's acceptability criteria, and the lab has conducted training on those procedures. The new lab director has also approved an enhanced SOP for CBC on the Siemens Advia 2120i that addresses the corrective actions to take when calibration or QC fail to meet the lab's acceptability criteria<br><br>Before the lab resumes any tests on the Siemens Advia 2120i, it will conduct training on those procedures. In addition, lab staff will be required to demonstrate competency to ensure that practice is consistent with these procedures. In addition, prior to resuming any test on this instrument, the lab will re-verified the test in accordance with its improved method verification procedures.<br><br>Lab management, including the lab director, technical supervisors, and quality director, is responsible for compliance with these procedures. | |

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| D5403 | Continued From page 10<br>procedure record review on November 19, 2015, the laboratory failed to have a procedure manual that included the corrective action to take when calibration or quality control results failed to meet the laboratory's criteria for acceptability. Findings included:<br><br>a. It was the practice of the laboratory to test patient venous complete blood counts (CBC) specimens using a Siemens Advia 2120i instrument.<br><br>b. In the laboratory's procedure titled "SOP Advia 2120i Operation and Maintenance," there was no written protocol for the corrective action to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability.<br><br>c. Between February 2015 and September 21, 2015, the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120i.<br><br>2. Based on review of the quality control (QC) procedure for the [redacted] and documentation provided by the laboratory, the laboratory failed to have a procedure for QC prior to 5/15/2014. Findings include:<br><br>a. CL SOP-15026 Revision A, [redacted] Daily QC Procedure" revealed an effective date of 5/15/2014.<br><br>b. A chart provided by the laboratory indicated that [redacted] analytes run on the above system were put into use for patient testing prior to 5/15/2014. The initial use dates of the [redacted] analytes ranged from 11/6/2013 through | D5403 | D5403 #1 (continued)<br>The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures.<br><br>D5403 #2<br>The lab performed QC for the [redacted] both before and after May 15, 2014. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures that address the corrective actions to take when QC | 2/12/16 |

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| D5403 | Continued From page 11<br>5/9/2014. | D5403 | D5403 #2 (continued)<br>fails to meet the lab's acceptability criteria, and the lab has conducted training on those procedures. | |
| D5407 | 493.1251(d) PROCEDURE MANUAL<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br>This STANDARD is not met as evidenced by:<br>Based on review of procedures and interview with the technical supervisor, the current laboratory director (LD) failed to sign, date and approve procedures prior to use. Findings include:<br><br>a. The current LD start date was 2/10/2015.<br><br>b. Eight procedures were reviewed. Seven of seven procedures did not include a LD signature prior to putting into use and one of one was not signed by the current LD.<br><br>c. CL SOP-09161, Revision A (Apolipoprotein) showed an effective date of 12/5/2014, but was not signed by the LD until 9/19/2015. It was signed by a technical supervisors "for the LD." The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>d. CL SOP-10001, Revision B (Measuring Prothrombin Time-Innovin (PT) on the Siemens BCS XP Instrument) showed an effective date of 12/5/2014, but was not signed by the LD until 9/19/2015. The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>e. CL SOP-06060, Revision A (SensoScientific Monitor) showed an effective date of 6/23/2015, but was not signed by the LD until 9/22/2015. | D5407 | Lab management, including technical supervisors, the lab director, and the quality director, will be responsible for ensuring compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5403 | Continued From page 11<br>5/9/2014. | D5403 | | |
| D5407 | 493.1251(d) PROCEDURE MANUAL<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br>This STANDARD is not met as evidenced by:<br>Based on review of procedures and interview with the technical supervisor, the current laboratory director (LD) failed to sign, date and approve procedures prior to use. Findings include:<br><br>a. The current LD start date was 2/10/2015.<br><br>b. Eight procedures were reviewed. Seven of seven procedures did not include a LD signature prior to putting into use and one of one was not signed by the current LD.<br><br>c. CL SOP-09161, Revision A (Apolipoprotein) showed an effective date of 12/5/2014, but was not signed by the LD until 9/19/2015. It was signed by a technical supervisors "for the LD." The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>d. CL SOP-10001, Revision B (Measuring Prothrombin Time-Innovin (PT) on the Siemens BCS XP Instrument) showed an effective date of 12/5/2014, but was not signed by the LD until 9/19/2015. The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>e. CL SOP-06060, Revision A (SensoScientific Monitor) showed an effective date of 6/23/2015, but was not signed by the LD until 9/22/2015. | D5407 | D5407<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The new lab director has approved enhanced document control policies and procedures to ensure that the relevant personnel approve new or revised documents before they become effective. The lab has conducted training on those procedures.<br><br>All active SOPs relevant to testing currently being performed have been approved by the new lab director.<br><br>The lab has appointed a Document Control Manager whose responsibilities include tracking new and revised policies and procedures to ensure they are reviewed, approved, and signed by the lab director before they become effective.<br><br>The lab will provide oversight of document control through monthly | 2/12/16 |

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| D5407 | Continued From page 12<br>f. CL SOP-15036, Revision A[redacted] Daily QC Procedure) showed an effective date of 12/5/2014, but was not signed by the LD until 9/19/2015. The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>g. CL PLN-14003, Revision A (Master Validation Chemistry Assays on[redacted]) showed an effective date of 11/4/2011, but was not signed by the LD until 9/19/2015. The procedure was not signed, dated and approved by any LD prior to 9/19/2015.<br><br>h. Three of three procedures for the[redacted] (Glucose/CL SOP-09118, Carbon Dioxide (CO2)/CL SOP-09111, Alkaline Phosphatase/CL SOP-81102) were put into use in December 2014. The CO2 and alkaline phosphatase procedures were not signed, dated and approved by the LD until 9/19/2015. The glucose procedure was not signed, dated and approved by the LD. | D5407 | D5407 (continued)<br>QA meetings, and will monitor compliance through its new audit procedures. | |
| D5413 | 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:<br>(1) Water quality.<br>(2) Temperature.<br>(3) Humidity.<br>(4) Protection of equipment and instruments from | D5413 | D5413 #1<br>A review of hourly data demonstrated that average hourly temperature for nearly all of the freezers at issue met the manufacturer temperature requirements for the materials stored. The lab has identified and discarded any materials that had the potential to have been affected. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue. | 2/12/16 |

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| D5413 | Continued From page 13<br>fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br>This STANDARD is not met as evidenced by:<br>1. Based on observation and document review, the laboratory failed to define freezer temperature ranges that were consistent with the manufacturer's instructions for freezers which stored reference materials and patient specimens. Findings include:<br><br>a. A tour of the laboratory where the freezers were kept showed that the freezer doors were labeled with the laboratory's acceptable temperature ranges.<br><br>b. Four of four -80 C freezers were marked with a temperature range of -60 to -90 C.<br><br>c. Six of six -20 C freezers were marked with a temperature range of -17 to -25 C.<br><br>d. Review of two manufacturer instructions for samples stored in the -80 freezers required that the samples be kept at "at least -80 C."<br><br>e. Review of 3 manufacturer instructions for samples stored in the -20 freezers required that the samples be kept at "at least -20 C."<br><br>f. The [redacted] and technical supervisor confirmed at 11/19/15 at approximately 11 am that the freezers were labeled with the above ranges and that the ranges did not meet the manufacturers instructions.<br><br>2. Based on review of the procedure, manufacturer package insert (PI) and | D5413 | D5413 #1 (continued)<br>The new lab director has approved enhanced temperature management procedures to reinforce monitoring of temperature and environmental conditions and storage of materials according to the manufacturer's temperature range. The lab has conducted training on those procedures.<br><br>The lab's management, including the new lab director and quality systems director, will ensure compliance with these procedures, including by making sure that supervisors perform their respective duties effectively. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5413 | Continued From page 14<br>observation, the laboratory failed to follow the manufacturer instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:<br><br>a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2015.<br><br>b. The general supervisor stated that the package inserts were usually white.<br><br>c. The package insert for lot number 539280 was pink which indicated that the manufacturer had included special instructions for the specific lot number of Innovin.<br><br>d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.<br><br>e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date.<br><br>f. CL SOP-10001 Revision A, "Measuring Prothrombin Time..." stated on page 10, section 12.1 that "the package insert for a new lot must be reviewed for any changes before use."<br><br>g. The general supervisor confirmed on 9/23/15 that the change in storage and stability of the Innovin reagent had not been identified from March 2015 through September 2015. | D5413 | D5413 #2<br>This PT/INR issue related to one lot. The lab paused testing on the Siemens BCS XP, including PT/INR, during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced reagent qualification and management procedures that reinforce the lab's practice of ensuring that manufacturer inserts and notifications are reviewed and followed. The lab has conducted training on those procedures.<br><br>Before the lab resumes PT/INR testing, the lab will reinforce with relevant testing personnel the importance of reviewing and following instructions on manufacturer inserts and notifications, including instructions concerning expiration dates. The same type of training will occur for personnel conducting other tests. These trainings, along with competency testing, will ensure that practice is consistent with these procedures. | 2/12/16 |
| D5421 | 493.1253(b)(1) ESTABLISHMENT AND VERIFICATION OF PERFORMANCE | D5421 | Lab management, including the new lab director, technical supervisors, and | |

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| D5413 | Continued From page 14<br>observation, the laboratory failed to follow the manufacturer instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:<br><br>a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2015.<br><br>b. The general supervisor stated that the package inserts were usually white.<br><br>c. The package insert for lot number 539280 was pink which indicated that the manufacturer had included special instructions for the specific lot number of Innovin.<br><br>d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.<br><br>e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date.<br><br>f. CL SOP-10001 Revision A, "Measuring Prothrombin Time..." stated on page 10, section 12.1 that "the package insert for a new lot must be reviewed for any changes before use."<br><br>g. The general supervisor confirmed on 9/23/15 that the change in storage and stability of the Innovin reagent had not been identified from March 2015 through September 2015. | D5413 | D5413 #2 (continued)<br>quality director, is responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |
| D5421 | 493.1253(b)(1) ESTABLISHMENT AND VERIFICATION OF PERFORMANCE | D5421 | | |

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|---|---|---|---|---|
| D5421 | Continued From page 15<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:<br>(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:<br>(1)(i)(A) Accuracy.<br>(1)(i)(B) Precision.<br>(1)(i)(C) Reportable range of test results for the test system.<br>(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br>This STANDARD is not met as evidenced by:<br>1. Based on review of the performance specification verification documentation and interview with the general supervisor and technical supervisor, the laboratory failed to maintain any documentation that the laboratory had participated in conducting the verification of the performance specifications on the Advia XPT. Findings include:<br><br>a. The general supervisor and techincal supervisor stated that the manufacturer performed all of the performance specification verification activities on the Advia XPT.<br><br>b. They further stated that the laboratory staff were available to prepare quality control material and gathering patient samples for the manufacturer representative to perform the verification.<br><br>c. The [redacted] confirmed that the manufacturer had performed the verification of performance specifications on the Advia XPT. | D5421 | D5421 #1:<br>The lab proactively paused testing on the Advia XPT during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>Before the lab resumes any test on the Advia XPT, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the new lab director. These improved procedures reinforce that the lab's testing personnel are required to actively participate in method verification and document their participation.<br><br>Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins.<br><br>The lab has conducted training on these procedures to ensure that practice is consistent with them. | 2/12/16 |

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| D5421 | Continued From page 15<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:<br>(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:<br>(1)(i)(A) Accuracy.<br>(1)(i)(B) Precision.<br>(1)(i)(C) Reportable range of test results for the test system.<br>(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br>This STANDARD is not met as evidenced by:<br>1. Based on review of the performance specification verification documentation and interview with the general supervisor and technical supervisor, the laboratory failed to maintain any documentation that the laboratory had participated in conducting the verification of the performance specifications on the Advia XPT. Findings include:<br><br>a. The general supervisor and techincal supervisor stated that the manufacturer performed all of the performance specification verification activities on the Advia XPT.<br><br>b. They further stated that the laboratory staff were available to prepare quality control material and gathering patient samples for the manufacturer representative to perform the verification.<br><br>c. The [redacted] confirmed that the manufacturer had performed the verification of performance specifications on the Advia XPT. | D5421 | D5421 #1 (continued)<br>Lab management, including the new lab director, technical supervisors, and quality systems director, is responsible for ensuring compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | 2/12/16 |

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| D5421 | Continued From page 16<br><br>2. Based on review of verification procedures, verification documentation and interivew with general supervisor and technical supervisor, the laboratory failed to verify accuracy, precision, and/or reportable range for calcium, albumin, apolipoprotein, triglyceride, carbon dioxide, and glucose. In addition, the laboratory failed to verify the reference interval (normal range) for carbon dioxide. Findings include:<br><br>a. CL QOP-00022, "Verification of Procedures Revision A", effective 8/12/14, stated in Section V.B.1.a. in order to determine accuracy "at least 20 samples of various reactivity's should be compared between the method and the old method...if a second method is not available onsite, compare 20 samples tested by a different method used by a different laboratory." The procdures also stated that the validation plan should determine what percentage of accuracy is acceptable.<br><br>b. CL QOP-00022, "Verification of Procedures Revision A", effective 8/12/14, stated in Section V.B.1.b. that "a replication experiment" is used to determine precision. The procedure further stated that "at least 20 samples of various reactivity's are run 2 or 3 times and results compared. Duplicate runs may be on different days or by different microbiologists..." The procedure also required that the percentage of precision for acceptability must be determined.<br><br>c. CL QOP-00022, "Verification of Procedures Revision A", effective 8/12/14, stated in Section V.B.1.c. that the reportable range "is the range of test results from the lowest to the highest that are reliable and therefore reportable." | D5421 | D5421 #2<br>The lab proactively paused testing on the Advia XPT during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>Before the lab resumes any test on the Advia XPT, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the new lab director. These enhanced procedures reinforce the required steps and acceptance criteria that must be followed to verify accuracy, precision, reportable range, and reference intervals before a test is put into use.<br><br>Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins.<br><br>The lab has conducted training on | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5421 | Continued From page 17<br><br>d. CL QOP-00022, "Verification of Procedures Revision A," effective 8/12/14, stated in Section V.B.1.d. required that the validation plan be approved by the laboratory director "before testing begins."<br><br>e. The general supervisor and techincal supervisor stated that the Advia XPT was put into use 12/18/14.<br><br>Calcium<br><br>i. Standard Operating Procedure (SOP) CL SOP-09107, "Calcium (CA, CA_2) in serum, plasma or urine on the [redacted] indicated that the reportable range for serum and plasma samples was 1.0-16.0 mg/dL.<br><br>ii. The manufacturer performed the verification of performance specifications for serum on 10/23/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>iii. The accuracy study included samples which ranged from 4.58-15.8 mg/dL.<br><br>iv. The accuracy study did not include samples across the entire reportable range.<br><br>v. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>vi. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vii. The precision study included samples which | D5421 | D5421 #2 (continued)<br>these procedures to ensure that practice is consistent with them.<br><br>The laboratory's management, including the new lab director, technical supervisors, and quality systems director, is responsible for ensuring compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5421 | Continued From page 18<br>ranged from 4.58-12.93 mg/dL.<br><br>viii. The precision study did not include samples across the entire reportable range.<br><br>ix. The precision study only included within run precision and did not include day-to-day, run-to-run, or different operators.<br><br>x. The summary report from the manufacturer showed that the reportable range for serum calcium was 0.5-16.0 mg/dL which differed from the calcium SOP.<br><br>xi. The reportable range data showed included samples from 1.0-13.4 mg/dL which did not cover the entire reportable range stated in the SOP.<br><br>Albumin<br><br>i. Standard Operating Procedure (SOP) CL SOP-09186 Revision A, "Albumin BCP (ALP) in serum or plasma[redacted] indicated that the reportable range for serum and plasma samples was 0.6-8.0 g/dL. The SOP was effective 7/31/15.<br><br>ii. The manufacturer performed the verification of performance specifications for serum on 10/23/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>iii. The accuracy study included samples which ranged from 2.0-4.4 g/dL.<br><br>iv. The accuracy study did not include samples across the entire reportable range. | D5421 | (Continued; see above) | |

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|---|---|---|---|
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| D5421 | Continued From page 19<br>v. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>vi. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vii. The precision study included samples which ranged from 0.5-5.5 g/dL.<br><br>viii. The precision study did not include samples across the entire reportable range.<br><br>ix. The SOP stated that for precision each sample 2 times per run, 2 runs per day, for at least 20 days.<br><br>x. The precision study only included within run precision and did not include 2 times per run, 2 runs per day, for at least 20 days.<br><br>xi. The summary report from the manufacturer showed that the reportable range for serum albumin was 0.8-8.0 g/dL which differed from the SOP.<br><br>xii. The reportable range data showed included samples from 0.4-6.9 g/dL which did not cover the entire reportable range stated in the SOP.<br><br>Apolipoprotein<br><br>i. Standard Operating Procedure (SOP) CL SOP-09161 Revision A, "Apolipoprotein A-1 in serum or plasma [redacted] indicated that the reportable range for serum and plasma samples was 15-(200-260) mg/dL. The SOP stated that the reference interval (normal range) for males was 79-169 mg/dL and females was 76 | D5421 | (Continued; see above) | |

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|---|---|---|---|
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|---|---|---|---|---|
| D5421 | Continued From page 20<br>-214 mg/dL.<br><br>ii. [redacted] performed the verification of performance specifications for serum on 11/6/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>iii. The accuracy study included samples which ranged from 88.6-412.0mg/dL.<br><br>iv. The accuracy study did not include samples across the entire reportable range.<br><br>v. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>vi. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vii. The precision study included samples which ranged from 100.9-314.7 mg/dL.<br><br>viii. The precision study did not include samples across the entire reportable range.<br><br>ix. The precision study only included within run precision and did not include day-to-day, run-to-run, or different operators.<br><br>x. The summary report from the manufacturer showed that the reportable range for serum was "15- " mg/dL which differed from the SOP.<br><br>Triglyceride<br><br>i. The manufacturer performed the verification of performance specifications on 10/23/14. The | D5421 | (Continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5421 | Continued From page 21<br>manufacturer summary report showed that the reportable range was 0-500 mg/dL. The manufacturer summary report revealed reference interval (normal range) was 0-300 mg/dL.<br><br>ii. The accuracy study included samples which ranged from 62.7-259 mg/dL.<br><br>iii. The accuracy study did not include samples across the entire reportable range.<br><br>iv. The acuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>v. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vi. The precision study included samples which ranged from 77.6-237.3 mg/dL.<br><br>vii. The precision study did not include samples across the entire reportable range.<br><br>viii. The precision study only included within run precision and did not include day-to-day, run-to-run, or different operators.<br><br>ix. The reportable range data included samples from 74.0-447.0 mg/dL which did not cover the entire reportable range stated in the SOP.<br><br>x. The laboratory director did not sign and approve the verification of performance specifications. Patient testing began 12/18/14.<br><br>Glucose<br><br>i. Standard Operating Procedure (SOP) CL | D5421 | (Continued; see above) | |

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|---|---|---|---|---|
| D5421 | Continued From page 22<br>SOP-09118 Revision A, "Glucose in serum, plasma, urine or CSF on the [redacted] indicated that the reportable range for serum and plasma samples was 4-700 mg/dL.<br><br>ii. The manufacturer performed the verification of performance specifications for serum on 10/23/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>iii. The accuracy study included samples which ranged from 47.2-384.0 mg/dL.<br><br>iv. The accuracy study did not include samples across the entire reportable range.<br><br>v. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>vi. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vii. The precision study included samples which ranged from 57.9-356.2 mg/dL.<br><br>viii. The precision study did not include samples across the entire reportable range.<br><br>ix. The precision study only included within run precision and did not include 2 times per run, 2 runs per day, for at least 20 days.<br><br>x. The reportable range data showed included samples from 10.6-557.27 mg/dLwhich did not cover the entire reportable range stated in the SOP. | D5421 | (Continued; see above) | |

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|---|---|---|---|
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|---|---|---|---|---|
| D5421 | Continued From page 23<br>Carbon Dioxide (CO2)<br><br>i. Standard Operating Procedure (SOP) CL SOP-09111 Revision B, "CO2 in serum or plasma on the [redacted] indicated that the reportable range for serum or plasma was 10-40 mEq/L. .<br><br>ii. The manufacturer performed the verification of performance specifications for serum on 10/23/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>iii. The accuracy study included samples which ranged from 12.9-34.3 mEq/L.<br><br>iv. The accuracy study did not include samples across the entire reportable range.<br><br>v. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>vi. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>vii. The precision study included samples which ranged from 14.3-23.0 mEq/L.<br><br>viii. The precision study did not include samples across the entire reportable range.<br><br>ix. The precision study only included within run precision and did not include 2 times per run, 2 runs per day, for at least 20 days.<br><br>x. The manufacturer summary report indicated that the verification of the reference interval did | D5421 | (Continued; see above) | |

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| D5421 | Continued From page 24<br>not pass.<br><br>xi. No further documentation verifying the reference interval was presented to the surveyor.<br><br>xii. The laboratory director approved the verification study on 11/18/14. Patient testing began on 12/18/14. | D5421 | (Continued; see above) | |
| D5423 | 493.1253(b)(2) ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:<br>(2)(i) Accuracy.<br>(2)(ii) Precision.<br>(2)(iii) Analytical sensitivity.<br>(2)(iv) Analytical specificity to include interfering substances.<br>(2)(v) Reportable range of test results for the test system.<br>(2)(vi) Reference intervals (normal values).<br>(2)(vii) Any other performance characteristic required for test performance.<br>This STANDARD is not met as evidenced by:<br>Based on review of the alkaline phosphatase procedure, manufacturer verification report and interview with the [redacted], the laboratory failed to establish performance specifications [redacted] | D5423 | D5423<br>The lab proactively paused testing on the Advia XPT during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>Before the lab resumes any test on that instrument, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the new lab director. These enhanced procedures reinforce the required steps and acceptance criteria that must be followed to verify accuracy, precision, reportable range, and reference intervals before a test is put into use.<br><br>Before any verification studies are performed, these improved procedures | 2/12/16 |

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| D5423 | Continued From page 25<br>[redacted] for alkaline phosphatase. Findings include:<br><br>a. Standard Operating Procedure (SOP) CL SOP-09102 Revision B, "Alkaline Phosphatase (ALP) in serum or plasma on the [redacted] indicated that the reportable range for serum and plasma samples was 0-1100 IU/L.<br><br>b. The [redacted] stated that the reportable range was 10-1100 IU/L and that the SOP was incorrect.<br><br>c. The manufacturer performed the verification of performance specifications for serum on 10/23/14. There was no documentation that the performance specifications had been verified for plasma samples.<br><br>d. The accuracy study included samples which ranged from 23.70-423.0 IU/L.<br><br>e. The accuracy study did not include samples across the entire reportable range.<br><br>f. The accuracy study did not include a comparison study as required by the laboratory's procedure.<br><br>g. The accuracy study did not indicate an acceptable percentage for accuracy.<br><br>h. The precision study included samples which ranged from 30.9-359.0 IU/L.<br><br>i. The precision study did not include samples across the entire reportable range.<br><br>j. The precision study included within run | D5423 | D5423 (continued)<br>require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins.<br><br>The lab has conducted training on these procedures to ensure that practice is consistent with them.<br><br>The lab's management, including the new lab director, technical supervisors, and quality systems director, is responsible for ensuring compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5423 | Continued From page 26<br>precision, but did not include day-to-day, run-to-run, or different operators.<br><br>k. The summary report from the manufacturer showed that the reportable range for serum ALP was 0-1100 IU/L.<br><br>l. The reportable range data showed included samples from 12-914 IU/L which did not cover the entire reportable range.<br><br>m. The [redacted] stated that analytic sensitivity and analytic specifictity was not established [redacted] | D5423 | | |
| D5429<br>220M | 493.1254(a)(1) MAINTENANCE AND FUNCTION CHECKS<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br>This STANDARD is not met as evidenced by:<br>Based on technical supervisor interviews and Evolis maintenance log record review on November 17, 2015, the laboratory failed to perform weekly Evolis maintenance as defined by the manufacturer. Findings included:<br><br>a. In general immunology, it was the practice of the laboratory to test patient ANA, HIV Ag/Ab, and quantiferon using the Bio-Rad Evolis system.<br><br>b. In August 2015, for 2 (weeks 1 and 3) of 4 weeks in which patient specimens were tested, the laboratory maintained no documentation to indicate that weekly manufacturer required maintenance had been performed. | D5429 | D5429<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. Following the survey, weekly maintenance on the Evolis has been performed. The new lab director has approved enhanced procedures addressing equipment maintenance, which reinforce the lab's systems for performing and documenting all required maintenance. The lab has conducted training on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including new lab director, technical supervisors, and quality director, is responsible for ensuring that these procedures are | 2/12/16 |

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| D5429 | Continued From page 27<br><br>c. In August 2015, the laboratory performed and reported [redacted] patient HIV Ag/Ab test results using the Evolis system. | D5429 | D5429 (continued)<br>followed. The lab will provide oversight of required maintenance through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |
| D5437<br><br>400M | 493.1255(a) CALIBRATION AND CALIBRATION VERIFICATION<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures--<br>(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;<br>(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--<br>(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and<br>(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and<br>(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and complete blood counts (CBC) calibration documentation record reviews on September 23, 2015, the laboratory failed to document all CBC instrument calibrations performed using the [redacted] Findings included:<br><br>a. It was the practice of the laboratory to test | D5437 | (D5437#1 begins on next page) | |

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| D5429 | Continued From page 27<br><br>c. In August 2015, the laboratory performed and reported [redacted] patient HIV Ag/Ab test results using the Evolis system. | D5429 | | |
| D5437<br><br>400M | 493.1255(a) CALIBRATION AND CALIBRATION VERIFICATION<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures--<br>(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;<br>(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--<br>(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and<br>(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and<br>(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and complete blood counts (CBC) calibration documentation record reviews on September 23, 2015, the laboratory failed to document all CBC instrument calibrations performed using the [redacted] Findings included:<br><br>a. It was the practice of the laboratory to test | D5437 | D5437 #1<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures addressing equipment systems, reinforcing that calibration documentation must be organized and maintained. The lab has conducted training on those procedures to ensure that practice and documentation is consistent with them. Assay-specific SOPs will identify the specific procedures used for each platform or instrument.<br><br>Lab management, including new lab director, technical supervisors, and quality director, is responsible for ensuring that these procedures are followed. The lab will provide | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D5437 | Continued From page 28<br>patient capillary CBC specimens using [redacted] the laboratory designated as [redacted] On September 23, 2015, information recorded on "Drew #2" indicated that the [redacted] was calibrated on August 24, 2015, and information recorded on [redacted] indicated that the [redacted] was calibrated on August 31, 2015.<br><br>b. The laboratory maintained no documentation of the August 24, 2015 and August 31, 2015 calibrations of the laboratory's two [redacted] CBC instruments.<br><br>c. According to laboratory personnel, between August 24, 2015 and September 23, 2015, the laboratory performed and reported [redacted] patient CBC specimens using the two [redacted] instruments.<br><br>2. Based on laboratory personnel interviews and complete blood counts (CBC) calibration documentation record reviews on November 19, 2015, the laboratory failed to document all CBC instrument calibrations performed using a Advia 2120i instrument. Findings included:<br><br>a. It was the practice of the laboratory to test patient venous CBC specimens using two Siemens Advia 2120i instruments, designated as #1 and #2.<br><br>b. For Advia 2120i #1, the laboratory maintained no documentation of any calibrations prior to September 21, 2015. For Advia 2120I #2, the laboratory maintained no documentation of any calibrations performed.<br><br>c. Between February 2015 and September 21, | D5437 | D5437 #1 (continued)<br>oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures.<br><br>D5437 #2<br>The laboratory proactively paused testing on the Advia 2120i during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures addressing equipment systems, reinforcing that calibration documentation must be organized and maintained. The lab has conducted training on those procedures. | 2/12/16 |

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| D5437 | Continued From page 29<br>[redacted], the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120i #1. From November 6, 2015 to November 19, 2015, the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120I #2. | D5437 | D5437 #2 (continued)<br>The new lab director has also approved specific calibration procedures for CBC on the Advia 2120i. Before the lab resumes any tests on the Advia 2120i, it will conduct training on those procedures. In addition, testing personnel will be required to demonstrate competency to ensure that practice is consistent with those procedures.<br><br>Lab management, including the new lab director, technical supervisors, and quality director, is responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |
| D5447<br>400H | 493.1256(d)(3)(i)(g) CONTROL PROCEDURES<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--<br><br>At least once a day patient specimens are assayed or examined perform the following for--<br><br>Each quantitative procedure, include two control materials of different concentrations;<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and WBC differential quality control record review on November 19, 2015, the laboratory failed to include two quality control materials with differing WBC differential patterns at least once each day patient WBC differential specimens were examined using the Cellavision instrument. Findings included:<br><br>a. It was the practice of the laboratory to use the Cellavision instrument to aid in the examination and reporting of patient WBC differentials performed from stained slides.<br><br>b. According to laboratory personnel, although the laboratory performed a function check (cell | D5447 | | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D5437 | Continued From page 29<br>[redacted], the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120i #1. From November 6, 2015 to November 19, 2015, the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120I #2. | D5437 | | |
| D5447<br>400H | 493.1256(d)(3)(i)(g) CONTROL PROCEDURES<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--<br><br>At least once a day patient specimens are assayed or examined perform the following for--<br><br>Each quantitative procedure, include two control materials of different concentrations;<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and WBC differential quality control record review on November 19, 2015, the laboratory failed to include two quality control materials with differing WBC differential patterns at least once each day patient WBC differential specimens were examined using the Cellavision instrument. Findings included:<br><br>a. It was the practice of the laboratory to use the Cellavision instrument to aid in the examination and reporting of patient WBC differentials performed from stained slides.<br><br>b. According to laboratory personnel, although the laboratory performed a function check (cell | D5447 | D5447<br>The lab proactively paused testing on the Cellavision during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures that reinforce the need to perform QC with at least two levels of control, unless otherwise specified, and the lab has conducted training on those procedures.<br><br>The new lab director has also approved enhanced procedures for the Cellavision instrument to reinforce that the daily WBC differential must include two QC materials with differing WBC patterns. Before the lab resumes any tests on the Cellavision, it will conduct training and competency testing on those procedures to ensure that practice is consistent with them. | 2/12/16 |

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|---|---|---|---|
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| D5447 | Continued From page 30<br>locator) each day the Cellavision was used to examine patient stained slides, the laboratory did not examine two quality control materials with differing WBC differential patterns each day the Cellavision was used to examine patient stained slides. Laboratory personnel also stated that all Cellavision examinations were reviewed by testing personnel and revised, if necessary, before the examination was release for reporting. However, the Cellavision did perform the primary WBC differential screening of patient stained slides.<br><br>c. According to laboratory personnel, since February 2015, the laboratory examined and reported [redacted] patient WBC differentials using the Cellavision. | D5447 | D5447 (continued)<br>Lab management, including technical supervisors, will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |
| D5449<br><br>110H<br>220H | 493.1256(d)(3)(ii)(g) CONTROL PROCEDURES<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--<br><br>At least once a day patient specimens are assayed or examined perform the following for--<br><br>Each qualitative procedure, include a negative and positive control material;<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>Based on technical supervisor interview and CT/NG quality control record review on November 17, 2015, at least once a day patient specimens were assayed, the laboratory failed to include a positive CT/NG quality control material. | D5449 | D5449<br>Prior to the survey, the lab followed the procedures for QC identified in the manufacturer's package insert for this FDA cleared device.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures that reinforce the need to perform QC with at least two levels of control, unless otherwise specified, and the lab has conducted training on those procedures. | 2/12/16 |

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| D5449 | Continued From page 31<br>Findings included:<br><br>a. It was the practice of the laboratory to perform and report patient CT/NG testing using a PCR method.<br><br>b. Laboratory records indicated that on November 13, 2015 the laboratory performed patient CT/NG testing without including a positive CT/NG quality control material in the assay. Although the laboratory included samples the manufacturer labeled as a "positive" CT/NG quality control material in the assay, the test results of this "positive" CT/NG quality control material were used to calculate the assay cutoff which determines whether patient test results tested as positive or negative for CT/NG. As a result, the manufacturer's "positive" CT/NG quality control material was considered a calibrator and not quality control material. The laboratory assayed no other positive CT/NG quality control materials.<br><br>c. On November 13, 2015, the laboratory tested [redacted] patient CT/NG specimens.<br><br>d. Pursuant to 42 C.F.R. 493.1256(d)(9), when using calibration material as control material, the laboratory must at least use calibration material from a different lot than that used to establish a cut-off value. | D5449 | D5449 (continued)<br>The new lab director has also approved enhanced procedures for CT/NG to require the use of a positive CT/NG control material that is not also used as a calibrator.<br><br>Lab management, including technical supervisors, will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |
| D5469<br><br>400H | 493.1256(d)(10)(g) CONTROL PROCEDURES<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- | D5469 | (D5469 #1 begins on next page) | 2/12/16 |

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|---|---|---|---|
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| D5469 | Continued From page 32<br>Establish or verify the criteria for acceptability of all control materials.<br><br>(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.<br>(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.<br>(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and complete blood counts (CBC) quality control record review on September 23, 2015, the laboratory failed to verify the stated values of the commercially assayed CBC quality control materials in use at the time of the survey. Findings included:<br><br>a. It was the practice of the laboratory to use commercially assayed CBC quality control materials to monitor patient CBC testing using two [redacted] instruments..<br><br>b. Laboratory CBC quality control records indicated that on June 27, 2015 the laboratory changed the lot of quality control material from lot number EX045 to EX075. | D5469 | D5469 #1<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures to reinforce the practice of parallel testing each new lot of control material with the lot of control material in use, and establishing a range based on the manufacturer's range. The lab has conducted training on those procedures.<br><br>Lab management, including technical supervisors and the quality director, will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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|---|---|---|---|---|
| D5469 | Continued From page 33<br><br>c. The laboratory maintained no documentation to indicate that the stated values of CBC quality control material lot number EX075 had been verified by the laboratory.<br><br>d. According to laboratory personnel, between June 27, 2015 and September 24, 2015, the laboratory used one of the [redacted] instruments on 30 different days to perform and report patient CBC specimens, and used the other [redacted] instrument on 87 different days to perform and report patient CBC specimens.<br><br>2. Based on interview with the general supervisor and chemistry quality control (QC) records on November 17, 2015, the laboratory failed to verify the stated values of the commercially assayed QC material. Findings include:<br><br>a. The general supervior stated that when a new lot number of QC was started, the QC ranges were entered into the chemistry analyzers [redacted] and Advia XPT) from [redacted] just prior to use.<br><br>b. The general supervisor further stated that the new lot number of QC was run one time prior to patient testing.<br><br>c. QC records show that MultiQual lot number 45660 was put into use in 2014 and discontinued in August 2015.<br><br>d. The general supervisor and [redacted] confirmed on 11/17/15 at 9:40 am that manufacturer's QC ranges for new lot numbers of chemistry controls were not verified. | D5469 | D5469 #2<br>The lab has completed assessments to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures to reinforce the practice of parallel testing each new lot of control material with the lot of control material in use, and establishing a range based on the manufacturer's range. The lab has conducted training on those procedures.<br><br>Lab management, including technical supervisors and quality systems director, will be responsible for ensuring that these procedures are followed. The lab will provide | 2/12/16 |

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| D5469 | Continued From page 33<br><br>c. The laboratory maintained no documentation to indicate that the stated values of CBC quality control material lot number EX075 had been verified by the laboratory.<br><br>d. According to laboratory personnel, between June 27, 2015 and September 24, 2015, the laboratory used one of the [redacted] instruments on 30 different days to perform and report patient CBC specimens, and used the other [redacted] instrument on 87 different days to perform and report patient CBC specimens.<br><br>2. Based on interview with the general supervisor and chemistry quality control (QC) records on November 17, 2015, the laboratory failed to verify the stated values of the commercially assayed QC material. Findings include:<br><br>a. The general supervior stated that when a new lot number of QC was started, the QC ranges were entered into the chemistry analyzers [redacted] and Advia XPT) from [redacted] just prior to use.<br><br>b. The general supervisor further stated that the new lot number of QC was run one time prior to patient testing.<br><br>c. QC records show that MultiQual lot number 45660 was put into use in 2014 and discontinued in August 2015.<br><br>d. The general supervisor and [redacted] confirmed on 11/17/15 at 9:40 am that manufacturer's QC ranges for new lot numbers of chemistry controls were not verified. | D5469 | D5469 #2 (continued)<br>oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5477 110H | 493.1256(e)(4)(g) CONTROL PROCEDURES<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following:<br><br>(e)(4) Before, or concurrent with the initial use--<br>(e)(4)(i) Check each batch of media for sterility if sterility is required for testing;<br>(e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and<br>(e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>Based on technical supervisor interview and bacteriology media quality control record review on November 18, 2015, the laboratory failed to check each batch of media for its ability to support growth before or concurrent with initial use. Findings included:<br><br>a. From November 15, 2015 to November 18, 2015, the laboratory performed patient bacteriology testing using Hardy blood agar plates (BAP), lot number 15300, expiration date 01/25/2016.<br><br>b. For this lot of BAP, the laboratory relied on manufacturer's documentation that the manufacturer performed quality control procedures on the BAP. The laboratory did not, before or concurrent with initial use, performed any quality control procedures to check whether this lot of BAP supported organism growth. | D5477 | D5477<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures for microbiology.<br><br>Lab management, including technical supervisors, will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | 2/12/16 |

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| D5477 | Continued From page 35<br>c. From November 15, 2015 to November 18, 2015, the laboratory performed [redacted] patient specimen cultures using Hardy BAP, lot number 15300, expiration date 01/25/2016. | D5477 | | |
| D5481 | 493.1256(f)(g) CONTROL PROCEDURES<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.<br><br>(g) The laboratory must document all control procedures performed.<br>This STANDARD is not met as evidenced by:<br>1. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records, patient results and interview with the general supervisor, the laboratory failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results from April 2015 through September 2015. Findings include:<br><br>a. CL SOP-10001 Revision A, "Measuring Prothrombin Time-Innovin (PT on the Siemens BCS XP Instrument" stated on page 6, section 8.6 that if control values are outside of the determined range, the controls, reagents and instrument performance should be checked and that identification and correction of the problem shoud be documented prior to reporting patient results.<br><br>b. QC records for Citrol 3 (Lot number 548425) were reviewed from 4/1/15 through 9/23/15.<br><br>c. The general supervisor stated that QC was acceptable if the values were +/- 2 SD from the | D5481 | D5481 #1<br>The laboratory paused testing on the Siemens BCS XP, including PT/INR, during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures, which reinforce and detail the required investigation and corrective action that must occur to address QC issues before patient tests are performed and clarify which employees are responsible for performing and documenting these activities. The lab has conducted training and competency on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including technical supervisors and the quality systems director, is responsible for ensuring compliance with these procedures. The lab will also provide oversight | 2/12/16 |

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|---|---|---|---|---|
| D5481 | Continued From page 36<br>mean.<br><br>d. On 9/7/15, Citrol 3 was run seven times without obtaining an acceptable QC value.<br><br>e. On 9/8/15, Citrol 3 was run twelve times without obtaining an acceptable QC value.<br><br>f. On 25 of 32 days, Citrol 3 was not rerun when the QC value was greater than - 2 SD.<br><br>g. On 5/15/15, 8/13/15, 8/21/15 and 9/10/15, Citrol 3 was run twice. All QC results were unacceptable.<br><br>h. The Rule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015, 13 of 13 in July 2015, 16 of 16 in August, and 24 of 24 during September 1-16, 2015 showed rule violation messages related to Citrol 3.<br><br>i. [redacted] patients were reported from 4/1/15 through 9/16/15.<br><br>2. Based on review of the quality control (QC) procedure, QC records, and raw data from patient test runs and interview with the general supervisor, the laboratory failed to ensure that the QC was acceptable for the [redacted] prior to reporting patient test results: Findings include:<br><br>a. CL SOP-15026 Revision A, [redacted] Daily QC Procedures", stated the following in section 10.1.1: "...For any single [redacted] instrument, reject QC if either level is greater than 2 SD or if either level falls on the same side of the mean for 10 consecutive days." | D5481 | D5481 #1 (continued)<br>through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures.<br><br>D5481 #2<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures, which reinforce that QC results must be acceptable before patient tests are performed, and detail the steps to take | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5481 | Continued From page 37<br><br>b. Section 11.1.1 of CL SOP-15026 Revision A further stated that "Daily QC automatically expires 24 hours after use."<br><br>c. The general supervisor stated that when the QC was unacceptable, the [redacted] device locked out patient testing for 24 hours or until the QC was acceptable and if the QC was unacceptable another device would be used for testing.<br><br>d. QC records for Sex Hormone Binding Globulin (SHBG) showed that on Device [redacted] QC Level 2's (QC2) 24 hour expiration was on 8/14/14 at 18:54 and was not run again until 8/15/14 at 00:05. Patient data showed that patient Accession #94389 was run on 8/14/14 at 19:09.<br><br>e. QC records for SHBG showed that on Device [redacted] QC Level 1's (QC1) 24 hour expiration was on 8/20/14 at 17:43 and was not run again until 8/21/14 at 17:50. Patient data showed that patient Accession #95403 was run on 8/20/14 at 19:08.<br><br>f. QC records for SHBG showed that on Device [redacted] QC1 was not run again until 11/1/14 at 22:15. Patient data showed that patient Accession #112807 was run on 11/1/14 at 00:02.<br><br>g. QC records for Vitamin B12 (VB12) showed that on Device [redacted] QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48.<br><br>h. QC records for VB12 showed that on Device | D5481 | D5481 #2 (continued)<br>when QC results are not acceptable. The lab has conducted training and competency on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including technical supervisors and the quality systems director, is responsible for ensuring that these procedures are followed. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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|---|---|---|---|---|
| D5481 | Continued From page 38<br>[redacted] QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48.<br><br>i. QC records for VB12 showed that on Device [redacted] QC2 24 hour expiration was on 8/19/14 at 08:00 and was not run again until 8/20/14 at 21:05. Patient data showed that 3 patients (Accession #s 95411, 95462, 95543) were run on 8/20/14 between 12:33 and 17:52.<br><br>j. QC records for VB12 showed that on Device [redacted] QC2 24 hour expiration was on 8/22/14 at 17:38 and was not run again until 8/23/14 at 21:05. Patient data showed that 2 patients (Accession #s 95984, 96106) were run on 8/22/14 at 18:56 and 21:21.<br><br>k. QC records for VB12 showed that on Device [redacted] QC1's 24 hour expiration was on 8/24/14 at 16:43 and was not run again until 8/25/14 at 07:59. QC2 24 hour expiration was on 8/24/14 at 21:05 and was not run again until 8/25/14 at 12:23. Patient data showed that 3 patients (Accession #s 96327, 96250, 96371) were run on 8/24/14 between 17:15 and 21:36.<br><br>l. QC records for VB12 showed that on Device [redacted] QC1 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 20:29 and again on 2/26/15 at 20:22. QC2 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 22:11 and again on 2/26/15 at 22:04. QC1 passed on 2/27/15 at 22:54 and QC2 was run and passed on 2/28/15 at 00:27. Patient data showed that 7 patients (Accession #s 146275, 146391, 146651, 146852, | D5481 | | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5481 | Continued From page 39<br>147149, 146596, 146898) were run between 2/26/15 and 2/27/15 during the time the laboratory had a 10x warning.<br><br>m. QC records for VB12 showed that on Device [redacted] QC1's 24 hour expiration was on 1/25/15 at 21:58 and was not run again until 1/28/15 at 2140. QC2 24 hour expiration was on 1/26/15 at 02:22 and was not run again until 1/28/15 at 23:19. Patient data showed that 5 patients (Accession #s 136351, 136139,136386, 136897, 135548) were run between 1/27/15 at 1359 and 1/28/15 at 11:50.<br><br>n. QC records for Vitamin D, 25-OH (VitD) showed that on Device [redacted] QC1's 24 hour expiration was on 7/6/14 at 14:11 and was not run again until 7/7/15 at 08:04. Patient data showed that Accession #88699 was run on 7/6/14 at 14:31.<br><br>o. Levey-Jennings charts revealed that SHBG Device [redacted] QC1 had 13 consecutive days and QC2 had 15 consecutive days that the results were at least 2 standard deviations (SDs) below the mean from 9/30/14 through 10/29/14.<br><br>p. Levey-Jennings charts revealed that SHBG Device [redacted] QC1 had 19 consecutive days that the results were at least 2 SDs below the mean from 3/31/15 through 4/29/15.<br><br>q. Levey-Jennings charts revealed that VitD Device [redacted] QC1 had 15 consecutive days that the results were at least 2 SDs above the mean from 6/30/15 through 7/25/14.<br><br>r. Levey-Jennings charts revealed that Total T3 (TT3) Device [redacted] QC1 had 11 consecutive | D5481 | | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5481 | Continued From page 40<br>days that the results were at least 2 SDs above the mean from 1/3/15 through 1/29/15.<br><br>s. Levey-Jennings charts revealed that TT3 Device [redacted] QC1 had 113 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 7/9/14 through 7/25/14.<br><br>t. Levey-Jennings charts revealed that VB12 Device [redacted] QC1 had 14 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 2/10/14 through 2/27/14. | D5481 | | |
| D5775<br><br>400B | 493.1281(a)(c) COMPARISON OF TEST RESULTS<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.<br>(c) The laboratory must document all test result comparison activities.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interview and manual WBC differential record review on November 19, 2015, the laboratory failed to have a system that twice a year evaluated and defined the relationship between WBC differential test results examined by multiple testing personnel. Findings included:<br><br>a. It was the practice of the laboratory for multiple testing personnel to examine and report patient WBC differentials from stained slides. | D5775 | D5775 #1<br>The lab proactively paused testing on the Cellavision during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced method comparison procedures, which reinforce that the lab will compare the results of any instruments running the same test(s) at least twice each year to ensure that their results are comparable and within defined acceptance criteria. The lab has conducted training on those procedures.<br><br>The new lab director has also | 2/12/16 |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D5775 | Continued From page 41<br><br>b. The laboratory had no system that twice a year evaluated and defined the relationship between WBC differential test results examined by multiple testing personnel. Other than through the distribution of proficiency testing samples, the laboratory had no documentation to indicate whether testing personnel were examining patient stained slides and reporting patient manual WBC differential similarly, accurately, and reliably.<br><br>2. Based on review of documentation, the laboratory failed to have a system that twice a year evaluated and defined the relationship [redacted] Findings include:<br><br>a. Undated documentation provided by the laboratory revealed a comparison study between [redacted] and a predicate device (Immulite, Centaur, or Liaison) for Sex Hormone Binding Globulin (SHBG), Total T3 (TT3), Vitamin D (VitD) and Vitamin B12 (VB12).<br><br>b. The method comparison documentation showed that the following devices [redacted] were used for SHBG comparison testing. SHBG testing occurred from 7/28/14 through 6/25/15.<br><br>c. Quality control (QC) monthly reports revealed that seven devices were used for SHBG from February 2015 through June 2015 but only three devices were included in the comparison study.<br><br>d. QC and patient result documentation for SHBG also revealed that [redacted] were used for patient | D5775 | D5775 #1 (continued)<br>approved enhanced procedures for the Cellavision instrument to ensure that the lab evaluates and defines the relationship between WBC differential test results examined by multiple testing personnel at least twice each year. Before the lab resumes any tests on the Cellavision, it will conduct training and competency testing on those procedures to ensure that practice is consistent with them.<br><br>The lab's technical supervisors and the quality systems director will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |

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|---|---|---|---|---|
| D5775 | Continued From page 41<br><br>b. The laboratory had no system that twice a year evaluated and defined the relationship between WBC differential test results examined by multiple testing personnel. Other than through the distribution of proficiency testing samples, the laboratory had no documentation to indicate whether testing personnel were examining patient stained slides and reporting patient manual WBC differential similarly, accurately, and reliably.<br><br>2. Based on review of documentation, the laboratory failed to have a system that twice a year evaluated and defined the relationship [redacted] Findings include:<br><br>a. Undated documentation provided by the laboratory revealed a comparison study between [redacted] and a predicate device (Immulite, Centaur, or Liaison) for Sex Hormone Binding Globulin (SHBG), Total T3 (TT3), Vitamin D (VitD) and Vitamin B12 (VB12).<br><br>b. The method comparison documentation showed that the following devices [redacted] were used for SHBG comparison testing. SHBG testing occurred from 7/28/14 through 6/25/15.<br><br>c. Quality control (QC) monthly reports revealed that seven devices were used for SHBG from February 2015 through June 2015 but only three devices were included in the comparison study.<br><br>d. QC and patient result documentation for SHBG also revealed that [redacted] were used for patient | D5775 | D5775 #2<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced method comparison procedures, which reinforce that the lab will compare the results of any instruments running the same test(s) at least twice each year, to ensure that their results are comparable and within defined acceptance criteria. The lab has conducted training on those procedures.<br><br>The lab's technical supervisors and the quality systems director will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor | 2/12/16 |

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|---|---|---|---|
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|---|---|---|---|---|
| D5775 | Continued From page 42<br>testing and were not included in the comparison study.<br><br>e. The method comparison documentation showed that the following devices [redacted] were used for TT3 testing. TT3 testing occurred from 2/2/14 through 2/4/15.<br><br>f. The method comparison documentation showed that the following devices [redacted] were used for VitD testing. VitD testing occurred from 11/6/13 through 3/10/15.<br><br>g. Quality control (QC) monthly reports revealed that twelve devices were used for VitD in February 2015 and eighteen devices were used from March 2015 through April 2015 but only seven devices were included in the comparison study.<br><br>h. QC and patient result documentation for VitD also revealed that device [redacted] was used for patient testing and was not included in the comparison study.<br><br>i. The method comparison documentation showed that the following devices [redacted] were used for VB12 testing. VB12 testing occurred from 8/12/14 through 3/6/15.<br><br>j. Quality control (QC) monthly reports revealed that twelve devices were used for VB12 in October 2014 and February 2015 through April 2015 but only eleven devices were included in the | D5775 | D5775 #2 (continued)<br>compliance through its improved occurrence management, and audit procedures. | |

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|---|---|---|---|
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|---|---|---|---|---|
| D5775 | Continued From page 43<br>comparison study. | D5775 | | |
| D5779 | 493.1282(a) CORRECTIVE ACTIONS | D5779 | D5779<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced QC procedures, which reinforce and detail the required investigation and corrective action that must occur to address QC issues before patient tests are performed. In addition, the procedures clarify which employees are responsible for performing and documenting these activities, and require regular technical supervisor review and analysis of QC results. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including technical supervisors and the quality systems director, is responsible for ensuring | 2/12/16 |
| 400B | Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and complete blood counts (CBC) quality control record review on September 23, 2015, the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory's operation for testing patient CBC specimens in a manner that ensure accurate and reliable patient test results and reports when the laboratory's criteria for acceptability of CBC quality control material test results were not met. Findings included:<br><br>a. It was the practice of the laboratory to test three levels (low, normal, and high) of quality control materials each day of patient testing and to use the stated values of commercially assayed quality control materials to monitor patient CBC testing using the [redacted] instruments. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control (document number CL QOP-00013, revision F)."<br><br>i. "Step 1" of the procedure was to "rerun the controls." | | | |

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|---|---|---|---|
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|---|---|---|---|---|
| D5779 | Continued From page 44<br>ii. "Step 2" of the procedure was to "repeat with fresh controls" "if the rerun of controls failed."<br><br>iii. "Step 3" of the procedure was to "check the operation of the instrument" "if the rerun of [fresh] controls failed."<br><br>iv. "Step 4" of the procedure was to "repeat using a new reagent kit" and "recalibrate" if quality control test results continued to fall outside the laboratory's criteria for acceptability.<br><br>v. "Step 5" of the procedure was to "call instrument support and inform [the] supervisor" if quality control test results continued to fall outside the laboratory's criteria for acceptability.<br><br>b. Laboratory records for the [redacted] instrument the laboratory designated as [redacted] indicated that on July 11, 12, 14, and 16, 2015 CBC quality control material test results failed to meet stated assay values. The laboratory's documentation of these quality control failures indicated that the laboratory's "Quality Control" protocol was not followed.<br><br>i. On July 12, 2015, laboratory records indicated that the high quality control material failed to meet the laboratory's criteria for acceptability (specific CBC analyte not designated). Testing of the high quality control material was repeated three times before being acceptable using a "new QC tube." "Step 1" was repeated three times before the laboratory followed "Step 2."<br><br>ii. On July 16, 2015, laboratory records indicated that the high quality control material failed to meet the laboratory's criteria for | D5779 | D5779 (continued)<br>compliance with these procedures. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|
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|---|---|---|---|---|
| D5779 | Continued From page 45<br>acceptability (specific CBC analyte not designated). Testing of the high quality control material was repeated two times before being acceptable on a third repeat. "Step 1" was repeated two times without following "Step 2."<br><br>iii. On July 17, 2015, laboratory records indicated that the high quality control material failed to meet the laboratory's criteria for acceptability (specific CBC analyte not designated). Testing of the high quality control material was repeated two times before being acceptable on a third repeat. "Step 1" was repeated two times without following "Step 2."<br><br>[NOTE: On July 11 and 14, 2015, laboratory records also indicated that the high quality control material failed to meet the laboratory's criteria for acceptability (specific CBC analyte not designated). Testing was repeated and was acceptable. "Step 1" was followed.]<br><br>[NOTE: On July 14, 2015, laboratory records also indicated that the normal quality control material failed to meet the laboratory's criteria for acceptability (specific CBC analyte not designated). Testing was repeated and was acceptable. "Step 1" was followed.]<br><br>c. Laboratory records indicated that the [redacted] instrument the laboratory designated as [redacted] was used to test and report [redacted] patient CBC specimens on July 11, 2015, [redacted] patient CBC specimens on July 12, 2015, [redacted] patient CBC specimens on July 14, 2015, and [redacted] patient CBC specimens on July 16, 2015. It is unknown how many patient CBC specimens were tested using [redacted] on July 17, 2015. | D5779 | | |

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| D5787 | Continued From page 46 | D5787 | | |
| D5787 | 493.1283(a) TEST RECORDS<br><br>110H The laboratory must maintain an information or record system that includes the following:<br>(a)(1) The positive identification of the specimen.<br>(a)(2) The date and time of specimen receipt into the laboratory.<br>(a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.<br>(a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br>This STANDARD is not met as evidenced by:<br>Based on technical supervisor interview and bacteriology media quality control record review on November 18, 2015, the laboratory failed to have an information or record system that included the records of all bacteriology patient specimen testing. Findings included:<br><br>Although the laboratory maintained documentation to indicate that all lots of bacteriology media used to test patient bacteriology specimens had been quality controlled by the manufacturer or laboratory, the laboratory maintained no documentation of the lot of media used to test any given patient bacteriology specimen. The laboratory maintained no such information or record system. | D5787 | D5787<br>The lab is keeping records that track the media used to test any given bacteriology patient specimen.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures regarding documentation of the bacteriology media used to test patient specimens.<br><br>The lab will ensure these procedures are followed through audits performed pursuant to the lab's new audit procedures, and through oversight during the monthly QA meetings. | 2/12/16 |
| D5791 | 493.1289(a)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in | D5791 | D5791 #1<br>A review of hourly data demonstrated that average hourly temperature for nearly all of the freezers at issue met the manufacturer temperature requirements for the materials stored. | 2/12/16 |

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| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D5791 | Continued From page 47<br>§§493.1251 through 493.1283.<br>(c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on the SensoScientific Monitoring Audit Node Report and intervew, the laboratory failed to identify and perform corrective action when ten of ten freezer temperatures did not meet the manufacturer temperature requirements. Findings include:<br><br>a. The Audit Node Reports for July 2015 and September 2015 were reviewed.<br><br>b. Six -20 C freezers were identified: 7059 -20 Freezer Sanyo JP lab, 7061 [redacted] -20 Freezer 4, 7063 -20 Freezer Accessioning, 7066 -20 Freezer 1 [redacted], 7075 -20 Freezer 2 JP, and 7077 -20 Freezer 3JP.<br><br>c. Four -80 C freezers were identified: 7098 -80 Freezer 1 Nuair, 7111 -80 Freezer 2 Thermo, 7113 -80 Freezer 2 CLIA Lab, and 7120 -80 Freezer 1 [redacted].<br><br>d. The Audit Node Report for 7/6/15 through 7/31/15 revealed the following number of days that the freezers did not meet the required acceptable temperature range of greater than or equal to -20 C or greater that or equal to -80 C:<br><br>7059 -20 Freezer Sanyo JP Lab 25/26 days<br>7098 -80 Freezer 1 Nuair 7/26 days<br>7111 -80 Freezer 2 Thermo 18/26 days<br>7113 -80 Freezer 2 CLIA Lab 14/26 days<br>7120 -80 Freezer 1 [redacted] 25/26 days<br><br>e. The Audit Node Report for 9/1/15 through | D5791 | D5791 #1 (continued)<br>The lab has identified and discarded any materials that had the potential to have been affected. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced temperature management procedures to reinforce monitoring of temperature and environmental conditions and storage of materials according to the manufacturer's temperature range. The lab has conducted training on those procedures.<br><br>The lab's management, including the new lab director and quality systems director, will ensure compliance with these procedures, including by making sure that supervisors perform their respective duties effectively. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5791 | Continued From page 48<br>9/24/15 revealed the following number of days that the freezers did not meet the required acceptable temperature range of greater than or equal to -20 C or greater that or equal to -80 C:<br><br>7059 -20 Freezer Sanyo JP Lab 12/24 days<br>7061 BUGS -20 Freezer 4 12/24 days<br>7063 -20 Freezer Accessioning 11/24 days<br>7066 -20 Freezer 1 [redacted] 9/24 days<br>7075 -20 Freezer 2 JP 6/24 days<br>7077 -20 Freezer 3JP 5/24 days<br>7098 -80 Freezer 1 Nuair 11/24 days<br>7111 -80 Freezer 2 Thermo 3/24 days<br>7113 -80 Freezer 2 CLIA Lab 10/24 days<br>7120 -80 Freezer 1 [redacted] 18/24 days<br><br>f. The Quality Assurance Quality Control Manager signed and dated the Audit Node Reports. The Quality Assurance Quality Control Manager could not explain if any corrective action was taken.<br><br>g. There was no documenation that the laboratory identified the days that the freezers did not meet the acceptable temperature ranges and did not take any corrective action for those days.<br><br>h. Refer to D5413.<br><br>2. Based on review of Quality Control (QC) data and Monthly QC Reports, the laboratory failed to have a quality assessment (QA) procedure to identify and correct problem with the QC values for the [redacted] when precision did not meet the laboratory's requirement for precision. Findings include:<br><br>a. CL PLN-14003 Revision A, "Master Validation Plan for Routine Chemistry Assays on [redacted] | D5791 | D5791 #2<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has | 2/12/16 |

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| D5791 | Continued From page 49<br>[redacted] in section 13.4.5 requires the %CV of replicates to be not more than 15% (20% at the lower and upper limits of detection).<br><br>b. QC results were reviewed from June 2014 through November 2014 and January through February 2015 for [redacted] which were used for patient testing on the [redacted] devices.<br><br>c. [redacted] QC Level 1 and Level 3 (QC1 and QC3) on Device [redacted] revealed the following %CV (coefficient of variation): [redacted] and [redacted] respectively, from 1/5/15 through 1/30/15.<br><br>d. [redacted] QC1 and QC3 on Device [redacted] revealed the following %CVs: [redacted] and [redacted], respectively, from 1/5/15 through 1/30/15.<br><br>e. [redacted] QC1 and QC3 on Device [redacted] revealed the following %CVs: [redacted] and [redacted], respectively, from 2/10/15 through 2/27/15.<br><br>f. [redacted] QC1 and QC3 on Device [redacted] revealed the following %CVs: [redacted] and [redacted] respectively, from 1/2/15 through 1/31/15.<br><br>g. [redacted] QC1 and QC3 on Device [redacted] revealed the following %CVs: [redacted] and [redacted] respectively, from 2/10/15 through 2/27/15.<br><br>h. [redacted] QC Level 1 and Level 2 (QC1 and QC2) on Device [redacted] revealed the following %CVs: [redacted] and [redacted], respectively, from 8/21/14 through 8/30/14.<br><br>i. [redacted] QC1 and QC2 on Device [redacted] revealed the following %CVs: [redacted] and [redacted] | D5791 | D5791 #2 (continued)<br>approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>These improved systems include QC procedures to reinforce that QC is effectively reviewed to identify precision that is inconsistent with the lab's CV requirements and that documented investigations and corrective action occur. In addition, the procedures clarify which employees are responsible for performing and documenting these activities, and require regular technical supervisor review and analysis of QC results. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including technical supervisors and the quality director, are responsible for compliance with these procedures. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5791 | Continued From page 50<br>respectively, from 6/29/14 through 7/24/14.<br><br>j. [redacted] QC1 and QC2 on Device [redacted] revealed the following %CVs: [redacted] and [redacted], respectively, from 6/29/14 through 7/25/14.<br><br>k. [redacted] QC1 on Device [redacted] revealed the following %CV: [redacted] from 9/30/14 through 11/5/14.<br><br>l. [redacted] QC1 on Device [redacted] revealed the following %CV: [redacted] from 7/31/14 through 8/28/14.<br><br>3. Based on review of Quality Assessment (QA) documentation and QA procedures, the laboratory failed to have a quality assessment (QA) procedure established to identify and correct problems with the Quality Control (QC) program for the [redacted] Findings include:<br><br>a. Monthly QC reports were reviewed for July 2014, October 2014, and February through June 2015.<br><br>b. All reports were signed by the laboratory director (LD) on 9/19/15, except the March 2015 report was signed by the LD on 11/19/15.<br><br>c. The total percentage of QC values greater than 2 standard deviations (SDs) was reviewed by the surveyor.<br><br>d. The July 2014 report indicated in the summary that 2179 controls had been run on the [redacted] devices; however, the specific report on the [redacted] device showed that only 1618 were run on all tests and all devices. | D5791 | D5791 #3<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>These improved systems include enhanced QC procedures, which reinforce and detail the required investigation and corrective action that must occur to address QC issues before patient tests are performed. In addition, they clarify which employees are responsible for performing | 2//12/16 |

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| D5791 | Continued From page 51<br><br>e. In July 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (28%), [redacted] (21%), [redacted] (28%). Overall 16% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>f. In October 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (33%), [redacted] (19%), [redacted] (47%), [redacted] (45%), [redacted] (26%), [redacted] (45%), [redacted] (32%), [redacted] (28%), [redacted] (19%), [redacted] (46%). Overall 29% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>g. In February 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (26%), [redacted] (87%), [redacted] (33%), [redacted] (24%), [redacted] (20%). Overall 24% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>h. In March 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (42%), [redacted] (20%). Overall 20% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>i. In April 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (16%), [redacted] | D5791 | D5791 #3 (continued)<br>and documenting these activities, and require regular technical supervisor review and analysis of QC results. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them.<br><br>Lab management, including technical supervisors and the quality director, is responsible for compliance with these procedures. The lab will also provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures. | |

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| D5791 | Continued From page 52<br>[redacted] (22%), [redacted] (60%). Overall 21% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>j. In May 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (34%) [redacted] (22%). Overall 26% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>k. In June 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: [redacted] (23%). Overall 14% of QC samples on all tests on all devices had values greater than 2 SDs.<br><br>4. Based on review of the quarterly Quality Assessment (QA) Power Points and interview with the QA/Quality Control (QC) Manager, the laboratory failed to identify and correct problems with drawing patient specimens. Findings include:<br><br>a. The QA/AC Manager stated that a Power Point presentation was prepared and presented to specific staff each quarter and that no minutes or corrective actions were documented.<br><br>b. The QA presentation from the 3rd quarter 2014 showed that the number 1 reason that patient specimens had to be redrawn was clots (293).<br><br>c. The QA presentation from the 1st quarter 2015 showed that the number 1 reason that patient specimens had to be redrawn was clots (246). | D5791 | D5791 #4<br>As noted by CMS above, if a patient specimen did not meet the lab's acceptance criteria, the lab's practice was to describe the issue in its electronic system, to notify relevant lab personnel, and to take, and electronically note, appropriate corrective action. Patient specimens that did not meet the lab's acceptance criteria were not used for testing.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight. | 2/12/16 |

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|---|---|---|---|---|
| D5791 | Continued From page 53<br>d. The QA presentation from the 2nd quarter 2015 showed that the number 1 reason that patient specimens had to be redrawn was clots (116).<br><br>e. There was no documentation which showed that the lab had identified the large number of redraws due to clots or that any action had been taken to correct the number of redraws due to clots. | D5791 | D5791 #4 (continued)<br>The new lab director has approved enhanced specimen rejection procedures, which require the relevant lab personnel to further monitor and assess received patient specimens and to correct problem as needed.<br><br>During monthly QA meetings, the lab will review, among other things, specimen rejection rates and any associated issues. In addition, the lab will monitor compliance through its improved occurrence management and audit procedures, both of which address preanalytic activities. | |
| D5793<br>400B | 493.1289(b)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.<br>(c) The laboratory must document all analytic systems assessment activities.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and complete blood counts (CBC) quality control and calibration record review on September 23, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's CBC processes. Finding included:<br><br>a. The laboratory's Siemens Advia 2120i procedure failed to include the corrective actions to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability. See D5403.<br><br>b. The laboratory's quality assessment | D5793 | | |

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| D5791 | Continued From page 53<br>d. The QA presentation from the 2nd quarter 2015 showed that the number 1 reason that patient specimens had to be redrawn was clots (116).<br><br>e. There was no documentation which showed that the lab had identified the large number of redraws due to clots or that any action had been taken to correct the number of redraws due to clots. | D5791 | | |
| D5793<br>400B | 493.1289(b)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.<br>(c) The laboratory must document all analytic systems assessment activities.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews and complete blood counts (CBC) quality control and calibration record review on September 23, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's CBC processes. Finding included:<br><br>a. The laboratory's Siemens Advia 2120i procedure failed to include the corrective actions to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability. See D5403.<br><br>b. The laboratory's quality assessment | D5793 | D5793 #1<br>The laboratory proactively paused testing on the Advia 2120i during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced QC procedures that address, among other things, parallel testing to verify QC values; review of QC data, including regular review by technical supervisors; and investigation and correction action to take when QC fails to meet the lab's criteria for | 2/12/16 |

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|---|---|---|---|---|
| D5793 | Continued From page 54<br>mechanism failed to ensure that all CBC calibration documentation was maintained. See D5437.<br><br>c. The laboratory's quality assessment mechanism failed to ensure that the stated values of commercially assayed CBC quality control materials were verified. See D5469.<br><br>d. The laboratory's quality assessment mechanism failed to ensure that laboratory personnel followed the established corrective action protocol when CBC quality control test results failed to meet the laboratory's criteria for acceptability even though the laboratory maintained documentation to indicate that the documented CBC quality control corrective actions had been reviewed during a quality assessment audit on August 6, 2015. In addition, the laboratory maintained no documentation it had recognized and investigated possible problems with the high quality control material being used as it had failed to meet the laboratory's criteria for acceptability upon initial testing for 5 of 7 days of patient specimen testing from July 11, 2015 to July 17, 2015. See D5779.<br><br>2. Based on laboratory personnel interviews and WBC differential [redacted] report record review on November 17, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of [redacted] corrective actions taken to resolve problems. Findings included:<br><br>a. For patient capillary specimens, it was the practice of the laboratory to use [redacted] instrumentation to perform and report patient | D5793 | D5793 #1 (continued)<br>acceptability. The lab has conducted training on those procedures.<br><br>The new lab director has also approved enhanced procedures addressing equipment systems and reinforcing that calibration documentation must be organized and maintained. The lab has conducted training on those procedures.<br><br>The new lab director has also approved an enhanced SOP for CBC on the Advia 2120i that addresses the corrective actions to take when calibration or QC fail to meet the lab's criteria for acceptability. Before the lab resumes any tests on the Advia 2120i, it will conduct training on those procedures. In addition, lab staff will be required to demonstrate competency to ensure that practice is consistent with these procedures.<br><br>Lab management, including technical supervisors and the quality director, is responsible for compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5793 | Continued From page 54<br>mechanism failed to ensure that all CBC calibration documentation was maintained. See D5437.<br><br>c. The laboratory's quality assessment mechanism failed to ensure that the stated values of commercially assayed CBC quality control materials were verified. See D5469.<br><br>d. The laboratory's quality assessment mechanism failed to ensure that laboratory personnel followed the established corrective action protocol when CBC quality control test results failed to meet the laboratory's criteria for acceptability even though the laboratory maintained documentation to indicate that the documented CBC quality control corrective actions had been reviewed during a quality assessment audit on August 6, 2015. In addition, the laboratory maintained no documentation it had recognized and investigated possible problems with the high quality control material being used as it had failed to meet the laboratory's criteria for acceptability upon initial testing for 5 of 7 days of patient specimen testing from July 11, 2015 to July 17, 2015. See D5779.<br><br>2. Based on laboratory personnel interviews and WBC differential [redacted] report record review on November 17, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of [redacted] corrective actions taken to resolve problems. Findings included:<br><br>a. For patient capillary specimens, it was the practice of the laboratory to use [redacted] instrumentation to perform and report patient | D5793 | D5793 #2<br>The lab proactively paused testing on the [redacted] during the survey.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D5793 | Continued From page 55<br>WBC differentials.<br><br>b. On August 23, 2015, in which the [redacted] was used to perform and report patient WBC differentials, laboratory [redacted] indicated that at 09:30 the [redacted] performance check failed. The performance check was repeated and again failed at 10:18. At 12:49, laboratory documentation indicated that the [redacted] performance check passed.<br><br>c. The laboratory maintained no documentation to indicate that the actions taken on August 23, 2015 to "pass" the [redacted] performance check had been reviewed for the effectiveness of the actions under the laboratory's quality assessment mechanism.<br><br>3. Based on technical supervisor interviews and human chorionic gonadotropin (HCG) quality control record review on November 19, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of HCG quality control corrective actions taken to resolve problems. Findings included:<br><br>a. It was the practice of the laboratory to use the Immulite 2000 XPi instrument to perform and report patient quantitative HCG test results. It was also the practice of the laboratory to use three levels of assayed quality control materials and the stated values of the commercially assayed quality control materials as the laboratory's criteria for acceptability to monitor patient quantitative HCG testing.<br><br>b. A review of the criteria for acceptability for the | D5793 | D5793 #2 (continued)<br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced procedures to reinforce the practice of addressing a performance check fail through documented investigations and corrective action. The lab has conducted training on those procedures.<br><br>Lab management, including technical supervisors and the quality director, are responsible for compliance with these procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5793 | Continued From page 55<br>WBC differentials.<br><br>b. On August 23, 2015, in which the [redacted] was used to perform and report patient WBC differentials, laboratory [redacted] indicated that at 09:30 the [redacted] performance check failed. The performance check was repeated and again failed at 10:18. At 12:49, laboratory documentation indicated that the [redacted] performance check passed.<br><br>c. The laboratory maintained no documentation to indicate that the actions taken on August 23, 2015 to "pass" the [redacted] performance check had been reviewed for the effectiveness of the actions under the laboratory's quality assessment mechanism.<br><br>3. Based on technical supervisor interviews and human chorionic gonadotropin (HCG) quality control record review on November 19, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of HCG quality control corrective actions taken to resolve problems. Findings included:<br><br>a. It was the practice of the laboratory to use the Immulite 2000 XPi instrument to perform and report patient quantitative HCG test results. It was also the practice of the laboratory to use three levels of assayed quality control materials and the stated values of the commercially assayed quality control materials as the laboratory's criteria for acceptability to monitor patient quantitative HCG testing.<br><br>b. A review of the criteria for acceptability for the | D5793 | D5793 #3<br>The lab proactively paused testing on the Siemens Immulite 2000 XPi during the survey.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight. | 2/12/16 |

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| D5793 | Continued From page 56<br>three quality control materials (Bio-Rad, lot number 40310, expiration date 12/31/2017) in use on November 19, 2015 indicated that for the level 1 quality control material the criteria for acceptability used to monitor patient HCG testing was 9.38 - 14.4 mIU/mL, the level 2 quality control material's criteria for acceptability used to monitor patient HCG testing was 20.6 - 32.4 mIU/mL, and the level 3 quality control material's criteria for acceptability used to monitor patient HCG testing was 264 - 376.<br><br>c. According to the manufacturer's package insert, the assayed values of the three quality control materials in use on November 19, 2015 to monitor patient HCG testing was 8.66 - 18.2 mIU/mL for level 1, 21.6 - 40.6 mIU/mL for level 2, and 306 - 460 mIU/mL for level 3.<br><br>d. According to laboratory records, the criteria for acceptability for the three quality control materials in use on November 19, 2015 to monitor patient HCG testing was changed on September 11, 2015 to the criteria for acceptability that was used until November 19, 2015. According to laboratory personnel, the change to the criteria for acceptability was made on September 11, 2015 because there was an apparent "shift" in the laboratory's quality control materials test results. The laboratory conducted no further investigation or review prior to changing the criteria for acceptability for the three quality control materials.<br><br>e. The laboratory's change of the criteria for acceptability for the two of the three HCG quality control materials resulted in criteria for acceptability outside the criteria established by the manufacturer. The laboratory maintained no | D5793 | D5793 #3 (continued)<br>These new procedures reinforce the need to document investigations and the reasons for corrective action when QC fails to meet the lab's criteria for acceptability, including the reasons for any changes to QC parameters. The lab has conducted training on those procedures.<br><br>These procedures require the technical supervisors to regularly review QC and to initiate investigations and corrective action when QC fails to meet the lab's acceptability criteria. In addition, oversight of QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab will also monitor compliance through its improved occurrence management, and audit procedures.<br><br>Before the lab resumes any test on the Siemens Immulite 2000 XPi, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the new lab director. The lab will also ensure that testing personnel have been trained and demonstrated competency to ensure that practice is consistent with these procedures and the other procedures for that test. | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D5793 | Continued From page 57<br>mechanism to assess the effectiveness of this corrective action.<br><br>f. From September 11, 2015 to November 19, 2015, the laboratory performed and reported [redacted] patient quantitative HCG tests.<br><br>4. Based on technical supervisor interviews and hepatitis B survey antibody (HBsAb) quality control record review on November 19, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of HBsAb quality control corrective actions taken to resolve problems. Findings included:<br><br>a. It was the practice of the laboratory to use the Immulite 2000 XPi instrument to perform and report patient HBsAb test results. It was also the practice of the laboratory to use three levels of assayed quality control materials and the stated values of the commercially assayed quality control materials as the laboratory's criteria for acceptability to monitor patient HBsAb testing.<br><br>b. A review of the criteria for acceptability for the three quality control materials (Siemens, lot number 0134, expiration date 11/2016) in use on November 19, 2015 indicated that for the negative quality control material the criteria for acceptability used to monitor patient HBsAb testing was 0.0 - 4.0, the low positive quality control material's criteria for acceptability used to monitor patient HBsAb testing was 10.3 - 19.6, and the positive quality control material's criteria for acceptability used to monitor patient HBsAb testing was 234 - 345.<br><br>c. According to the manufacturer's package | D5793 | D5793 #4<br>The lab proactively paused testing on the Siemens Immulite 2000 XPi during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced QC procedures to reinforce the need to document investigations and the reasons for corrective action when QC fails to meet the lab's acceptability criteria, including the reasons for any changes to QC parameters. The lab has conducted training on those procedures.<br><br>These procedures require the technical | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D5793 | Continued From page 58<br>insert, the assayed values of the three quality control materials in use on November 19, 2015 to monitor patient HBsAb testing was 0.0 - 4.0 for the negative quality control material, 11 - 21 for the low positive quality control material, and 226 - 340 for the positive quality control material.<br><br>d. According to laboratory records, the criteria for acceptability for two of the three quality control materials in use on November 19, 2015 to monitor patient HBsAb testing was changed on September 11, 2015 to the criteria for acceptability that was used until November 19, 2015. According to laboratory personnel, the change to the criteria for acceptability was made on September 11, 2015 because there was an apparent "shift" in the laboratory's quality control materials test results. The laboratory conducted no further investigation or review prior to changing the criteria for acceptability for the three quality control materials.<br><br>e. The laboratory's change of the criteria for acceptability for the two of the three HBsAb quality control materials resulted in criteria for acceptability outside the criteria established by the manufacturer. The laboratory maintained no mechanism to assess the effectiveness of this corrective action.<br><br>f. From September 11, 2015 to November 19, 2015, the laboratory performed and reported [redacted] patient HBsAb tests.<br><br>5. Based on technical supervisor interviews and luteinizing hormone (LH) quality control record review on November 19, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of | D5793 | D5793 #4 (continued)<br>supervisors to regularly review QC and to initiate investigations and corrective action when QC fails to meet the lab's acceptability criteria. In addition, oversight of QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab will also monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5793 | Continued From page 59<br>the effectiveness of LH quality control corrective actions taken to resolve problems. Findings included:<br><br>a. It was the practice of the laboratory to use the Siemens Advia Centaur XP Immunoassay System instrument to perform and report patient LH test results. It was also the practice of the laboratory to use three levels of assayed quality control materials and the stated values of the commercially assayed quality control materials as the laboratory's criteria for acceptability to monitor patient LH testing.<br><br>b. A review of the criteria for acceptability for the three quality control materials (Bio-Rad, lot number 50980, expiration date 11/30/2016) in use on November 19, 2015 indicated that for the level 1 quality control material the criteria for acceptability used to monitor patient LH testing was 2.86 - 4.18 mIU/mL, the level 2 quality control material's criteria for acceptability used to monitor patient LH testing was 16.98 - 25.48 mIU/mL, and the level 3 quality control material's criteria for acceptability used to monitor patient LH testing was 57.6 - 84.8 mIU/mL.<br><br>c. According to the manufacturer's package insert, the assayed values of the three quality control materials in use on November 19, 2015 to monitor patient LH testing was 2.86 - 4.18 mIU/mL for level 1, 16.6 - 23.9 mIU/mL for level 2, and 57.6 - 84.8 mIU/mL for level 3.<br><br>d. According to laboratory records, the criteria for acceptability for one of the three quality control materials in use on November 19, 2015 to monitor patient LH testing was changed on July 9, 2015 to the criteria for acceptability that was used | D5793 | D5793 #5<br>The lab proactively paused testing on the Siemens Advia Centaur XP Immunoassay System during the survey.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>These new procedure reinforce the need to document investigations and the reasons for corrective action when QC fails to meet the lab's acceptability criteria, including the reasons for any changes to QC parameters. The lab has conducted training on those procedures.<br><br>These procedures require the technical supervisors to regularly review QC and to initiate investigations and corrective action when QC fails to meet the lab's criteria for acceptability. In addition, oversight of QC reviews, investigations and corrective action occurs through | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D5793 | Continued From page 60<br>until November 19, 2015. According to laboratory personnel, the change to the criteria for acceptability was made on July 9, 2015 because there was an apparent "shift" in the laboratory's quality control materials test results. The laboratory conducted no further investigation or review prior to changing the criteria for acceptability for the three quality control materials.<br><br>e. The laboratory's change of the criteria for acceptability for the one of the three LH quality control materials resulted in criteria for acceptability outside the criteria established by the manufacturer. The laboratory maintained no mechanism to assess the effectiveness of this corrective action.<br><br>f. From July 9, 2015 to November 19, 2015, the laboratory performed and reported [redacted] patient LH tests.<br><br>6. Based on technical supervisor interviews and CA-125 quality control record review on November 19, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of CA-125 quality control corrective actions taken to resolve problems. Findings included:<br><br>a. It was the practice of the laboratory to use the Immulite 2000 XPi instrument to perform and report patient CA-125 test results. It was also the practice of the laboratory to use three levels of assayed quality control materials and the stated values of the commercially assayed quality control materials as the laboratory's criteria for acceptability to monitor patient CA-125 testing. | D5793 | D5793 #5<br>monthly QA meetings. The lab will also monitor compliance through its improved occurrence management and audit procedures.<br><br>D5783 #6<br>This finding appears to have a typographical error because CA-125 was tested on the Siemens Advia Centaur XP Immunoassay System during this period, not the Siemens Immulite 2000 XPi.<br><br>The lab proactively paused testing on the Siemens Advia Centaur XP Immunoassay System during the survey.<br><br>The lab has completed an assessment | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D5793 | Continued From page 61<br><br>b. A review of the criteria for acceptability for the three quality control materials (Bio-Rad, lot number 19980, expiration date 09/30/2016) in use on November 19, 2015 indicated that for the level 1 quality control material the criteria for acceptability used to monitor patient CA-125 testing was 18.6 - 28.7 U/mL, the level 2 quality control material's criteria for acceptability used to monitor patient CA-125 testing was 53.5 - 82.2 U/mL, and the level 3 quality control material's criteria for acceptability used to monitor patient CA-125 testing was 92.5 - 141 U/mL.<br><br>c. According to the manufacturer's package insert for quality control materials Bio-Rad, lot number 19980, there were no assayed values for the three quality control materials in use on November 19, 2015 to monitor patient CA-125. According to laboratory personnel, the quality control material's manufacturer could not publish the criteria for acceptability at the time the quality control material was received by the laboratory, and was told by the manufacturer to use the criteria for acceptability from the previous lot of quality control materials. The laboratory maintained no documentation to support the manufacturer's instructions for the use of the criteria for acceptability from the previous lot of quality control materials.<br><br>d. A review of the manufacturer's criteria for acceptability from the previous lot of CA-125 quality control materials revealed that the criteria for acceptability for the quality control materials used by the laboratory on November 19, 2015 to monitor patient CA-125 testing did not match the criteria for acceptability from the previous lot of CA-125 quality control materials. | D5793 | D5793 #6 (continued)<br>to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced QC procedures to reinforce the need to document investigations and the reasons for corrective action when QC fails to meet the lab's acceptability criteria, including the reasons for any changes to QC parameters. The lab has conducted training on those procedures.<br><br>These procedures require the technical supervisors to regularly review QC and to initiate investigations and corrective action when QC fails to meet the lab's criteria for acceptability. In addition, oversight of QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab will also monitor compliance through its improved occurrence management, and audit procedures. | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D5793 | Continued From page 62<br><br>e. Upon further review, it was discovered that the criteria for acceptability for the quality control materials used by the laboratory on November 19, 2015 to monitor patient CA-125 testing was the criteria for acceptability established by the manufacturer for Bio-Rad, lot number 19980, for use on a different instrument and not the Siemens Advia Centaur XP Immunoassay System instrument.<br><br>f. From the date quality control materials Bio-Rad, lot number 19980 to November 19, 2015, the laboratory performed and reported [redacted] patient CA-125 tests.<br><br>7. Based on laboratory personnel interviews and the laboratory's "Alternative Assessment Program" (AAP) record review on November 20, 2015, the laboratory failed to have an analytic systems quality assessment mechanism that included the timely review of the effectiveness of actions taken. Findings included:<br><br>a. To comply with the CLIA requirement at 42 C.F.R. 493.1281(a), the laboratory maintained a protocol titled "Proficiency Testing for [redacted] that included a laboratory process called AAP in which tests performed using [redacted] would be evaluated and defined in relationship to the Advia XPT.<br><br>b. A review of laboratory documents indicated that for the following AAP events, the laboratory's evaluation was not timely and, therefore, ineffective:<br><br>i. On April 1, 2014, the laboratory completed testing for [redacted] analytes using the | D5793 | D5793 #7<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced procedures requiring that alternative assessments must be subject to timely review and | 2/12/16 |

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| D5793 | Continued From page 63<br>[redacted] and compared these test results to test results on the same samples using the Advia XPT. Laboratory records indicated that the review of this AAP was not completed until November 16, 2015 by appropriate laboratory personnel and was not reviewed by the laboratory director as required by laboratory protocol.<br><br>ii. On May 15, 2014, the laboratory completed testing for [redacted] analytes using [redacted] and compared these test results to test results on the same samples using the Advia XPT. Laboratory records indicated that the review of this AAP was not completed until November 15, 2015 by appropriate laboratory personnel.<br><br>iii. On July 31, 2014, the laboratory completed testing for [redacted] analytes using [redacted] and compared these test results to test results on the same samples using the Advia XPT. Laboratory records indicated that the review of this AAP was not completed until November 16, 2015 by appropriate laboratory personnel and was not reviewed by the laboratory director as required by laboratory protocol.<br><br>iv. On November 20, 2014, the laboratory completed testing for [redacted] analytes using [redacted] and compared these test results to test results on the same samples using the Advia XPT. Laboratory records indicated that the review of this AAP was not completed until November 15, 2015 by appropriate laboratory personnel.<br><br>8. Based on review of the quality control (QC) procedure, Levey-Jennings reports for [redacted] and Advia XPT, proficiency testing (PT) | D5793 | D5793 #7 (continued)<br>evaluation by the lab director and/or a technical supervisor.<br><br>The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management and audit procedures. | 2/12/16 |

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| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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| D5793 | Continued From page 64<br>results and quality assessment (QA) documentation the laboratory failed to take corrective actions when chemistry QC in the venipuncture laboratory was observed ten consecutive times on the same side of the mean. Findings include:<br><br>a, CL QOP-00013 Revision D, "Quality Control in Chemistry", stated in section 6.3.1.7.2 that QC is deemed to have passed when...Westgard rules hae not been violated (see following monthly QC section 6.3.2)."<br><br>b. CL QOP-00013 Revision D also stated in section 6.3.2.5 that ten consecutive observations on the same side of the mean should be monitored.<br><br>c. The Advia XPT was put into use for chemistry testing on 12/18/14. Prior to 12/18/14, the Advia 1800 was used for chemistry testing.<br><br>Albumin<br><br>i. Review of the PT results for albumin for the 1st and 2nd events of 2015 revealed that the submitted results showed a negative bias ranging from -3.3 to -4.9 and -1.8 to -3.5, respectively.<br><br>ii. Review of Levey-Jenning reports from April 2014 and September 2014, revealed that MultiQual Level 1 (MQ1) and Multi Qual Level 2 (MQ2) had at least 10 consecutive results below the mean but within 2 standard deviations (SD).<br><br>iii. Review of Levey-Jenning reports for January 2015 through April 2015 revealed MQ1 (Lot number 45661) had 10 consecutive results below the mean, MQ2 (Lot number 45662) had 10 | D5793 | D5793 #8<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced QC procedures to reinforce that regular review of QC data is required and that investigations and corrective actions must be taken when QC fails to meet the lab's criteria for acceptability. The lab has conducted training on those procedures to ensure that practice is consistent with them.<br><br>These procedures require the technical supervisors to regularly review QC and to initiate investigations and corrective action when QC fails to meet the lab's criteria for acceptability. In addition, oversight of QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab will also monitor compliance through its improved occurrence management, and audit procedures. | |

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| D5793 | Continued From page 65<br>consecutive results below the mean and MultiQual Level3 (MQ3, Lot number 45663) had 10 consecutive results below the mean but within 2 SDs for all four months.<br><br>iv. MQ1 data revealed 125 of 125 below the mean for January 2015 through April 2015 but within 2 SDs.<br><br>v. MQ2 data revealed 126 of 126 below the mean for January 2015 through April 2015 but within 2 SDs.<br><br>vi. MQ3 data revealed 123 of 125 below the mean for January 2015 through April 2015 but within 2 SDs.<br><br>vii. Review of Levey-Jenning reports from May 2015 revealed that MQ1, MQ2 and MQ3 were below the mean for 21 of 31 days.<br><br>viii. The mean for all three levels was adjusted on 5/22/15 to fit the data without investigation or documentation of an investigation. After 5/22/15 all 3 levels of QC were above the mean.<br><br>ix. The manufacturer ranges for MQ1 (Lot number 45661) was 2.03-3.04 g/dL; MQ2 (Lot number 45662) was 3.04-4.56 g/dL; MQ3 (Lot number 45663) was 3.26-4.89 g/dL.<br><br>x. After adjusting the acceptable ranges on 5/22/15, the laboratory's ranges fell outside the manufacturer's assayed ranges and were as follows: MQ1 (1.77-2.665 g/dL); MQ2 (2.5-3.74 g/dL; MQ3 (3.02-4.52 g/dL).<br><br>xi. Quarterly Quality Assessment PowerPoint presentations from the 3rd quarter of 2014 | D5793 | (continued; see above) | |

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| D5793 | Continued From page 66<br>through the 2nd quarter of 2015 did not identify the negative bias for albumin or the 10 consecutive QC values above or below the mean.<br><br>xii. [redacted] albumins were reported from January 2015 through June 2015.<br><br>Calcium<br><br>i. Review of the PT results for calcium for the 2nd events of 2015 revealed that the submitted results showed a negative bias ranging from -3.9 to -5.1.<br><br>ii. Review of Levey-Jenning reports from April 2014 and May 2015 revealed 27 of 27 and 25 of 25 QC consecutive results below the mean but within 2 SDs.<br><br>iii. [redacted] calciums were reported from January 2015 through June 2015.<br><br>Other Chemistries<br><br>Review of Levey-Jenning reports from April 2014, September 2014, and January 2014 revealed that Creatinine, Glucose, High density lipoprotein (HDL), Low density lipoprotein (LDL), Total Bilirubin, Chloride, Potassium, Triglycerides, Cholesterol, Alkaline Phosphatase, and Alanine Transaminase had at least one event of 10 consecutive QC results above or below the mean but within 2 SDs for one to 3 levels of QC.<br><br>9. Based on review of the alternative assessment procedure (AAP) and results of AAP from August 2014 through March 2015, the laboratory failed to identify through the quality assessment (QA) activities that the AAP for the | D5793 | (continued; see above) | |

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| D5793 | Continued From page 67<br>[redacted] was not performed every 6 months and was not reviewed and reviewed and approved by the laboratory (LD) in a timely manner as required by the laboratory's procedures, and therefore, ineffective. Findings include:<br><br>a. CL SOP-00020 Revision B, "Proficiency testing for [redacted], effective 1/1/2014, stated in section 3.1 that the technical supervisor (TS) was responsible for ensuring that the AAP was conducted every 6 months for all analytes.<br><br>b. Section 3.3.2 of the procedures stated that the TS was reponsible for evaluating testing samples results and section 3.4 stated that the LD was responsible for reviewing and approving each testing event documentation.<br><br>c. Review of the AAP result forms (CL FRM-00022-F3) revealed that the AAP was performed on 8/18/14, 10/21/14, and 3/13/15.<br><br>d. All three result forms did not include a documented evaluation by the TS.<br><br>e. The result documents from 8/18/14 and 3/15/15 were not signed by the LD until 11/15/15 and the result form from 10/12/14 was not signed by the LD.<br><br>f. [redacted] tests [redacted] were initially implemented in November 2013.<br><br>10. Based on review of patient raw data reports and the validation report for [redacted] the | D5793 | D5793 #9<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The new lab director is responsible for the lab's QA program. The lab has also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced quality systems to ensure that the lab's procedures are followed. Among other things, the lab's management, including the new lab director and new quality systems director, will provide oversight over proficiency testing and AAP through monthly QA meetings. The lab will also monitor compliance through its improved occurrence management, and audit procedures.<br><br>Before the survey, the lab proactively paused testing on its laboratory developed tests. It is not currently performing AAP testing. | 2/12/16 |

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| D5793 | Continued From page 68<br>laboratory failed to have a quality assessement mechanism to identify that the laboratory's reference ranges established from the validation study were accurately reflected on the patient raw data reports. Findings include:<br><br>a. The validation report for [redacted] stated that the reference range was 9.3-47.9 ng/mL.<br><br>b. The patient raw data reports revealed that the reference range was "30-100."<br><br>c. Patient raw data reports were reviewed from 6/15/14 through 8/31/14 and from 2/1/15 through 2/17/15.<br><br>d. Thirty (30) of ninety-four (94) patient results were flagged as "Insufficiency" on the patient raw data report when the result was normal according to the laboratory's reference range.<br><br>e. Twenty seven (27) of ninety four (94) patient results were flagged as normal on the patient raw data report when the result was above the normal range according to the laboratory's reference range. | D5793 | | |
| D5801 | 493.1291(a) TEST REPORT<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:<br>(a)(1) Results reported from calculated data.<br>(a)(2) Results and patient-specific data electronically reported to network or interfaced | D5801 | D5801<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has | 2/12/16 |

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| D5793 | Continued From page 68<br>laboratory failed to have a quality assessement mechanism to identify that the laboratory's reference ranges established from the validation study were accurately reflected on the patient raw data reports. Findings include:<br><br>a. The validation report for [redacted] stated that the reference range was 9.3-47.9 ng/mL.<br><br>b. The patient raw data reports revealed that the reference range was "30-100."<br><br>c. Patient raw data reports were reviewed from 6/15/14 through 8/31/14 and from 2/1/15 through 2/17/15.<br><br>d. Thirty (30) of ninety-four (94) patient results were flagged as "Insufficiency" on the patient raw data report when the result was normal according to the laboratory's reference range.<br><br>e. Twenty seven (27) of ninety four (94) patient results were flagged as normal on the patient raw data report when the result was above the normal range according to the laboratory's reference range. | D5793 | D5801 (continued):<br>also appointed a Quality Director who will provide additional oversight.<br><br>The new lab director has approved enhanced procedures for reagent qualification and management that include procedures to ensure manufacturer inserts are reviewed. Training on these procedures has occurred.<br><br>Before PT/INR testing resumes, the lab will also prepare a revised assay-specific procedure for PT/INR to reinforce that the International Normalized Ratio (INR) must be calculated accurately prior to reporting patient test results. The relevant testing personnel will be required to demonstrate competency to ensure that practice is consistent with these procedures. | |
| D5801 | 493.1291(a) TEST REPORT<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:<br>(a)(1) Results reported from calculated data.<br>(a)(2) Results and patient-specific data electronically reported to network or interfaced | D5801 | The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management, and audit procedures. | |

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|---|---|---|---|---|
| D5801 | Continued From page 69<br>systems.<br>(a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br>This STANDARD is not met as evidenced by:<br>Based on review of the patient results, manufacturer International Sensitivity Index (ISI) number, and the laboratory's mean normal prothrombin time (MNPT), the laboratory failed to ensure that the reported International Normalized Ratio (INR) was calculated accurately prior to reporting final patient test results. Findings include:<br><br>a. Laboratory quality control records revealed that Dade Innovin (thromboplastin) lot number 539280 was put into use in March 2015. The MNPT for this lot number was determined to be 8.0 seconds and the manufacturer stated that the ISI was 0.89.<br><br>b. A review of the INR results from 4/3/15 through 9/21/15 revealed that 81 of 81 reported final patient results were not accurate when the patient prothrombin time (PT) was used with the above MNPT and ISI numbers to calculate the INR.<br><br>c. The final reported results varied from the true results by 0.1-0.5 units. | D5801 | | |
| D5805 | 493.1291(c) TEST REPORT<br><br>The test report must indicate the following:<br>(c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. | D5805 | D5805:<br>The lab revised its patient reports for PT/INR during the survey so that the interpretive note appears only under the heading for patients with therapy. | 2/12/16 |

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| D5805 | Continued From page 70<br>(c)(2) The name and address of the laboratory location where the test was performed.<br>(c)(3) The test report date.<br>(c)(4) The test performed.<br>(c)(5) Specimen source, when appropriate.<br>(c)(6) The test result and, if applicable, the units of measurement or interpretation, or both.<br>(c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br>This STANDARD is not met as evidenced by:<br>Based on review of final reports and interview with the Senior Vice President, the laboratory failed to differentiate the intrepretive data for Warfarin therapy vs. Non-Warfarin Therapy. Findings include:<br><br>a. Thirteen of thirteen final patient test reports reviewed indicated that the International Normalized Ratio (INR) interpretive data on the final report was identical for Warfarin therapy and non-Warfarin therapy.<br><br>b. The Senior Vice President confirmed the above finding on 9/22/15 at approximately 4:45 pm. | D5805 | D5805 (continued):<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced reporting procedures that require the technical supervisor to verify that interpretive information is accurate and to obtain approval from the lab director or clinical consultant before any updates are implemented.<br><br>The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management, and audit procedures. | |
| D5821 | 493.1291(k) TEST REPORT<br><br>When errors in the reported patient test results are detected, the laboratory must do the following:<br>(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.<br>(k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.<br>(k)(3) Maintain duplicates of the original report, as | D5821 | D5821:<br>The new lab director has approved enhanced procedures to address correcting potential errors in patient reports. These procedures require that the person ordering the test is promptly notified after the lab determines that a correction is required. | 2/12/16 |

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|---|---|---|---|---|
| D5821 | Continued From page 71<br>well as the corrected report.<br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports and interview with the technical supervisor, the laboratory failed to notify the authorized person for approximately seven weeks after the surveyor identified a quality control problem with Prothrombin Time/International Normalized Ratio (PT/INR). Findings include:<br><br>a. Refer to D6093.<br><br>b. Five of thirteen final patient reports reviewed showed corrected reports were faxed between 11/11/15 and 11/15/15.<br><br>c. Eight of thirteen final patient reports reviewed did not show documentation that the authroized person was notified when an error in patient test results was detected.<br><br>d. [redacted] PT/INR patient test results were reported from 4/1/15 through 9/16/15.<br><br>e. The technical supervisor stated that all authorized persons were notified of the error in PT/INR results, including those without documentation. | D5821 | D5821 (continued):<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management and audit procedures. | |
| D6076 | 493.1441 LABORATORY DIRECTOR<br><br>The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the | D6076 | D6076:<br>The laboratory has completed assessments to identify any patients affected or having the potential to be affected by the issues identified in this observation, and has taken corrective and preventative action. Among other things, the lab has hired a new lab | 2/12/16 |

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| D6076 | Continued From page 72<br>deficiencies cited herein, the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director failed to ensure that appropriate personnel were responsible for the quality control (QC) and quality assessment (QA) programs (see D6079); failed to ensure that the freezer temperatures were appropriate for storage of specimens and reference materials (see D6083); failed to ensure the methodologies selected provided quality results (see D6085); failed to ensure the verification procedures were adequate (see D6086); failed to ensure that the QC programs (see D6093) and QA programs (see D6094) are established and maintained; failed to ensure that the final patient test reports included appropriate interpretation information for PT/INR (see D6098); and failed to ensure that all personnel were appropriately trained (see D6102). | D6076 | D6076 (continued)<br>director and established improved quality systems and related procedures addressing the issues identified in this observation. (D6079, D6083, D6085, D6086, D6093, D6094, D6102). | |
| D6079 | 493.1445(a)(b) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.<br>(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively.<br>(b) If the laboratory director reapportions | D6079 | D6079<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures, including | 2/12/16 |

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| D6079 | Continued From page 73<br>performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br>This STANDARD is not met as evidenced by:<br>Based on the Plan of Correction (POC) from the 12/3/2013 recertification survey and review of quality control (QC) and quality assessment (QA) documentation and the Laboratory Personnel Report (CMS-209), the laboratory director (LD) failed to ensure that the laboratory's QC and QA programs were delegated to a qualified technical supervisor (TS). Findings include:<br><br>a. The POC from the laboratory's 12/3/2013 recertification survey stated that a QA/QC Manager was hired and began employment on 12/10/13.<br><br>b. The QA/QC Manager stated on 9/23/15 and again on 11/19/15 that evaluating and monitoring the QA and QC programs was solely the QA/QC Manager's responsibility.<br><br>c. The QA/QC Manager was not listed on the CMS-209 forms dated 9/19/15, 9/23/15, or 11/15/15 in any capacity.<br><br>d. The QA/QC Manager was not qualified to oversee and maintain the QC and QA programs. | D6079 | D6079 (continued)<br>revised QC procedures to ensure the appropriate supervisors are involved in review of quality metrics. The lab has conducted training on those procedures. The new lab director is the technical supervisor for chemistry, hematology, and immunohematology. During the survey, CMS determined that Technical Supervisor #3 was qualified in bacteriology, mycology, virology, and diagnostic immunology. These technical supervisors are now responsible for QC assessments in their respective specialties.<br><br>The lab will ensure that the new lab director is effective in overseeing compliance with these procedures through audits performed pursuant to the lab's new audit procedures, through oversight during monthly QA meetings, and through use of a new on-site visit log that records the lab director's time spent physically in the lab. | |
| D6083 | 493.1445(e)(2) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.<br>This STANDARD is not met as evidenced by:<br>Based on review of temperature documentation | D6083 | D6083<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed. | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D6083 | Continued From page 74<br>and interview with the [redacted] the laboratory director failed to ensure that the freezer temperatures were appropriate for storage of reference materials and patient specimens. Refer to D5413 and D5791. | D6083 | D6083 (continued)<br>A review of hourly data demonstrated that average hourly temperature for nearly all of the freezers at issue met the manufacturer temperature requirements for the materials stored. | |
| D6085 | 493.1445(e)(3) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.<br>This STANDARD is not met as evidenced by:<br>Based on review of validation documents on the [redacted] the laboratory director failed to ensure that the quality of results on the [redacted], failed to ensure the establishment of performance specifications followed the laboratory's procedures to establish accuracy, precision, reportable range, and/or reference range. Findings include:<br><br>a. Validations Reports for [redacted] were reviewed.<br><br>b. The laboratory presented the procedure, CL PLN-14003 Revision A, "Master Validation Plan for [redacted] when the surveyor requested their procedure for establishing performance specifications.<br><br>c. [redacted] validation reports included [redacted] results without an explanation as to how the "[redacted] Result" was corrected or which result was reported. | D6085 | The lab has identified and discarded any materials that had the potential to have been affected. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including temperature management procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced temperature management procedures, which reinforce the proper monitoring of temperature and environmental conditions and the storage of materials according to the manufacturer's temperature range. | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D6083 | Continued From page 74<br>and interview with the [redacted] the laboratory director failed to ensure that the freezer temperatures were appropriate for storage of reference materials and patient specimens. Refer to D5413 and D5791. | D6083 | D6083 (continued)<br>The lab has conducted training on those procedures | |
| D6085 | 493.1445(e)(3) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.<br>This STANDARD is not met as evidenced by:<br>Based on review of validation documents on the [redacted] the laboratory director failed to ensure that the quality of results on the [redacted], failed to ensure the establishment of performance specifications followed the laboratory's procedures to establish accuracy, precision, reportable range, and/or reference range. Findings include:<br><br>a. Validations Reports for [redacted] were reviewed.<br><br>b. The laboratory presented the procedure, CL PLN-14003 Revision A, "Master Validation Plan for [redacted] when the surveyor requested their procedure for establishing performance specifications.<br><br>c. [redacted] validation reports included [redacted] results without an explanation as to how the "[redacted] Result" was corrected or which result was reported. | D6085 | D6085<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including verification and validation procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced procedures for method verification. Before any | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
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| D6085 | Continued From page 75<br><br>d. Accuracy for [redacted] was not determined following CL PLN-14003.<br><br>e. Precision for [redacted] was not determined following CL PLN-14003.<br><br>f. Reportable range data for [redacted] was not determined following CL PLN-14003.<br><br>g. Percent (%) Recovery did not meet the laboratory's accetable criteria for [redacted]<br><br>h. Allowable Bias did not meet the laboratory's acceptable criteria for [redacted]<br><br>i. Refer to D6115. | D6085 | D6085 (continued)<br>verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures.<br><br>The lab will ensure that the new lab director also implements enhanced validation procedures, which will include review processes and acceptance criteria similar to the improved method verification procedures, along with other required procedures. Relevant lab personnel will receive training and competency on those procedures to ensure that practice is consistent with them. | |
| D6086 | 493.1445(e)(3)(ii) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interview and establishment of vitamin B12 performance specifications record review on September 22, 2015, the laboratory director failed to ensure that verification procedures used were adequate to determine pertinent performance characteristics for the laboratory's vitamin B12 testing methods. Findings included:<br><br>a. A review of the laboratory's vitamin B12 | D6086 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6085 | Continued From page 75<br><br>d. Accuracy for [redacted] was not determined following CL PLN-14003.<br><br>e. Precision for [redacted] was not determined following CL PLN-14003.<br><br>f. Reportable range data for [redacted] was not determined following CL PLN-14003.<br><br>g. Percent (%) Recovery did not meet the laboratory's accetable criteria for [redacted]<br><br>h. Allowable Bias did not meet the laboratory's acceptable criteria for [redacted]<br><br>i. Refer to D6115. | D6085 | (continued: see above) | |
| D6086 | 493.1445(e)(3)(ii) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interview and establishment of vitamin B12 performance specifications record review on September 22, 2015, the laboratory director failed to ensure that verification procedures used were adequate to determine pertinent performance characteristics for the laboratory's vitamin B12 testing methods. Findings included:<br><br>a. A review of the laboratory's vitamin B12 | D6086 | D6086 #1<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D6086 | Continued From page 76<br>establishment of performance specifications document indicated that the laboratory obtained an allowable bias greater than the laboratory's criteria for acceptability. When asked to explain this discrepant result, upon close examination, laboratory personnel indicated that there was an error in the written information provided and reviewed. The laboratory was able to provided corrected data and appropriate supporting documents.<br><br>b. In spite of the erroneous information included in the vitamin B12 establishment of performance specifications document provided during this survey for review on September 22, 2015, laboratory records indicated that eleven people from the laboratory's staff approved this document between August 5, 2014 and September 19, 2015 without recognizing the document error.<br><br>2. Based on laboratory personnel interviews and establishment of performance specifications policies and procedures record review on September 22, 2015, the laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the laboratory's [redacted] testing methods. Findings included:<br><br>a. It was the practice of the laboratory to use the [redacted] to perform and report patient testing. Examples of analytes the laboratory tested using the [redacted] included [redacted]<br><br>b. According to the laboratory's protocol titled | D6086 | D6086 #1 (continued)<br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including verification and validation procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced procedures for method verification. Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures.<br><br>The lab will ensure that the new lab director also implements enhanced validation procedures, which will include review processes and acceptance criteria similar to the improved method verification | |

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|---|---|---|---|
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| D6086 | Continued From page 76<br>establishment of performance specifications document indicated that the laboratory obtained an allowable bias greater than the laboratory's criteria for acceptability. When asked to explain this discrepant result, upon close examination, laboratory personnel indicated that there was an error in the written information provided and reviewed. The laboratory was able to provided corrected data and appropriate supporting documents.<br><br>b. In spite of the erroneous information included in the vitamin B12 establishment of performance specifications document provided during this survey for review on September 22, 2015, laboratory records indicated that eleven people from the laboratory's staff approved this document between August 5, 2014 and September 19, 2015 without recognizing the document error.<br><br>2. Based on laboratory personnel interviews and establishment of performance specifications policies and procedures record review on September 22, 2015, the laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the laboratory's [redacted] testing methods. Findings included:<br><br>a. It was the practice of the laboratory to use the [redacted] to perform and report patient [redacted] testing. Examples of analytes the laboratory tested using the [redacted] included [redacted]<br><br>b. According to the laboratory's protocol titled | D6086 | D6086 #1 (continued)<br>procedures, along with the other required procedures. Relevant lab personnel will receive training and competency on those procedures to ensure that practice is consistent with them.<br><br>D6086 #2<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab | |

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|---|---|---|---|
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|---|---|---|---|---|
| D6086 | Continued From page 77<br>"Master Validation Plan for [redacted] Assays on [redacted]" "for establishing the trueness or comparability of two procedures. . .at least 50% of samples should be outside the reference interval."<br><br>c. A review of the test results used by the laboratory to establish "the trueness or comparability of two procedures" for [redacted] testing using the [redacted] showed that the laboratory did not follow its established protocol and use "at least 50% of samples. . .outside the reference interval."<br><br>i. For a validation document dated April 2, 2015, [redacted] test results used to establish "the trueness or comparability of two procedures" for tests performed using the [redacted], 6 of 110 [redacted] test results used were outside the laboratory's reference interval.<br><br>ii. For a validation document dated April 21, 2015, [redacted] test results used to establish "the trueness or comparability of two procedures" for tests performed using the [redacted] 1 of 109 [redacted] test result used was outside the laboratory's reference interval.<br><br>iii. For a validation document dated April 21, 2015, [redacted] test results used to establish "the trueness or comparability of two procedures" for tests performed using the [redacted] 1 of 110 [redacted] test result used was outside the laboratory's reference interval.<br><br>iv. For a validation document dated April 21, 2015, [redacted] test results used to establish "the trueness or comparability of two procedures" for tests performed using the [redacted], 6 of 110 | D6086 | D6086 #2 (continued)<br>director effectively implements and monitors lab procedures, including verification and validation procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced procedures for method verification. Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures.<br><br>The lab will ensure that the new lab director also implements enhanced validation procedures, which will nclude review processes and acceptance criteria similar to the improved method verification | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6086 | Continued From page 78<br>[redacted] test results used were outside the laboratory's reference interval.<br><br>v. For a validation document dated April 1, 2015, [redacted] test results used to establish "the trueness or comparability of two procedures" for tests performed using the [redacted], 1 of 113 [redacted] test result used was outside the laboratory's reference interval.<br><br>3. Based on laboratory personnel interviews and establishment of performance specifications record review on November 17, 2015, the laboratory director failed to ensure that [redacted] verification procedures used were adequate to determine the precision of the laboratory's [redacted] testing methods. Findings included:<br><br>a. It was the practice of the laboratory to use the [redacted] to perform and report patient testing. Examples of analytes the laboratory tested using the [redacted] included [redacted]<br><br>b. A review of laboratory documents establishing performance specifications fo[redacted] performed using the [redacted] indicated that the coefficient of variation (CV) determined by the laboratory's testing [redacted]<br><br>i. For [redacted], based on a laboratory document dated April 2, 2015, the laboratory determined [redacted] | D6086 | D6086 #2 (continued)<br>procedures, along with the other required procedures. Relevant lab personnel will receive training and competency on those procedures to ensure that practice is consistent with them.<br><br>D6086 #3<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including verification and validation procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6086 | Continued From page 79<br><br>ii. For [redacted], based on a laboratory document dated April 21, 2015, the laboratory determined [redacted]<br><br>iii. For [redacted], based on a laboratory document dated April 21, 2015, the laboratory determined [redacted]<br><br>iv. For [redacted] based on a laboratory document dated April 21, 2015, the laboratory determined [redacted]<br><br>v. For [redacted], based on a laboratory document dated April 1, 2015, the laboratory determined [redacted]<br><br>c. The laboratory provided no written explanation/investigation as to why the laboratory obtained [redacted] using the [redacted] that were greater than [redacted] Laboratory records indicated that these laboratory documents were approved by the laboratory director on September 19, 2015.<br><br>4. Based on laboratory personnel interviews and establishment of performance specifications record review on November 17, 2015, the laboratory director failed to ensure that [redacted] verification procedures | D6086 | D6086 #3 (continued)<br>that the new lab director implements the lab's enhanced procedures for method verification. Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures.<br><br>The lab will ensure that the new lab director also implements enhanced validation procedures, which will include review processes and acceptance criteria similar to the improved method verification procedures, along with the other required procedures. Relevant lab personnel will receive training and competency on those procedures to ensure that practice is consistent with them.<br><br>D6086 #4<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6086 | Continued From page 80<br>used were adequate to determine pertinent performance characteristics, such as reference range, of the laboratory's [redacted] testing methods. Findings included:<br><br>a. It was the practice of the laboratory to use the [redacted] to perform and report patient [redacted] testing. Examples of analytes the laboratory tested using the [redacted] included [redacted].<br><br>b. A review of laboratory documents establishing performance specifications for [redacted] performed using the [redacted] indicated that the reference range determined by the laboratory's testing differed from the reference range on the laboratory's test reports.<br><br>i. For [redacted], based on a laboratory document dated April 2, 2015, the laboratory determined the [redacted] reference range as 0 - 52 U/L. However, the laboratory's reference range on the test reports was 8 - 41 U/L.<br><br>ii. For [redacted], based on a laboratory document dated April 21, 2015, the laboratory determined [redacted] reference range as 5.3 - 22.5 mg/dL. However, the laboratory's reference range on the test reports was 6 - 24 mg/dL.<br><br>iii. For [redacted], based on a laboratory document dated April 21, 2015, the laboratory determined the [redacted] reference range as 8.18 - 10.3 mg/dL. However, the laboratory's reference range on the test reports was 8.3 - 10.6 mg/dL.<br><br>iv. For [redacted] based on a laboratory document dated April 21, 2015, the laboratory determined | D6086 | D6068 #4 (continued)<br>lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including verification and validation procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced procedures for method verification. Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. | |

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|---|---|---|---|
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| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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| D6086 | Continued From page 81<br>the [redacted] reference range as 64.0 - 112.3 mg/dL. However, the laboratory's reference range on the test reports was 73 - 99 mg/dL.<br><br>c. The laboratory provided no written explanation/investigation as to why the laboratory obtained reference ranges [redacted] were different than than the reference ranges indicated on the test reports.. Laboratory records indicated that these laboratory documents were approved by the laboratory director on September 19, 2015.<br><br>5. Based on laboratory personnel interviews and complete blood counts (CBC) verification of method specifications record review on November 19, 2015, the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics for the two Siemens Advia 2120i instruments. Findings included:<br><br>a. It was the practice of the laboratory to test patient venous CBC specimens using two Siemens Advia 2120i instruments, designated as #1 and #2.<br><br>b. Although the laboratory maintained verification of test performance specifications documents for the two Advia 2120i instruments, the laboratory maintained no documentation to indicate that verification results for the two instruments were acceptable to the laboratory, no evidence that the laboratory director had reviewed and approved the verification documents, and no date the verification documents were reviewed and approved. | D6086 | D6068 #4 (continued)<br>The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures.<br><br>Any update to a reference range is reviewed and approved by the lab director or a clinical consultant, and the lab has procedures to ensure that data on patient reports are consistent with established reference ranges. In addition, the lab will ensure that the new lab director also implements enhanced validation procedures, which will include review processes and acceptance criteria similar to the improved method verification procedures, along with the other required procedures. Relevant lab personnel will receive training and competency on those procedures to ensure that practice is consistent with them. | |

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| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D6086 | Continued From page 81<br>the [redacted] reference range as 64.0 - 112.3 mg/dL. However, the laboratory's reference range on the test reports was 73 - 99 mg/dL.<br><br>c. The laboratory provided no written explanation/investigation as to why the laboratory obtained reference ranges [redacted] were different than than the reference ranges indicated on the test reports.. Laboratory records indicated that these laboratory documents were approved by the laboratory director on September 19, 2015.<br><br>5. Based on laboratory personnel interviews and complete blood counts (CBC) verification of method specifications record review on November 19, 2015, the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics for the two Siemens Advia 2120i instruments. Findings included:<br><br>a. It was the practice of the laboratory to test patient venous CBC specimens using two Siemens Advia 2120i instruments, designated as #1 and #2.<br><br>b. Although the laboratory maintained verification of test performance specifications documents for the two Advia 2120i instruments, the laboratory maintained no documentation to indicate that verification results for the two instruments were acceptable to the laboratory, no evidence that the laboratory director had reviewed and approved the verification documents, and no date the verification documents were reviewed and approved. | D6086 | D6086 #5<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including verification procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit | 2/12/16 |

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| D6086 | Continued From page 82<br><br>c. Between February 2015 and September 21, 2015, the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120i #1. From November 6, 2015 to November 19, 2015, the laboratory performed and reported 67 patient CBC test results using the Advia 2120I #2.<br><br>6. Based on review of documentation, lack of documentation, observation and interview with the general supervisor, the laboratory director failed to ensure that the laboratory determined the mean normal prothrombin time (MNPT) prior to implementing a new lot number of Innovin (thromboplastin) on the Siemens BCS XP. Findings include:<br><br>a. Dade Innovin (thromboplastin) lot number 539280 was put into use in March 2015.<br><br>b. The test system required that the MNPT (in seconds) be calculated for each new lot number of Innovin.<br><br>c. The MNPT specific to the lot number of Innovin was to be entered into the BCS XP.<br><br>d. The MNPT was observed on 9/23/15 at approximately 3:25 pm revealed the correct MNPT was entered into the BCS XP.<br><br>e. Review of the MNPT data revealed that the MNPT data was performed on 9/18/15.<br><br>f. The general supervisor stated that there should be date from March 2015; however, the documentation could not be located. | D6086 | D6068 #5 (continued)<br>procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced procedures for method verification. Before any verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before any patient testing begins. The lab has conducted training on those procedures. | |

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| D6086 | Continued From page 82<br><br>c. Between February 2015 and September 21, 2015, the laboratory performed and reported [redacted] patient CBC test results using the Advia 2120i #1. From November 6, 2015 to November 19, 2015, the laboratory performed and reported 67 patient CBC test results using the Advia 2120I #2.<br><br>6. Based on review of documentation, lack of documentation, observation and interview with the general supervisor, the laboratory director failed to ensure that the laboratory determined the mean normal prothrombin time (MNPT) prior to implementing a new lot number of Innovin (thromboplastin) on the Siemens BCS XP. Findings include:<br><br>a. Dade Innovin (thromboplastin) lot number 539280 was put into use in March 2015.<br><br>b. The test system required that the MNPT (in seconds) be calculated for each new lot number of Innovin.<br><br>c. The MNPT specific to the lot number of Innovin was to be entered into the BCS XP.<br><br>d. The MNPT was observed on 9/23/15 at approximately 3:25 pm revealed the correct MNPT was entered into the BCS XP.<br><br>e. Review of the MNPT data revealed that the MNPT data was performed on 9/18/15.<br><br>f. The general supervisor stated that there should be date from March 2015; however, the documentation could not be located. | D6086 | D6068 #6:<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>This PT/INR issue related to one reagent lot. The lab paused testing on the Siemens BCS XP, including PT/INR, during the survey. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including reagent qualification and management procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use | 2/12/16 |

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| D6093<br>D6093 | Continued From page 83<br>493.1445(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews, direct observations, and quality control document reviews, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory director failed to ensure that the laboratory included two quality control materials at least once each day patient specimens were examined (see D5447), the laboratory included a positive control material at least once each day patient specimens were assayed (see D5449), stated values of commercially assayed quality control materials were verified (see D5469), each batch of media was checked for its ability to support growth (see D5477), results of quality control materials met the laboratory's criteria for acceptability (see D5481), and the laboratory followed established quality control corrective action protocols (see D5779).<br><br>2. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records and interview with the general supervisor, the laboratory director failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results and failed to identify that the QC data revealed a shift greater than 2 standard | D6093<br>D6093 | D6086 #6 (continued)<br>of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>The lab's enhanced procedures for reagent qualification and management include procedures to ensure manufacturer inserts are reviewed. Training on these procedures has occurred.<br><br>Before PT/INR testing resumes, the lab will also ensure that the new lab director prepares and implements a revised assay-specific procedure for PT/INR to reinforce that the Mean Normal Prothrombin Time (MNPT) must be calculated for each new lot number of Innovin. The relevant testing personnel will be required to demonstrate competency to ensure that practice is consistent with these procedures. | |

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| D6093 | Continued From page 83 | D6093 | D6093 #1 | 2/12/16 |
| D6093 | 493.1445(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews, direct observations, and quality control document reviews, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory director failed to ensure that the laboratory included two quality control materials at least once each day patient specimens were examined (see D5447), the laboratory included a positive control material at least once each day patient specimens were assayed (see D5449), stated values of commercially assayed quality control materials were verified (see D5469), each batch of media was checked for its ability to support growth (see D5477), results of quality control materials met the laboratory's criteria for acceptability (see D5481), and the laboratory followed established quality control corrective action protocols (see D5779). | D6093 | The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including the lab's improved quality systems and related procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab. | |
| | 2. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records and interview with the general supervisor, the laboratory director failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results and failed to identify that the QC data revealed a shift greater than 2 standard | | D6093 #2<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed. | 2/12/16 |

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|---|---|---|---|---|
| D6093 | Continued From page 84<br>deviations (SD) from April 2015 through September 2015. Findings include:<br><br>a. CL SOP-10001 Revision A, "Measuring Prothrombin Time-Innovin (PT on the Siemens BCS XP Instrument" stated on page 6, section 8.6 that if control values are outside of the determined range, the controls, reagents and instrument performance should be checked and that identification and correction of the problem shoud be documented prior to reporting patient results.<br><br>b. QC records for Citrol 3 (Lot number 548425) were reviewed from 4/1/15 through 9/23/15.<br><br>c. The general supervisor stated that QC was acceptable if the values were +/- 2 SD from the mean.<br><br>d. From April 1, 2015 through September 16, 2015, 32 of 69 days showed Citrol 3 QC values were greater than 2 SD (- 2 SD) below the mean.<br><br>e. On 4/7/15, Citrol 3 was run six times before an acceptable QC value was obtained.<br><br>f. On 9/7/15, Citrol 3 was run seven times without obtaining an acceptable QC value.<br><br>g. On 9/8/15, Citrol 3 was run twelve times without obtaining an acceptable QC value.<br><br>h. On 25 of 32 days, Citrol 3 was not retrun when the QC value was greater than - 2 SD.<br><br>i. On 5/15/15, 8/13/15, 8/21/15 and 9/10/15, Citrol 3 was run twice. All QC results were unacceptable. | D6093 | D6093 #2 (continued)<br>In addition, the lab paused testing on the Siemens BCS XP, including PT/INR, during the survey. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including QC procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced QC procedures, which reinforce and detail the required investigation and corrective action that must occur to address QC issues before patient tests are performed and clarify which employees are responsible for performing and documenting these activities. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them. | |

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| D6093 | Continued From page 85<br><br>j. TheRule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015; 13 of 13 in July 2015, 16 of 16 in August and 24 of 24 9/1-9/16 2015 showed rule violation messages related to Citrol 3.<br><br>k. On approximately 9/16/15, the labortory adjusted the acceptable range for Citrol 3 to match the data. This change was implemented without any investigation as to the reason for the shift in control values.<br><br>l. [redacted] patients were reported from 4/1/15 through 9/16/15. | D6093 | | |
| D6094 | 493.1445(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews, direct observations, and quality control document reviews, the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory director failed to ensure that preanalytic (see D5391 and D5393) and analytic (see D5791 and D5793) systems quality assessment programs were established, followed, and effective.<br><br>2. Based on review of documentation and lack of documentation, the laboratory director failed to | D6094 | D6094 #1:<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures concerning pre-analytic, analytic, and post-analytic issues (see D5391, D5393, D5791, and D5793). | 2/12/16 |

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| D6093 | Continued From page 85<br><br>j. TheRule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015; 13 of 13 in July 2015, 16 of 16 in August and 24 of 24 9/1-9/16 2015 showed rule violation messages related to Citrol 3.<br><br>k. On approximately 9/16/15, the labortory adjusted the acceptable range for Citrol 3 to match the data. This change was implemented without any investigation as to the reason for the shift in control values.<br><br>l. [redacted] patients were reported from 4/1/15 through 9/16/15. | D6093 | D6094 #1 (continued)<br>The lab will ensure that the new lab director effectively implements and monitors these procedures through audits performed pursuant to the lab's new audit procedures, through oversight during monthly QA meetings, and through use of a new on-site visit log that records the lab director's time spent physically in the lab. | |
| D6094 | 493.1445(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br>This STANDARD is not met as evidenced by:<br>1. Based on laboratory personnel interviews, direct observations, and quality control document reviews, the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory director failed to ensure that preanalytic (see D5391 and D5393) and analytic (see D5791 and D5793) systems quality assessment programs were established, followed, and effective.<br><br>2. Based on review of documentation and lack of documentation, the laboratory director failed to | D6094 | D 6094 #2:<br>The lab directors during the period covered by the survey no longer | 2/12/16 |

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|---|---|---|---|---|
| D6094 | Continued From page 86<br>identify failures in Prothrombin Time/International Normalized Ratio (PT/INR) testing which affected the quality of the PT/INR patient results. Findings include:<br><br>a. The Dada Innovin (thromboplastin) reagent was used past the expiration date. Refer to D5413.<br><br>b. The quality control data from 4/1/2015 through 9/16/15 revealed that patient results above normal were biased low (i.e., reported value was lower than it should have been reported).<br><br>c. The target INR value for patients on Warfarin therapy was 2-3.<br><br>d. [redacted] patients were reported from 4/1/15 through 9/21/15.<br><br>e. [redacted] patients had INRs greater than or equal to 2 reported and of the [redacted] of the [redacted] had INR greater than or equal to 3 reported.<br><br>f. There was no quality assessment (QA) or other documentation to indicate that the PT/INR failure had been identified and corrected. | D6094 | D6094 #2 (continued)<br>hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>In addition, the lab paused testing on the Siemens BCS XP, including PT/INR, during the survey. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including QC procedures, through oversight during monthly QA meetings, through audits performed pursuant to the lab's new audit procedures, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>This improved oversight will ensure that the new lab director implements the lab's enhanced QC procedures, which reinforce and detail the required investigation and corrective action that must occur to address QC issues before patient tests are performed, and clarify which employees are responsible for performing and | |
| D6098 | 493.1445(e)(8) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.<br>This STANDARD is not met as evidenced by:<br>Based on review of final test reports and interview with the Senior Vice President, the laboratory director failed to ensure that the | D6098 | | |

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| D6094 | Continued From page 86<br>identify failures in Prothrombin Time/International Normalized Ratio (PT/INR) testing which affected the quality of the PT/INR patient results. Findings include:<br><br>a. The Dada Innovin (thromboplastin) reagent was used past the expiration date. Refer to D5413.<br><br>b. The quality control data from 4/1/2015 through 9/16/15 revealed that patient results above normal were biased low (i.e., reported value was lower than it should have been reported).<br><br>c. The target INR value for patients on Warfarin therapy was 2-3.<br><br>d. [redacted]patients were reported from 4/1/15 through 9/21/15.<br><br>e. [redacted] patients had INRs greater than or equal to 2 reported and of the[redacted] of the[redacted] had INR greater than or equal to 3 reported.<br><br>f. There was no quality assessment (QA) or other documentation to indicate that the PT/INR failure had been identified and corrected. | D6094 | D6094 #2 (continued)<br>documenting these activities. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them. | |
| D6098 | 493.1445(e)(8) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.<br>This STANDARD is not met as evidenced by:<br>Based on review of final test reports and interview with the Senior Vice President, the laboratory director failed to ensure that the | D6098 | D6098<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab revised its patient reports for PT/INR during the survey so that the | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6098 | Continued From page 87<br>interpretive data on the Prothrombin Time/International Normalized Ratio (PT/INR) final reports was clear to differentiate between Warfarin therapy and non-Warfarin therapy. Refer to D5805. | D6098 | D6098 (continued)<br>interpretive note appears only under the heading for patients under therapy. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved revised reporting procedures that require the technical supervisor to verify that interpretive information is accurate and to obtain approval from the lab director or clinical consultant before any updates are implemented.<br><br>The lab will ensure that the new lab director effectively implements and monitors these procedures through audits performed pursuant to the lab's new audit procedures, through oversight during monthly QA meetings, and through use of a new on-site visit log that records the lab director's time spent physically in the lab.<br><br>(D6102 begins on next page) | |
| D6102 | 493.1445(e)(12) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br>This STANDARD is not met as evidenced by:<br>Based on review of training documents and interview with the QA/QC (Quality Assurance/Quality Control) Manager, technical supervisor and testing personnel, the laboratory failed to document training of testing personnel on the [redacted] prior to patient testing and failed to document training in the vacutainer laboratory of testing personnel prior to patient testing. Findings include:<br><br>a. [redacted]<br><br>i. The QA/QC Manager and technical supervisor stated that all training documentation was kept in each testing person's employee file.<br><br>ii. Eleven testing personnel files were reviewed.<br><br>iii. Eight of eleven personnel files did not include any documentation of training on the [redacted] prior to running and reporting patient test results. | D6102 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D6098 | Continued From page 87<br>interpretive data on the Prothrombin Time/International Normalized Ratio (PT/INR) final reports was clear to differentiate between Warfarin therapy and non-Warfarin therapy. Refer to D5805. | D6098 | | |
| D6102 | 493.1445(e)(12) LABORATORY DIRECTOR RESPONSIBILITIES<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br>This STANDARD is not met as evidenced by:<br>Based on review of training documents and interview with the QA/QC (Quality Assurance/Quality Control) Manager, technical supervisor and testing personnel, the laboratory failed to document training of testing personnel on the [redacted] prior to patient testing and failed to document training in the vacutainer laboratory of testing personnel prior to patient testing. Findings include:<br><br>a. [redacted]<br><br>i. The QA/QC Manager and technical supervisor stated that all training documentation was kept in each testing person's employee file.<br><br>ii. Eleven testing personnel files were reviewed.<br><br>iii. Eight of eleven personnel files did not include any documentation of training on the [redacted] prior to running and reporting patient test results. | D6102 | D6102<br>The lab directors during the period covered by the survey no longer hold any position with the lab. The new lab director was hired after the on-site survey had been completed.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures to ensure that testing personnel are qualified, have received training, and are competent before performing any test on any instrument, and to ensure that those qualifications, training, and competency are documented. Training on these procedures has occurred to ensure the practice is consistent with them.<br><br>The lab will ensure that the new lab director effectively implements and monitors lab procedures, including personnel procedures, through audits performed pursuant to the lab's new | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6102 | Continued From page 88<br><br>b. Venipuncture Laboratory<br><br>a. The QA/QC Manager and technical supervisor stated that all training documentation was kept in each testing person's employee file.<br><br>b. Three testing personnel files were reviewed.<br><br>c. Testing Person #6 (TP6) training records did not include documentation for the Siemens XPT, Advia 2120i, Eldon Card, and were incomplete for the Centaur, IRIS, BC SXP and Cellavision.<br><br>d. TP6 stated that training had not been completed as of 9/23/15; however PT6 had been running and reporting patient test results since April 2015. TP6 also stated that activities listed on the training documentation which were not signed off were performed by TP6, but training had not occurred.<br><br>e. TP6 confirmed the above findings on 9/23/15 at approximately 3:30 pm.<br><br>f. Testing Person #11 (TP11) training records did not include documentation for the Advia, Immulite, BC SXP, Advia 2120i, Centaur, MacroVu RPR, Multispot HIV, and Diasorin Liaison.<br><br>g. TP6 stated that TP11 ran and reported patient test results from these systems.<br><br>h. Testing Person #31 (TP31)'s training documentation included documents on critical values and critical values logsheets. No other training documentation was found. | D6102 | D6102 (continued)<br>audit procedures, through oversight during monthly QA meetings, and through use of a new on-site visit log that records the lab director's time spent physically in the lab. | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6102 | Continued From page 89<br>i. The general supervisor stated that TP31 had been running and releasing patient test results.<br><br>j. The general supervisor confirmed that the training documents were missing or incomplete for three of three testing personnel on 11/19/15 at 11:40 am. | D6102 | | |
| D6108 | 493.1447 LABORATORY TECHNICAL SUPERVISOR<br><br>The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; technical supervisor was not met. Two of three technical supervisors failed to meet the training or experience requirement in one or more specialties/subspecialties (see D6111), and the technical supervisors failed to ensure the establishment of performance specifications for the [redacted] were complete and followed the laboratory's procedure (see D6115). | D6108 | D6108<br>The lab has corrected this issue by ensuring that all of its technical supervisors meet the training and experience requirements. The new lab director is the technical supervisor for chemistry, hematology, and immunohematology. CMS already qualified the lab's other technical supervisor for microbiology and diagnostic immunology.<br><br>TS1 and TS2 are no longer technical supervisors for the lab. It is worth noting, however, that CMS qualified TS1 as a technical supervisor for chemistry and found that TS1 was just months away from qualifying for hematology and immunology. In addition, TS2 is still endeavoring to obtain documents from TS2's former employers to show the requisite experience.<br><br>The lab has completed an assessment to identify any patients affected or | 2/12/16 |
| D6111 | 493.1449 TECHNICAL SUPERVISOR QUALIFICATIONS<br><br>(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and<br>(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all | D6111 | | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|
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| D6102 | Continued From page 89<br>i. The general supervisor stated that TP31 had been running and releasing patient test results.<br><br>j. The general supervisor confirmed that the training documents were missing or incomplete for three of three testing personnel on 11/19/15 at 11:40 am. | D6102 | D6108 (continued)<br>having the potential to be affected by this issue (see 06111, 06115).<br><br>The new lab director has approved enhanced policies and procedures governing personnel qualification and defining, among other things, the education and experience requirements for a technical supervisor (see 06111). The new lab director has also approved enhanced procedures related to the establishment of performance specifications (see 06115). The lab has conducted training on these procedures to ensure that its practice is consistent with them (see 06111 and 06115).<br><br>In addition, the lab has improved its quality systems and procedures—including quality assurance review, monitoring, and audits—to prevent recurrence (see 06111 and 06115). | |
| D6108 | 493.1447 LABORATORY TECHNICAL SUPERVISOR<br><br>The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; technical supervisor was not met. Two of three technical supervisors failed to meet the training or experience requirement in one or more specialties/subspecialties (see D6111), and the technical supervisors failed to ensure the establishment of performance specifications for the [redacted] were complete and followed the laboratory's procedure (see D6115). | D6108 | | |
| D6111 | 493.1449 TECHNICAL SUPERVISOR QUALIFICATIONS<br><br>(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and<br>(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all | D6111 | (D6111 begins on next page) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|
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| D6102 | Continued From page 89<br>i. The general supervisor stated that TP31 had been running and releasing patient test results.<br><br>j. The general supervisor confirmed that the training documents were missing or incomplete for three of three testing personnel on 11/19/15 at 11:40 am. | D6102 | | |
| D6108 | 493.1447 LABORATORY TECHNICAL SUPERVISOR<br><br>The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; technical supervisor was not met. Two of three technical supervisors failed to meet the training or experience requirement in one or more specialties/subspecialties (see D6111), and the technical supervisors failed to ensure the establishment of performance specifications for the [redacted] were complete and followed the laboratory's procedure (see D6115). | D6108 | | |
| D6111 | 493.1449 TECHNICAL SUPERVISOR QUALIFICATIONS<br><br>(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and<br>(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all | D6111 | D6111<br>The lab has corrected this issue by ensuring that all of its technical supervisors meet the training and experience requirements. The new lab director is the technical supervisor for chemistry, hematology, and | 2/12/16 |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|
| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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| D6111 | Continued From page 90<br>specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor--<br>(b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.<br>(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must--<br>(c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or | D6111 | D6111 (continued)<br>immunohematology. CMS already qualified the lab's other technical supervisor for microbiology and diagnostic immunology.<br><br>TS1 and TS2 are no longer technical supervisors for the lab. It is worth noting, however, that CMS qualified TS1 as a technical supervisor for chemistry and found that she was just months away from qualifying for hematology and immunology. In addition, TS2 is still endeavoring to obtain documents from his former employers to show that he has the requisite experience (see 06111).<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue (see 06111, 06115).<br><br>The new lab director has approved enhanced policies and procedures governing personnel qualification and defining, among other things, the education and experience requirements for a technical supervisor (see 06111). The new lab director has also approved enhanced procedures related to the | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
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|---|---|---|---|---|
| D6111 | Continued From page 91<br>(c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or<br>(c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or<br>(c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and<br>(c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.<br>(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must--<br>(d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and | D6111 | D6111 (continued)<br>establishment of performance specifications (see 06115). The lab has conducted training on these procedures to ensure that its practice is consistent with them (see 06111 and 06115).<br><br>In addition, the lab has improved its quality systems and procedures—including quality assurance review, monitoring, and audits—to prevent recurrence (see 06111 and 06115). | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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|---|---|---|---|---|
| D6111 | Continued From page 92<br>(d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or<br>(d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or<br>(d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or<br>(d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; | D6111 | (continued; see above) | |

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|---|---|---|---|
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| D6111 | Continued From page 93<br>and<br>(d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.<br>(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must--<br>(e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or<br>(e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a | D6111 | (continued; see above) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

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| D6111 | Continued From page 94<br>minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or<br>(e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or<br>(e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.<br>(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must--<br>(f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(f)(2)(i) Be a doctor of medicine, doctor of | D6111 | (continued; see above) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| D6111 | Continued From page 95<br>osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;<br>(f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or<br>(f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or<br>(f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of | D6111 | (continued; see above) | |

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| D6111 | Continued From page 96<br>parasitology.<br>(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must--<br>(g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or<br>(g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or<br>(g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and | D6111 | (continued; see above) | |

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| D6111 | Continued From page 97<br>(g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or<br>(g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.<br>(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-<br>(h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or | D6111 | (continued; see above) | |

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| D6111 | Continued From page 98<br>(h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or<br>(h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or<br>(h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.<br>(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must--<br>(i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is | D6111 | (continued; see below) | |

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| D6111 | Continued From page 99<br>located; and<br>(i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or<br>(i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or<br>(i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or<br>(i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.<br>(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must--<br>(j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(j)(2)(i) Be a doctor of medicine, doctor of | D6111 | (continued; see above) | |

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| D6111 | Continued From page 100<br>osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or<br>(j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or<br>(j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or<br>(j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.<br>(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must--<br>(k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and | D6111 | (continued; see above) | |

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| D6111 | Continued From page 101<br>(k)(1)(ii) Meet one of the following requirements--<br>(k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;<br>(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must--<br>(l)(1) Meet one of the following requirements:<br>(l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;<br>(l)(1)(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.<br>(l)(2) For tests in dermatopathology, meet one of the following requirements:<br>(l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is | D6111 | (continued; see above) | |

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| D6111 | Continued From page 102<br>located and--<br>(l)(2)(i)(B) Meet one of the following requirements:<br>(l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or<br>(l)(2)(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.<br>(l)(3) For tests in ophthalmic pathology, meet one of the following requirements:<br>(l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and--<br>(l)(3)(i)(B) Must meet one of the following requirements:<br>(l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(l)(3)(i)(B)(2) Be certified by the American Board | D6111 | (continued; see above) | |

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| D6111 | Continued From page 103<br>of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or<br>(l)(3)(ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or<br>(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:<br>(m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and--<br>(m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or<br>(m)(3) An individual qualified under §493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.<br>(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs | D6111 | (continued; see above) | |

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| D6111 | Continued From page 104<br>tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must--<br>(n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or<br>(n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and<br>(n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or<br>(n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and<br>(n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or<br>(n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and<br>(n)(5)(ii) Have at least 4 years of laboratory | D6111 | (continued; see above) | |

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| D6111 | Continued From page 105<br>training or experience, or both, in high complexity testing for the specialty of radiobioassay.<br>(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either--<br>(o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(o)(1)(ii) Have training or experience that meets one of the following requirements:<br>(o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or<br>(o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and<br>(o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or<br>(o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and<br>(o)(2)(ii) Have training or experience that meets one of the following requirements:<br>(o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or<br>(o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and<br>(o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.<br>(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- | D6111 | (continued; see above) | |

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| D6111 | Continued From page 106<br>(p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and<br>(p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or<br>(p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and<br>(p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.<br>(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must--<br>(q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br><br>Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in | D6111 | (continued; see above) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6111 | Continued From page 107<br>high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of training documentation, two of three technical supervisors failed to have the required 4 years of training or experience, or both, in a specialty or subspecialty as required to qualify as a technical supervisor. Findings include:<br><br>a. Training documents from the personnel file for three technical supervisors were reviewed.<br><br>b. Technical Supervisor #1 (TS1) and the QA/QC Manager stated that all training documentation was kept in the personnel file for each employee.<br><br>c. TS1 was unable to provided documentation which showed 4 years of training and/or experience in high complexity testing for hematology or immunology.<br><br>d. Technical Supervisor #2 (TS2) was unable to provided documentation which showed 4 years of training and/or experience in high complexity testing for hematology, chemistry or immunology.<br><br>e. TS1 confirmed on 9/23/2015 at 10:30 am that the documentation did not show the required training or experience in immunology and hematology for TS1. | D6111 | (continued; see above) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6111 | Continued From page 108<br><br>f. TS2 confirmed on 11/18/2015 at approximately 9:50 am that the documentation did not show the required training or experience in hematology, chemistry or immunology for TS2. | D6111 | | |
| D6115 | 493.1451(b)(2) TECHNICAL SUPERVISOR RESPONSIBILITIES<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br>This STANDARD is not met as evidenced by:<br>Based on review of validation documents on the [redacted], the technical supervisor failed to ensure that the validation procedures performed on the [redacted] established performance specifications for accuracy, precision, reportable range, and/or reference range and failed to ensure establishment of the performance specifications followed the laboratory's procedures. Findings include:<br><br>a. Validations Reports for [redacted] were reviewed.<br><br>b. The laboratory presented the procedure, CL PLN-14003 Revision A, "Master Validation Plan for [redacted] Assays on [redacted]" when the surveyor requested their procedure for establishing performance specifications.<br><br>c. [redacted] validation reports | D6115 | D6115<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The lab's management, including the new lab director and newly appointed quality director, is responsible for ensuring that technical supervisors are effective in supervising method verification and validation procedures. The lab will further ensure that these procedures are effective through oversight during monthly QA meetings. In addition, the lab will monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures. | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6115 | Continued From page 109<br>included "[redacted]-corrected" results without an explanation as to how the "Theranos Result" was corrected or which result was reported.<br><br>d. The procedure requires in Section 4.1 that the laboratory director (LD) ensures that the chemistry assays are qualified and validated according to the procedure.<br><br>e. The validation report for [redacted] had an effective date of 7/14/14 but was not signed by the LD until 9/19/15. [redacted] testing was performed on the [redacted] from 7/28/14 through 6/24/15.<br><br>Accuracy<br><br>a. The procedure required in Section 16 that the samples used to calculate accuracy were to cover the entire reportable range, samples were to be run in at least 2 replicates, and 50% of samples were to be outside the reference range.<br><br>b. [redacted] reports all indicated that the predicate method was performed in duplicate, but did not indicate if [redacted] samples were run in duplicate.<br><br>c. [redacted] had a reportable range of 47.6-1420 ng/dL however the accuracy data only covered the range of 42.8-350 ng/dL.<br><br>d. The laboratory used a total of 148 specimens to perform the accuracy study for [redacted]. Of the 148 specimens only six (4%) were outside the reference range. 50% of the specimens were not outside the reference range as required.<br><br>Precision | D6115 | (continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6115 | Continued From page 110<br><br>a. The procedure required in Section 13 that the samples used to calculate precision were to cover the entire reportable range, include data from the familiarization study, include at least 1 quality control sample, have study performed over 20 operating days, and have a CV% less than or equal to 15% (less than or equal to 20% at the lower and upper level of detection).<br><br>b. [redacted] reports revealed that none of the precision studies covered 20 operating days.<br><br>c. [redacted] reports revealed that the precision study did not cover the entire reportable range.<br><br>d. [redacted] reports did not document that the familiarization data was used in the validation report and did not document 1 level of quality control was included in the study.<br><br>e. [redacted] precision data showed that two of three levels (15, 33.5 ng/mL) used showed a CV% greater than 20% and 15% respectively.<br><br>f. [redacted] precision data showed that two of three levels (85, 109 ng/dL) used showed a CV% greater than 15%.<br><br>g. [redacted] precision revealed that 47 of 96 samples had %CV greater than 20%.<br><br>Reportable Range<br><br>a. The procedure required in Section 17 that the samples used to calculate reportable range were to cover the entire reportable range. | D6115 | (continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6115 | Continued From page 111<br><br>b. The validation report for [redacted] stated that the reportable range was 10-150 ng/mL. Samples tested covered a range of 14.17-108.25 ng/mL.<br><br>c. The validation report for [redacted] stated that the reportable range was 47.6-1420 ng/dL. Samples tested covered a range of less than 40-266 ng/dL.<br><br>d. The validation report for [redacted] stated that the reportable range was 2.5-200 nM. Samples tested covered a range of 2.4-106 nM.<br><br>e. The validtion report for [redacted] also stated that the R2 value for the dilution linearity should be equal to or greater than 0.95. However, the valuation report states on page 46 that "Two of the seven samples did not meet the optimal percent recovery and show slighty higher % recovery than the upper desired limit, however the R2 value of 0.92 seems very compariable to the 0.95 acceptance value."<br><br>Reference Range<br><br>a. The procedure required in Section 18 that the reference range data should include "...a minimum of 120 samples for each partition. For instance, if a reference interval needs partitions for gender, then samples from 120 men and 120 women will be needed."<br><br>b. Reference range data for [redacted] included 20 samples.<br><br>c. Reference range data for [redacted] included 14 samples from females and 10 samples from males. | D6115 | (continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6115 | Continued From page 112<br>Percent (%) Recovery<br><br>a. The laboratory validation reports required a Recovery Rate of 100 +/- 20% (100 +/- 25% at the upper limit and lower limit of reportable range) for [redacted].<br><br>b. The "Clinical Correlation (Historical)" table, Table 7, for [redacted] revealed that twelve (12) of twenty nine (29) samples showed a % Recovery greater than +/- 20%. Ten (10) of the 12 samples had a % Recovery greater than +/- 25%. Of these 10 samples, eight of ten were not at the upper or lower limit of the reportable range.<br><br>c. The "Clinical Correlation (Historical)" table, Table 8, for [redacted] revealed that twenty eight (28) of eighty one (81) samples showed a % Recovery greater than +/- 20%. Twenty (20) of the 28 samples had a % Recovery greater than +/- 25%. Of these 28 samples, seventeen (17) of twenty eight (28) were not at the upper or lower limit of the reportable range.<br><br>d. The "Clinical Correlation and Bias Correction" table, Table 6, for [redacted] revealed that thirty six (36) of one hundred and seven (107) samples showed a % Recovery greater than +/- 20%. Twenty four (24) of the 36 samples had a % Recovery greater than +/- 25%. Of these 36 samples, 23 of 36 were not at the upper or lower limit of the reportable range.<br><br>e. The [redacted] Linearity" table, Table 21, for [redacted] revealed that the [redacted] (nominal value = 53.4 nM) had a % Recovery of 131% and the [redacted] (nominal value 2.4 nM) had a % Recovery of 150%. The laboratory's reportable range for [redacted] was 2.5-200 nM. | D6115 | (continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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|---|---|---|---|---|
| D6115 | Continued From page 113<br><br>f. The "Summary of normal patient samples for Reference Range" table, Table 24, for [redacted] revealed that ten (10) of fourteen (14) samples for females and nine (9) of ten (10) samples for males showed a % Recovery greater than +/- 20%. Fourteen (14) of the twenty four (24) total samples had a % Recovery greater than +/- 25%. Of these 24 samples, 24 of 24 were not at the upper or lower limit of the reportable range.<br><br>Allowable Bias<br><br>a. The Alternative Assessment Program procedure stated that allowable bias between a predicate method and the [redacted] was equal to or less than 20%.<br><br>b. The terms Total Allowable Error and Allowable Bias seemed to be used interchangably.<br><br>c. The formula used to determine allowable bias was: Laboratory value minus the Predicate value divided by Predicate value (Laboratory value - Predicate value/Predicate value).<br><br>d. Nine random samples (01, 20, 30, 41, 91, 32, 74, H2, H58) were reviewed from the [redacted] clinical correlation studies (Table 7 and 8) from the validation report. The allowable bias calculation for these nine samples ranged from 21-130%. The reference ranges for both the Predicate method and the [redacted] were the same for [redacted].<br><br>e. Nine random samples (2, 60, 62, 18, 57, 43, 68, 73, 92) were reviewed from the [redacted] clinical correlation study (Table 6) from the validation report. The allowable bias calculation for these | D6115 | (continued; see above) | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
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|---|---|---|---|---|
| D6115 | Continued From page 114<br>nine samples ranged from 21-39%. The reference ranges for both the Predicate method and the [redacted] were the same for [redacted].<br><br>f. Nine random samples (5, 8, 25, 36, 54, 74, 76, 131, 145) were reviewed from the [redacted] clinical correlation study (Table 20) from the validation report. The allowable bias calculation for these nine samples ranged from 22-146%. The reference ranges for both the Predicate method and the [redacted] were the same for [redacted]. | D6115 | | |
| D6124 | 493.1451(b)(8)(iv) TECHNICAL SUPERVISOR RESPONSIBILITIES<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.<br>This STANDARD is not met as evidenced by:<br>Based on review of the 2015 competency assessment form and interview, the technical supervisor failed to include direct observations of performance of instrument maintenance and function checks in competency assessment. Findings include:<br><br>a. Competency Assessment form, CL FRM-0316-F59, stated the following: "Review documentation of assigned instrument maintenance and function checks as applicable."<br><br>b. Testing personnel and the technical supervisor stated on 9/23/15 at approximately 1:30 pm that instrument maintenance and function check documention was reviewed as part of annual competency assessment and that direct obervation of these activities was not performed. | D6124 | D6124<br>All testing personnel currently performing tests have completed competency testing with direct observation of, among other things, maintenance and function checks for the tests they are performing.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The laboratory management, including the new lab director and newly appointed quality director, will ensure that technical supervisors follow required procedures, including personnel procedures. The lab will further assure the adequacy and competency of staff during monthly QA meetings. In addition, the lab will | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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|---|---|---|---|---|
| D6168 | 493.1487 TESTING PERSONNEL<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; testing personnel was not met. The laboratory failed to have qualified testing personnel performing high complexity testing. Refer to D6170 and D6171. | D6168 | D6124 (continued)<br>monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures.<br><br>This improved oversight will ensure that technical supervisors implement and monitor the lab's enhanced training and competency procedures. These procedures require, among other things, direct observation of instrument maintenance and function checks in competency assessments. The lab has conducted training on these procedures to ensure that practice is consistent with them. | |
| D6170 | 493.1489(a) TESTING PERSONNEL QUALIFICATIONS<br><br>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and WBC differential record review on November 17, 2015, each individual performing high complexity WBC differential testing failed to possess a current license issued by the State of California. Findings included:<br><br>a. For patient capillary specimens, it was the practice of the laboratory to use [redacted] instrumentation to perform and report patient WBC differentials.<br><br>b. Between June 1, 2015 and September 21, 2015, California unlicensed testing personnel reviewed and released patient [redacted] | D6170 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
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| D6168 | 493.1487 TESTING PERSONNEL<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; testing personnel was not met. The laboratory failed to have qualified testing personnel performing high complexity testing. Refer to D6170 and D6171. | D6168 | D6168:<br>The lab has corrected this issue by ensuring that all of its testing personnel who perform high complexity testing are qualified, with strict adherence to the regulatory requirements (see D6170, D6171).<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue (see D6170, D6171).<br><br>The new lab director has approved enhanced policies and procedures governing personnel qualification and defining, among other things, the responsibilities of licensed and unlicensed personnel, respectively. The lab has conducted training on these procedures to ensure that its practice is consistent with them (see 06170 and 06171).<br><br>In addition, the lab has improved its quality systems and procedures—including quality assurance review, monitoring, and audits—to prevent recurrence (see 06170 and 06171). | 2/12/16 |
| D6170 | 493.1489(a) TESTING PERSONNEL QUALIFICATIONS<br><br>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and WBC differential record review on November 17, 2015, each individual performing high complexity WBC differential testing failed to possess a current license issued by the State of California. Findings included:<br><br>a. For patient capillary specimens, it was the practice of the laboratory to use [redacted] instrumentation to perform and report patient WBC differentials.<br><br>b. Between June 1, 2015 and September 21, 2015, California unlicensed testing personnel reviewed and released patient [redacted] | D6170 | | |

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|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| THERANOS INC | 7333 GATEWAY BLVD NEWARK, CA 94560 |

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|---|---|---|---|---|
| D6168 | 493.1487 TESTING PERSONNEL<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; testing personnel was not met. The laboratory failed to have qualified testing personnel performing high complexity testing. Refer to D6170 and D6171. | D6168 | | |
| D6170 | 493.1489(a) TESTING PERSONNEL QUALIFICATIONS<br><br>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and WBC differential record review on November 17, 2015, each individual performing high complexity WBC differential testing failed to possess a current license issued by the State of California. Findings included:<br><br>a. For patient capillary specimens, it was the practice of the laboratory to use [redacted] instrumentation to perform and report patient WBC differentials.<br><br>b. Between June 1, 2015 and September 21, 2015, California unlicensed testing personnel reviewed and released patient [redacted] | D6170 | D6170:<br>The lab has reviewed its personnel files to ensure testing personnel satisfy the educational and experiential requirements.<br><br>The lab proactively paused WBC tests, including manual differentials.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures to ensure that all testing personnel satisfy the qualification requirements, including the required license and education. | 2/12/16 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 05D2025714 | A. BUILDING _____ B. WING _____ | 11/20/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| D6170 | Continued From page 116<br>WBC differential scatter plots. The scatter plots were released by California unlicensed testing personnel without any further review by a California licensed testing person.<br><br>c. Between June 1, 2015 and September 21, 2015, the laboratory reported [redacted] patient WBC differential performed using the [redacted] instrumentation. | D6170 | D6170 (continued)<br>These procedures also define, among other things, the responsibilities of licensed and unlicensed personnel, respectively. The responsibilities and approved activities of unlicensed personnel are limited, with strict adherence to regulatory requirements, and may only be performed under the direct supervision of licensed personnel. The lab has conducted training on these procedures to ensure that its practice is consistent with them.<br><br>The laboratory management, including the new lab director and newly appointed quality director, is responsible for ensuring that practice is consistent with these procedures. The lab will further assure the adequacy and competency of staff during monthly QA meetings. In addition, the lab will monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures. | |
| D6171 | 493.1489(b) TESTING PERSONNEL QUALIFICATIONS<br><br>(b) Meet one of the following requirements:<br>(b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;<br>(b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--<br>(b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--<br>(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--<br>(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or<br>(b)(2)(ii)(A)(2) 24 semester hours of science courses that include--<br>(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry;<br>(b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and | D6171 | | |

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| D6170 | Continued From page 116<br>WBC differential scatter plots. The scatter plots were released by California unlicensed testing personnel without any further review by a California licensed testing person.<br><br>c. Between June 1, 2015 and September 21, 2015, the laboratory reported [redacted] patient WBC differential performed using the [redacted] instrumentation. | D6170 | | |
| D6171 | 493.1489(b) TESTING PERSONNEL QUALIFICATIONS<br><br>(b) Meet one of the following requirements:<br>(b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;<br>(b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--<br>(b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--<br>(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--<br>(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or<br>(b)(2)(ii)(A)(2) 24 semester hours of science courses that include--<br>(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry;<br>(b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and | D6171 | D6171:<br>TP14 has been retrained to ensure that TP14 only performs activities within the scope of TP14's job description as a clinical laboratory associate, under the supervision of testing personnel. Because TP14 is not testing personnel, the high complexity personnel educational requirements do not apply.<br><br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved enhanced procedures to ensure that testing personnel meet the requisite educational qualifications. These procedures also define, among other things, the responsibilities of licensed and unlicensed personnel, respectively. The responsibilities and approved activities of unlicensed | 2/12/16 |

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| D6171 | Continued From page 117<br>(b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and<br>(b)(2)(ii)(B) Have laboratory training that includes either of the following:<br>(b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)<br>(b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.<br>(b)(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;<br>(b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either--<br>(b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or<br>(b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);<br>(b)(5)(i) Until September 1, 1997--<br>(b)(5)(i)(A) Have earned a high school diploma or equivalent; and<br>(b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has--<br>(b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, | D6171 | D6171 (continued)<br>personnel are limited, with strict adherence to regulatory requirements, and may only be performed under the direct supervision of licensed personnel. The lab has conducted training on these procedures to ensure that its practice is consistent with them.<br><br>The laboratory management, including the new lab director and newly appointed quality director, is responsible for ensuring that practice is consistent with these procedures. The lab will further assure the adequacy and competency of staff during monthly QA meetings. In addition, the lab will monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures. | |

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| D6171 | Continued From page 118<br>if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;<br>(b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures;<br>(b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use;<br>(b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;<br>(b)(5)(i)(B)(5) A working knowledge of reagent stability and storage;<br>(b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory;<br>(b)(5)(i)(B)(7) An awareness of the factors that influence test results; and<br>(b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and<br>(b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;<br>(b)(6) For blood gas analysis--<br>(b)(6)(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);<br>(b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or<br>(b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or<br>(b)(7) For histopathology, meet the qualifications | D6171 | | |

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| D6171 | Continued From page 119<br>of §493.1449 (b) or (l) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel documentation and interview, one of thirty five testing personnel (TP14)failed to meet the high complexity personnel educational qualifications. Findings include:<br><br>a. Review of TP14's personnel records revealed a bachelors degree in Liberal Studies.<br><br>b. The general supervisor and technical consultant stated that all personnel documents were kept in the personnel records.<br><br>c. No further records were identified which showed a bachelor's degree in a chemical, physical, biological, clinical laboratory science or medical technology. | D6171 | | |
| D6178 | 493.1495(b)(4) TESTING PERSONNEL RESPONSIBILITIES<br><br>Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.<br>This STANDARD is not met as evidenced by:<br>Based on laboratory personnel interviews and complete blood counts (CBC) quality control corrective action record review on September 23, 2015, the testing personnel, high complexity testing, failed to follow the laboratory's established policies and procedures whenever CBC test systems were not with the laboratory's established acceptable levels of performance. | D6178 | D6178:<br>The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.<br><br>The new lab director has approved revised QC procedures to ensure that QC is acceptable before patient results are reported. Lab personnel have been trained on these procedures.<br><br>The laboratory management, including | 2/12/16 |

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| D6178 | Continued From page 120<br>Findings included:<br><br>a. It was the practice of the laboratory to use the stated values of commercially assayed quality control materials to monitor patient CBC testing using the [redacted] instrument. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control (document number CL QOP-00013, revision F)."<br><br>b. Laboratory records for the [redacted] instrument the laboratory designated as [redacted] indicated that on July 11, 12, 14, and 16, 2015 CBC quality control material test results failed to meet stated assay values. The laboratory's documentation of these quality control failures indicated that the laboratory's "Quality Control" protocol was not followed.<br><br>c. Laboratory records indicated that the [redacted] instrument the laboratory designated as [redacted] was used to test and report [redacted] patient CBC specimens on July 11, 2015, [redacted] patient CBC specimens on July 12, 2015, [redacted] patient CBC specimens on July 14, 2015, and [redacted] patient CBC specimens on July 16, 2015. | D6178 | D6178 (continued)<br>the new lab director and newly appointed quality director, is responsible for ensuring that practice is consistent with these procedures. In addition, the lab will monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures. | |