| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2039533 | 06/04/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| American Health, S Llc Dba American Health Associa | 10270 Old Columbia Road Suite 600, Columbia, MD | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the lab director failed to be in compliance with The Code of Maryland Regulations (COMAR) 10.10.07B(5) Medical Laboratories - Personnel. 04 Permitted Laboratory Other than a POL or POCL - Director. The lab director failed to make monthly onsite visits to the laboratory as required. Findings: 1. According to the lab manager, the lab director visits are documented on the "Director Log"; 2. The director log has monthly entries recorded until September 15, 2017, and after this date the documentation in the log has only two later entries for December 19, 2017 and May 23, 2018; 3. The entry dated for September 15, 2017 has no records for time in and time out, comments and initials. The records made for December 19, 2017 and May 23, 2018 do not include initials of the lab director, showing onsite presence; 4. When interviewed on May 22, 2018 the regional laboratory manager stated that the new policy is to have the lab director make onsite visits every six months; 5. The CLIA 116 audit record shows that on November 8, 2017 the current director was approved as lab director; 6. The lab director has not documented her initials on the "Medical Director Log' since taking over as lab director; and 7. The lab director has failed to be onsite monthly as required by COMAR. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems |

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| | activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the written procedure manual, interview with the lead technologist, and the testing person, the laboratory did not maintain all quality control (QC) printouts when performing bacteriology testing. Findings: 1. The laboratory did not maintain failed Clostridium Difficile QC results. 2. The C. Diff QC failed on March 15th, 14th, and 9th during the year 2018. 3. The review of the C. Diff QC log sheet showed that only the repeated passing QC result was documented. 4. The lead technologist stated that they were not documenting the failed QC results on the QC log sheet and he was unaware that they needed to maintain the failed QC result along the repeated and passing result. B. Based on quality control (QC) record review and interview with the hematology supervisor, the laboratory did not retain QC records for at least 2 years. Findings: 1. The hematology laboratory utilizes a monthly "QC Review Logsheet" or "Daily QC Sheet" for each of its 3 Beckman Coulter DxH hematology analyzers. The acceptability of daily QC is recorded by marking, "Y" or "N" and noting details of corrective actions on the bottom of the log sheet. In addition, QC data for each lot number of reticulocyte and hematology control is uploaded to Beckman Coulter and the laboratory receives "Interlaboratory Quality Assurance Program" (IQAP) reports comparing their instruments' means with other analyzers utilizing the same lot number of controls. 2. A review of monthly "QC Review Logsheets" from June, 2017 to December, 2017 showed that for the "DxH1," "QC Review Logsheets" were missing for 1/2017 through 4/2017 and 7/2017 through 9 /2017. 3. Monthly "QC Log Bench Review" sheets for the "DxH2" were missing for 1 /2017, 7/2017 through 9/2017, and 12/2017. 4. Monthly "QC Log Bench Review" sheets for the "DxH3" were misssing for 1/2017, 5/2017, 7/2017 through 10/2017, and 12/2017. 5. A review of IQAP reports from January through December, 2017 showed that IQAP reports were not available at the time of the survey for the "Retic-x Cell Control" for 3/12/17, 7/30/17 through 8/16/17, and for the "Coulter 6C Cell Control" for 4/15/17 through 6/25/17, 7/30/17, and 9/23/17 through 10/15/17. 5. During an interview on 6/8/18 at 12:00 PM, the hematology supervisor stated that each day of testing, the daily hematology QC print outs are stored with patient print outs. They are stored in a box in the hematology laboratory. 6. The hematology supervisor confirmed that the daily QC and patient print outs for April, 2018 and earlier were stored off-site and were unavailable for review at the time of the survey, as well as the above listed monthly QC Review Logsheets and IQAP reports. 7. During an interview on 6/8/18 at 1:00 PM, the hematology supervisor confirmed that laboratory did not retain QC records for at least 2 years. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the written procedures, the laboratory did not correctly identify its address in the written procedures. Findings: 1. The address identified in the written procedures "Architect TSH" and "Glucose-Olympus" is 10290 Old Columbia Rd |

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| | #302, Columbia MD and not the labs current address; and 2. The address is documented in the procedure header. B. Based on review of the procedure manual and quality assurance (QA) records, the laboratory did not follow written procedures for performing biannual hematology instrument correlations. Findings: 1. The procedure, "TECH Instrument Correlations" states that, "The laboratory monitors and evaluates all methods for the same test performed on different instruments. This evaluation is done at least twice a year, using five samples of each analyte monitored." 2. A review of hematology records showed that the "Semi-Annual Comparability CBC & Retics" was performed once in 12/2017 and had not been performed in 2018. 3. During an interview on June 8, 2018 at 1:00 PM, the hematology supervisor confirmed that biannual hematology instrument comparisons had not been performed as written in the procedure manual. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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>A. Based on review of the written procedure manual, interview with the lead technologist, and the testing person, the laboratory did not have step by step instructions for entering patient samples in the bacteriology analyzer when performing stool samples. Findings: 1. The laboratory started performing Clostridium Difficile samples in August 2017. 2. The laboratory did not have written procedures for testing person to follow when entering patient information into the analyzer. 3. The testing person stated that she will scan the C. Diff kit bar code with the lot number and expiration date information into the analyzer when entering the patient name and accession number. 4. The lead technologist stated that he told testing personnel not to scan the C. Diff kit bar code with the lot number and expiration date information into the analyzer with the patient information. 5. The lead Technologist stated that possible error could occur if an incorrect lot number and expiration date is entered for the current kit being used at the time of patient testing. B. Based on record review and interview with the laboratory regional manager, the lab did not include the reportable range for TSH in the written procedure. Findings: 1. The written procedure for TSH did not include the reportable range for the TSH; 2. The regional lab manager stated that the study to verify the reportable range was not performed, and the lab uses the |

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| | manufacturers stated analytical range and would dilute the sample if it were too elevated (even though an elevated or reportable limit was not defined). C. Based on review of the procedure manual and interview with the technical supervisor (TS), the laboratory did not ensure that there was a clear policy for when to refer hematology differential slides for pathologist review. Findings: 1. The procedure, "HEME Manual Differential Criteria, Performance and Smear Scans" includes a chart labeled "Attachment B," "Supervisor/Pathologist Smear Review Criteria." The chart states that "Smear Reviews are performed by qualified Hematology Supervisors at High Complexity Labs or by Pathologists, according to the criteria below" and "A log of smear reviews is helpful in tracking patient history." 2. The chart lists the hematological "Abnormality" in the first column, followed by columns for "High Complexity Lab" under which there is the comment, "After initial Path Review" or "X," and a column labeled, "Pathologist Review," under which there is the comment, "First Time," or "If unresolved by supervisor." The "abnormality" "Presence of parasites (such as Malaria) or bacteria" states "X" "Immediately" under "High Complexity Lab" and "X" "Confirmation" under "Pathologist Review." 3. During an interview on 5/22/18 at 2:45 PM, the TS stated that if abnormalities are seen on the differential slide, testing personnel are supposed to do a "look back" at the patient history. If the abnormality has been reported previously, the testing person can report the abnormality without additional pathologist review. The TS also stated that the "presence of parasites" is "immediately reported" as "presumptive" and that they then "get confirmation" from the pathologist. 4. The policies stated by the TS were not written in the "HEME Manual Differential Criteria, Performance and Smear Scans" procedure and were not clear on the "Supervisor/Pathologist Smear Review Criteria" chart. 5. During an interview on 5/22/18 at 3:00 PM, the TS confirmed that the procedure manual did not clearly state when hematology differential slides should be reported by laboratory testing personnel and when they should be referred to the pathologist for review. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on record review and interview, the lab director did not review, approve, sign and date the labs written procedures and also delayed reviewing and signing chemistry procedures numbered 18, 20, 21 and 22. Findings: 1. The written procedure: "Subject Personnel Competency" was not reviewed, approved, signed and dated by the current lab director; 2. The regional lab manager stated that the director did not have enough time to perform these reviews, even though she has been directing the lab for at least six months; and 3. Chemistry procedures numbered 18, 20, 21 and 22 were all signed by the lab director on May 21, 2018, one day prior to the Survey. The effective date for all these procedures was November 16, 2016. The current lab director was approved for the director position on November 8, 2017 (as reported by the CLIA 116 audit record). There was a delay of over six months to obtain the directors approval of these chmistry procedures. 30112 B. Based on review of the written procedures for Prothrombin time, Clostridium Difficile, and Employee Competency and Checklists, interview with the laboratory manager, and the technical supervisor, the laboratory director did not review and approve all procedures prior to performing patient testing. Findings: 1. The Clostridium Difficile procedure was not |

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| | reviewed and signed by the current laboratory director for performing patient testing. 2. The Prothrombin time procedure was reviewed and signed by the current director on May 21, 2018, one day before the survey date of May 22, 2018. 3. The Employee Competency and Checklists were reviewed and signed by the current director on June 3, 2018 after the intial survey date of May 22, 2018. C. Based on review of the "Chemistry Procedure Manual", the "Quality and Technical Policies and Procedures" and interview with the laboratory manager, the new laboratory director (LD) failed to approve (signed and dated) the policies and procedures in a timely manner. Findings: 1. The current laboratory director started working at the laboratory on October 1, 2017. 2. Review of the "Chemistry Procedure Manual" showed that 53 of the 54 procedures in the manual were approved on May 21, 2018 which was the day before the recertification survey and 6.5 months after the LD started working at the laboratory. One of the 54 procedures was not approved by the LD. 3. Review of the "Quality and Technical Policies and Procedures" showed that 1 of the 19 procedures was signed on December 19, 2017; 9 of the 19 procedures were signed on January 3, 2018; 7 of the 19 procedures were signed on May 21, 2018; and 2 of the 19 were not approved. 4. During the survey on May 22, 2017 at 10:30 AM the laboratory manager confirmed that the procedures manuals were not signed and dated by the current laboratory director in a timely manner. D. Based on review of the normal patient values listed in the "Chemistry Procedure Manual", the "Chemistry Reference Ranges" worksheet, the AU 5800 chemistry analyzer computer and interview with the chemistry supervisor, the new laboratory director (LD) failed to ensure that the normal patient ranges that were provided to the staff in the approved policies and procedures were the same values in all three sources. Findings: 1. Review of the normal patient values in the "Chemistry Procedure Manual", the "Chemistry Reference Ranges" worksheet, and the AU 5800 chemistry analyzer computer showed that the normal patient values were not the some in all three sources. 2. The "Chemistry Procedure Manual" lists the normal patient range for Calcium as 8.2 - 10.0. The "Chemistry Reference Ranges" worksheet lists the normal patient range for Calcium as 8.5 - 10.8. The AU 5800 chemistry analyzer lists the normal patient range for Calcium as 8.4 - 10.2. 3. The "Chemistry Procedure Manual" lists the normal patient range for HDL cholesterol as 23 - 92. The "Chemistry Reference Ranges" worksheet lists the normal patient range for HDL cholesterol as 23 - 92. The AU 5800 chemistry analyzer lists the normal patient range for HDL cholesterol as 23 - 200. 4. During the survey on 06/08/18 at 9:30 AM the chemistry supervisor confirmed that the normal patient values were not the some in all three sources. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's product inserts, incubator temperature records and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for incubation of the QuantiFERON- TB GOLD (indirect test for M. tuberculosis infection) test kit and the urine bi-plate agar at the correct temperature. Findings: 1. The manufacturer's product insert for the QuantiFERON-TB GOLD test kit requires the laboratory to incubate the specimens collected in the |

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| | QuantiFERON- TB GOLD blood collection tubes at a temperature of 36-38 degrees Celsius. 2. The manufacturer's product insert for the urine bi-plate agar requires the laboratory to incubate the plates at a temperature of 33-37 degrees Celsius. 3. The manager confirmed that the QuantiFERON- TB GOLD tubes and the urine bi-plates are incubated in the same incubator with a reference range of 35-37 degrees Celsius. 4. The incubator temperature was wide for the QuantiFERON- TB GOLD incubation and not wide enough for the urine bi-plate incubation. 5. The incubator records for May 2018 through September 2018 were reviewed. The reference range listed on the worksheet was 35-37 degrees Celsius. The laboratory is open six day a week. The findings are listed below: -During the month of May 2018 the incubator temperature that was recorded was unacceptable 14 of 31 days and was not recorded 2 of 31 days; -During the month of April 2018 the incubator temperature that was recorded was unacceptable 10 of 30 days and was not recorded 2 of 30 days; -During the month of March 2018 the incubator temperature that was recorded was unacceptable 10 of 31 days; -During the month of February 2018 the incubator temperature that was recorded was unacceptable 5 of 28 days and was not recorded 7 of 28 days; -During the month of January 2018 the incubator temperature that was recorded was unacceptable 15 of 31 days and was not recorded 4 of 31 days; -During the month of December 2017 the incubator temperature that was recorded was unacceptable 11 of 30 days and was not recorded 9 of 30 days; -During the month of November 2017 the incubator temperature that was recorded was unacceptable 10 of 30 days and was not recorded 7 of 30 days; -During the month of October 2017 the incubator temperature that was recorded was unacceptable 9 of 31 days and was not recorded 11 of 31 days; and -During the month of September 2017 the incubator temperature that was recorded was unacceptable 7 of 30 days and was not recorded 16 of 30 days; 6. From September 2017 through January 2018 there was no corrective action documented when the incubator temperature was not within acceptable limits. From February 2018 through May 2018 the laboratory staff noted that the incubator temperature was unacceptable and that the temperature was adjusted. The records failed to include documentation showing that the incubator temperature was acceptable after the adjustment in the "Conclusion" section of the worksheet. 7. The laboratory failed to ensure that the QuantiFERON- TB GOLD tubes and the urine bi-plate agar were being incubated at the correct temperature to ensure accurate and reliable patient test results. 8. During the survey on 06/04/2018 at 1:00 PM the laboratory manager confirmed that the QuantiFERON- TB GOLD tubes and the urine bi-plate agar were not being incubated at the temperature required by the manufacturer and the laboratory staff were not documenting that corrective actions showing that the incubator temperature had been corrected and found to be acceptable. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure manual, interview with the lead |

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| | technologist, and the testing person, the laboratory did not document the heating block temperature each day of patient testing when performing Clostridium Difficile. Findings: 1. The laboratory began C. Diff testing in August 2017. 2. The C. Diff procedure states a heat block capable of 95 Degrees Celsius plus or minus two degrees was needed to perform the test. 3. The testing person stated that she has never documented the heating block temperature when performing the test. 4. The lead technologist confirmed that the heat block temperature for performing C.Diff has never been documented since testing began in August 2017. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the regional lab manager, the chemistry lab failed to demonstrate that it obtains performance specifications (characteristics) comparable to those established by the manufacturer for reportable range of test results for the test system, and the lab failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings: 1. The laboratory validation studies for B-type natriuretic peptide, total triiodothyronine, Thyroid-stimulating hormone, Vitamin B12, vitamin D and folate (performed on the "Architect" chemistry analyzer) did not include verification of the reportable range and patient normal values. The reportable range studies for these analytes was not complete as the linearity studies stated that they were not intended to show reportable range and the patient normal range studies for these analytes was not performed, as there was no patient data to verify the labs stated ranges. There was no record that the lab director reviewed the necessary test records or results to approve either of these two characteristics prior to testing patient specimens; and 2. During interview on May 22, 2018, the laboratory regional manager stated that the lab was using the manufacturer recommendations for these two characteristics and did not verify them in the lab and did not present data (lab test records) to the lab director to obtain approval for these characteristics. |
| **D5427** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(c)<br><br>(c) Documentation. The laboratory must document all activities specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of verification and validation studies performed on the "Architect" chemistry analyzer, the lab failed to perform and failed to provide documentation of validation studies. Findings: Cross reference D5421 |
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| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on calibration record review and interview with the hematology supervisor, the laboratory failed to ensure that calibrations for the hematology analyzers and the TOSOH hemoglobin A1c analyzer were verified at least once every 6 months. Findings: 1. A review of calibration records from 2017 and 2018 for the 3 Beckman Coulter DxH hematology analyzers showed that calibration verifications were performed 3/28/17 and 5/30/18; 2. A review of calibration records from 2017 and 2018 for the TOSOH hemoglobin A1c analyzer showed that one calibration verification was performed on 12/25/17; and 3. During an interview on June 4, 2018 at 11:30 AM, the hematology supervisor confirmed that calibration verifications were not performed at least once every 6 months on the hematology and hemoglobin A1c analyzers. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure manual, interview with the laboratory manager, and the lead technologist, the laboratory did not perform an Indivualized |

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| | Quality Control Plan (IQCP) when performing Influenza testing. Findings: 1. The laboratory began performing a Influenza moderately complex test in 2016. 2. The laboratory did not perform a IQCP plan prior to performing the test. 3. The laboratory tested quality control( QC) with each new lot or shipment for the Influenza kits from the year 2016 to May 15, 2018. 4. The laboratory began performing QC each day of patient testing starting May 5, 2018. 5. The laboratory began performing an IQCP that is not finalized. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality control log for bacteriology and interview with the lab manager, the lab did not take corrective action when quality control results failed to meet the labs criteria for acceptability. Findings: 1. The lab documents the time that "Quantiferon Samples" are removed from the incubator as a quality control check. Quantiferon is a check for Mycobacterium tuberculosis; and 2. From March 7, 2018 to May 25, 2018 three patient sample records for "Tubes Removed From Incubator" were not recorded, and from April 7 to October 10 (year not documented on report, reviewed 10/24/17), eight of twenty-eight patient sample entries for "Date/Time Removed From Incubator/Initials" were not documented. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the procedure manual and interview with laboratory staff it was determined that the laboratory director failed to provide overall management and direction of the laboratory. Based on review of the corporate memorandum and interview with laboratory staff, the laboratory director failed to have responsibility for the overall operation of the laboratory, and the medical director has been given responsibilities that the lab director should have responsibility (See D6004); failed to established QC procedures to monitor the overall operation of the laboratory were maintained and failed to ensure that the chemistry maintenance requirements for the AU 5800 (chemistry analyzer) were being performed as required (See D6020): failed to ensure that quality assessment programs were maintained to assure quality of laboratory services (See D6021); and failed to ensure that remedial actions were taken when multiple analytes failed to produce acceptable results during the semi-annual comparability testing ( See D6024). The commutative effect of these systemic |

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| | problems resulted in the laboratory directors inability to ensure the accuracy and reliability of laboratory testing. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the corporate memorandum and interview with lab staff, the lab director is not given responsibility for the overall operation of the laboratory,and the medical director has been given responsibilities that the lab director should have responsibility for. Findings: 1. The corporate memorandum: Medical Director Designee and Delegation signed by the Chief Medical Officer states that the medical director is authorized to supervise specific activities including but not limited to: New Reagent Lots and Assays; Proficiency testing and Attestation Statement; and Routine Analyzer Quality Control and Routine Analyzer Maintenance, this memorandum signed November 15, 3013 is in the labs written policies, and takes away lab responsibilities from the laboratory director and gives them to individuals (medical director and chief medical officer) who are not reported on the laboratory personnel report (CMS-209); 2. During interview with lab staff on May 22, 2018, the staff were not able to explain the intent of this memorandum; and 3. This memorandum also contradicts the "Statement of Responsibility: High Complexity Lab" approved by the lab director on December 19, 2017 that states the lab director delegates responsibilities to the technical supervisor, including quality control and quality assessment programs that are established and maintained, proficiency testing oversight and establishment and maintenance of acceptable levels of analytical performance for each test system. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the quality control (QC) activities for the chemistry department and interview with the chemistry supervisor, the laboratory director did not ensure that the established QC procedures to monitor the overall operation of the laboratory |

were maintained. Findings: 1. The laboratory's procedure labeled "QUAL Internal Quality Control" under section D requires the following: "Each month a comprehensive review of the past month's quality control data is performed by the department supervisor,..." 2. The laboratory's chemistry QC records from March 2017 through May 2018 were reviewed. There are three instruments in the chemistry department. The AU 2700, AU 5800 and an Architect (chemistry analyzers that perform therapeutic drug monitoring (TDM) and general chemistry). The findings are listed below: -The records for April 2017 show that there was no documented review of the QC for all three analyzers. -The records for May 2017 show that there was no documented review of the QC for the AU 2700 and AU 5800 analyzers. -The records for June 2017 show that there was no documented review of the QC for the Architect analyzer and the AU 2700 analyzer was not being used. -The records for July 2017 show that there was no documented review of the QC for the AU 2700 and Architect analyzers. -The records for August and September 2017 show that there was no documented review of the QC for the AU 5800 analyzer until 05/06/18. -The records for October, November and December 2017 show that there was no documented review of the QC for all three analyzers. -The records for January through May 2018 show that there was no documented review of the QC for all three analyzers until 06 /02/18. 3. The chemistry supervisor stated that he reviewed the QC data during the months of August and September 2017 for the Architect analyzer. During October 2017 the "Director of technical operations" told him that he had not been trained to perform that activity so he discontinued reviewing the QC data. 4. When the surveyors returned on 06/04/18 to continue the survey it was determined that the chemistry supervisor had been trained and then documented review of six month worth of QC data. The QC data from April 2017 and October through December 2017 had still not been reviewed. 5. The laboratory hired the current chemistry supervisor in July 2017. The laboratory records do not include documented training of the new supervisor until ?? The QC records show that the previous chemistry supervisor was not performing the required monthly reviews of the QC results. The laboratory director did not ensure that the pervious chemistry supervisor performed and documented the required QC review. The laboratory director did not ensure that the new supervisor received the required training to perform the QC review at the time he was hired. 6. During the survey on 06/04/18 the chemistry supervisor and laboratory manager confirmed that the QC data had not been reviewed and the "department supervisor" had not been trained to perform the monthly QC reviews per the requirements of the "QUAL Internal Quality Control" procedure. B. Based on review of the QC documentation for the chemistry department, review of the "Job Description, Technical Supervisor/Consultant" policy and interview with the chemistry supervisor, the laboratory director did not ensure that the chemistry maintenance records were being reviewed as defined in the "Job Description, Technical Supervisor/Consultant" policy. Findings: 1. The "Job Description, Technical Supervisor/Consultant" policy requires the supervisor to "Manage laboratory instrumentation and ensure maintenance is complete, current and documented." 2. The maintenance records for the AU 2700, AU 5800 and an Architect (chemistry analyzers that perform therapeutic drug monitoring (TDM) and general chemistry) for March 2017 through May 2018 were reviewed. None of the worksheets included the required review signature and date that the review was performed. 3. The laboratory hired the current chemistry supervisor in July 2017. The laboratory records do not include documented training of the new supervisor until ?? The maintenance records show that the previous chemistry supervisor was not performing the required monthly reviews of the worksheets. The laboratory director did not ensure that the pervious chemistry supervisor performed and documented the required maintenance review. The laboratory director did not ensure that the new

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| | supervisor received the required training to perform the maintenance review at the time he was hired. 4. During the survey on 06/04/18 the chemistry supervisor confirmed that the maintenance worksheets had not been reviewed and the chemistry supervisor had not been trained to perform the maintenance reviews per the requirements of the "Job Description, Technical Supervisor/Consultant" policy. C. Based on review of the QC documentation for the chemistry department and interview with the chemistry supervisor, the laboratory director did not ensure that the chemistry maintenance requirements for the AU 5800 (chemistry analyzer) were being performed as required. Findings: 1. The maintenance records for the AU 5800 for March 2017 through May 2018 were reviewed. None of the worksheets showed that the ISE (Ion Selective Electrode) bleaching was performed every 2 weeks as required by the manufacturer's maintenance worksheet. 2. When interviewed the chemistry supervisor stated that when the AU 5800 service representative was servicing the analyzer in August 2017 he stated that the ISE did not need to be bleached every two weeks. According to the chemistry supervisor the service representative did not provide written documentation verifying that the bleaching of the ISE unit was no longer required. 3. The laboratory hired the current chemistry supervisor in July 2017. The AU 5800 maintenance records show that the bleaching of the ISE had not been performed prior to the visit of the service representative in August 2017. The laboratory director did not ensure that the laboratory staff had access to the current maintenance standards for the AU 5800 analyzer. 4. During the survey on 06/04/18 at 11:00 PM the chemistry supervisor confirmed that the bleaching of the ISE was not being performed every 2 weeks and that the laboratory did not have the manufacturer's current standards for maintenance. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on record review and interview with lab staff, the lab director did not ensure that quality assessment programs are maintained to assure quality of lab services. Findings: 1. The lab director signed and dated a "QM Indicator List" on June 3, 2018. The list includes the "Metric" "Critical Value Call Turn Around Time" with a 90% goal for compliance; 2. The lab director signed and dated a "QM Indicator Dashboard". The dashboard is a monthly summary of the metrics and the percentage of compliance for each metric. The metric for "Critical Value Call Turn Around Time" is recorded as "N/A" for the months of January, February and March (year not given) and there was no entry for the months of April and May (year not given); 3. The lab has two written procedures for calling results of patient critical care values because home care patient physicians are not available to take the results after the physician office closes. The first procedure is for critical care values and the second procedure is for patient priority critical call values. The critical care values may be called the next business day, but priority critical call values are called on the same day the result is obtained; and 4. The director did not have data that she monitored the reporting of critical care values to ensure that patient results are called to the user in a |

timely and reliable manner. B. Based on record review and interview with lab staff, the lab director did not ensure that quality assessment programs are maintained to assure quality of lab services. Findings: 1. According to the form CMS-116, the lab performs approxamately 180, 000 tests annually; 2. According to lab staff, the lab has not reported any incident reports or problems to the lab director for review, and the lab director has not questioned staff concerning the lack of documentation; 3. The lab manager stated that there were no incidents to report to the director and the regioanal phlebotomy manager stated that phlebotomy issues are managed by human resources and are not reported to the lab director. The lab director does not meet and discuss trending and identification of pre analytical test problems with the regional phlebotomy manager. This is based on interview with the regional phlebotomy manager, and review of reports submitted to the lab director for review; 4. The labs written procedure "QUAL-107M" attachment A is a record for the lab director to document patient report reviews, quality control and lab meeting minutes, remedial action effectiveness and client concerns, but the lab does not complete and report this document to the lab director; and 5. The lab director did not ensure that "Corrective Action Documentation Form" is complete, The report dated January 3, 2018 at 12:10 pm was not reviewed and dated, as these fields on the form were not completed. C. Based on review of the quality assurance (QA) documentation for the chemistry department and interview with the laboratory manager, the laboratory director did not ensure that the established QA procedures for analyte comparison for the AU5800 and AU2700 (chemistry analyzers that perform therapeutic drug monitoring (TDM) and general chemistry) were performed and reviewed. Findings: 1. The laboratory's chemistry QA plan requires the laboratory to perform comparability studies between analyzers that report the same test result twice a year (June and December). 2. On 05 /22/18 the worksheet on the front of one of the QA binder was labeled "Annual and Semi-Annual Quality Assurance Activities 2017." The worksheet did not have any recorded completion dates showing that the data in Tabs 1-15 had been reviewed and found to be acceptable. On 06/04/18 when the QA binder was reviewed the worksheet labeled "Annual and Semi-Annual Quality Assurance Activities 2017" had been changed. There were only 13 Tabs on the new worksheet; all the completion dates were completed except for Tab 1 and one half of Tab 7, 8, 10 and 11. 3. On 05/22/18 the "Annual and Semi-Annual Quality Assurance Activities 2017" worksheet was reviewed. Tab 9 was labeled "Analyte Comparisons: AU5800, AU2700 Set 1" and "Analyte Comparisons: AU5800, AU2700 Set 2." The tab included documentation of the "Semi-annual Comparability TDM" and "Semi-annual Comparability General Chemistry" for December 2017. The laboratory manager confirmed that there were no records for Semi-annual Comparability for June 2017. 4. The "Semi-annual Comparability TDM" and "Semi-annual Comparability General Chemistry" records were reviewed by the manager on 04/25/18. According to the laboratory manager the documented review was not performed by her but by the "Director of technical operations" because the manager had not been trained to perform this evaluation. The "Director Review/date" section was blank on both of the records. 5. The manager /director of technical operations noted that the following analyte's needed follow-up: Theophylline, Total Bilirubin, Preablumin, Creatinine Kinase, Sodium and Carbon Dioxide. There was no documented follow-up for the analyte's that were found to have unacceptable comparability results. There was no documented look back to ensure that patient test results were not affected by the unacceptable comparability results. 6. Both chemistry analyzers, AU5800 and AU2700, continued to be used to perform testing and reporting of patient test results until March 30, 2018 when the AU2700 stopped working. 7. During the survey on 06/04/18 at 2:00 PM the laboratory manager confirmed that the comparability study for June 2017 had not been performed; there was no documented follow-up for the unacceptable

comparability results for December 2017; and the laboratory had not performed a review of the patients tested during that time period to ensure that patient test results were not affected by the unacceptable comparability results. D. Based on review of the incubator records and interview with the laboratory manager, the laboratory director failed to ensure that the changes in processing the QuantiFERON- TB GOLD specimens decreased the number of indeterminate test results that the reference laboratory was providing to the parent laboratory and then to the Maryland laboratory. Findings: 1. The laboratory manager explained that the parent laboratory in Florida has been receiving the QuantiFERON- TB GOLD specimens once they are collected in Maryland and sending them to the reference laboratory for testing after incubation at the parent laboratory. 2. The reference laboratory informed the parent laboratory in Florida that they were getting a large number of test results for the QuantiFERON- TB GOLD test results were indeterminate. The reference laboratory told the parent laboratory to have the Maryland laboratory incubate the specimens within 16 hours of collection prior to shipping them to the parent laboratory. The manufacturer's instructions require the specimens are to be incubated 16-24 hours prior to shipping. This should decrease the number of indeterminate test results. 3. During the survey on 06/08/18 at 10:00 AM the laboratory manager confirmed that there was no documentation showing that the incubation at the Maryland laboratory decreased the number of indeterminate QuantiFERON- TB GOLD test results. E. Based on review of the "Corrective Action Documentation Form" for the AU 2700, AU 5800 and an Architect (chemistry analyzers that perform therapeutic drug monitoring (TDM) and general chemistry) and interview with the laboratory manager and chemistry supervisor, the laboratory director failed to ensure that the forms were completed, reviewed and dated by the appropriate person. Findings: 1. The "Corrective Action Documentation Form" worksheets from March 2017 through May 2018 for the AU 2700, AU 5800 and an Architect were reviewed. 2. The "Corrective Action Documentation Form" worksheets for the AU 2700 showed that 3 of the 3 had not been reviewed and 2 of the 3 did not identify the tech who completed the form and the time. 3. The "Corrective Action Documentation Form" worksheets for the AU 5800 showed that 9 of the 11 had not been reviewed and 4 of the 11 did not identify the tech who completed the form and the time. 4. The "Corrective Action Documentation Form" worksheets for the Architect showed that 4 of the 4 had not been reviewed and 1 of the 4 did not identify the tech who completed the form and the time. 5. The corrective action binder also included documentation of a "Customer Support Call" that was performed on January 23, 24 and 25, 2017 and February 21, 2017. The records included documentation of Simple Precision and Linearity Summary. The evaluation stated that the linearity had been performed and that the accuracy and reportable range were not evaluated in this experiment. 6. The problem listed on the "Customer Support Call" worksheet was that the lab was having an ongoing problem with GGT, ALP and Amylase quality control failures. The service representative performed the required repairs to correct the problem. The service representative also addressed the issues the laboratory was having with the Ion Selective Electrode (ISE). The laboratory stated that they were not running the enhanced clean on a weekly basis. The service representative referred the laboratory to the "User Guide" to ensure they were performing all required maintenance. 7. In August 2017 the service representative stated that the bleaching of the ISE every 2 weeks was no longer required. Cross refer to D6020 III. The laboratory was not performing the bleaching of the ISE every 2 weeks per the service representative who did not provide the laboratory with documentation. 8. During the survey on 06/04/18 at 10:30 AM the laboratory manager confirmed that the chemistry "Corrective Action Documentation Form" worksheets were not all being reviewed. 9. During the survey on 06/04/18 at 10:30 AM the chemistry supervisor confirmed that the chemistry issues with the ISE

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| | bleaching not being performed was still not resolved. |
| **D6024** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assurance QA data for analyte comparison for the AU5800 and AU2700 (chemistry analyzers that perform therapeutic drug monitoring (TDM) and general chemistry), laboratory director failed to ensure that remedial actions were taken when multiple analytes failed to produce acceptable results during the semi-annual Comparability testing. Findings: Cross reference D6021 |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the coagulation quality control monthly review logs and interview with the laboratory manager, the technical consultant (TC) did not review all QC and QC logs for coagulation testing. Findings: 1. The June 2017, monthly review for coagulation QC was not performed by the TC. 2. The "monthly review" log states that the review of the QC logs are to be performed to ensure that all QC was performed and any corrective actions procedures were completed. 3. The laboratory manager stated that it was the responsibility of the TC to review all QC logs. |
| **D6043** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(5)<br><br>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the corrective action documentation forms and interview with the laboratory manager, the technical consultant (TC) did not ensure problems were resolved once the error was documented by the lead technologists. Findings: 1. The hematology analyzer was having problems on May 29th and April 30th during the |

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| | year 2018. The lead technologist documented the problem on the "corrective action documentation form". The TC is supposed to review the form for completion. 2. The review of the written problem and actions taken on May 29th and April 30th during the year 2018 for the hematology analyzer was not reviewed by the TC. 3. The hematology analyzer had a problem on October 19, 2017. The lead technologist documented the problem on the "corrective action documentation form". The TC is supposed to review the form for completion. 4. The review of the written problem and actions performed on October 19, 2017 for the hematology analyzer was not reviewed by the TC. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency records and interview with the laboratory manager, the technical consultant (TC) did not perform training and competency procedures for all laboratory staff . Findings: 1. Laboratory testing personnel did not receive training prior to performing patient testing in the areas of hematology , bacteriology, and chemistry. 2. Testing personnel did not receive semi annual competency procedures performed by the TC. 3. The laboratory manager stated that persons performing laboratory testing did receive training prior to performing patient testing and semi annual competency procedures were not performed. |
| **D6049** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the incubator temperature worksheets and interview with the laboratory manager, the technical consultant failed ensure that the testing personnel were documenting the correct incubator temperatures and corrective actions were documented when the incubator temperatures was unacceptable. Findings: Cross reference D5411 B. Based on review of the chemistry quality control (QC) and maintenance worksheets and interview with the laboratory manager, the technical consultant failed ensure that the chemistry worksheets were reviewed on a monthly basis as required by the policies and procedures. Findings: Cross reference D6020. |
| **D6070** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(1)<br><br>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the incubator temperature worksheets and interview with the laboratory manager, the testing personnel failed to ensure that the incubator temperature that was recorded was within acceptable limits and that corrective actions were documented when the incubator temperature was unacceptable. Findings: Cross reference D5411 |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<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 review of the written procedure and interview with the technical supervisor, the laboratory director failed to ensure that there was a clear policy for when to refer hematology differential slides for pathologist review (D6087) |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure and interview with the technical supervisor, the laboratory director failed to ensure that there was a clear policy for when to refer hematology differential slides for pathologist review. Findings: Cross reference D5403 Part "C" 1. The procedure, "HEME Manual Differential Criteria, Performance and Smear Scans" includes a chart labeled "Attachment B," "Supervisor/Pathologist Smear Review Criteria." The chart states that "Smear Reviews are performed by qualified Hematology Supervisors at High Complexity Labs or by Pathologists, according to the criteria below" and "A log of smear reviews is helpful in tracking patient history." 2. The chart lists the hematological "Abnormality" in the first column, followed by columns for "High Complexity Lab" under which there is the comment, "After initial Path Review" or "X," and a column labeled, "Pathologist Review," under which there is the comment, "First Time," or "If unresolved by supervisor." The "abnormality" "Presence of parasites (such as Malaria) or bacteria" states "X" "Immediately" under "High Complexity Lab" and "X" "Confirmation" under "Pathologist Review." 3. During an interview on 5/22/18 at 2:45 PM, the TS stated that if abnormalities are seen on the differential slide, testing personnel are supposed to do a "look back" at the patient history. If the abnormality has been reported previously, the testing person can report the abnormality without additional pathologist review. The TS also stated that the "presence of parasites" is "immediately reported" as "presumptive" and that they then "get confirmation" from the pathologist. 4. The policies stated by the TS were not written in the "HEME Manual Differential Criteria, Performance and Smear Scans" procedure and were not clear on the "Supervisor/Pathologist Smear Review Criteria" chart. 5. During an interview on 5/22 /18 at 3:00 PM, the TS confirmed that the procedure manual did not clearly state when |

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| | hematology differential slides should be reported by laboratory testing personnel and when they should be referred to the pathologist for review. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency records and interview with the laboratory manager, the technical supervisor (TS) did not perform training and competency procedures for the three technical consultants (TC's). Findings: 1.The TC's did not receive training prior to performing patient testing in the areas of hematology , bacteriology, and chemistry. 2. The TC's did not receive semi annual competency procedures performed by the TS. 3. The laboratory manager stated that TC's performing laboratory testing did receive training prior to performing patient testing and semi annual competency procedures were not performed by the TS. |
| **D6123** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the hematology quality control (QC) and maintenance worksheets and interview with the hematology supervisor, the technical supervisor (TS) failed to ensure that the hematology worksheets were reviewed on a monthly basis as required by the policies and procedures. Findings: 1. The procedure, "Statement of Responsibility: High Complexity Lab" details the duties and responsibilities that the laboratory director delegates to the TS. The procedure states that the TS is to, "Ensure that quality control and quality assessment programs are established and maintained to assure the quality of laboratory serices provided and to identify failures in quality as they occur." 2. A review of monthly "QC Review Logsheets" and "QC Log Bench Review" records for the 3 Beckman Coulter DxH hematology analyzers from January through December, 2017 showed that monthly QC log sheets were not reviewed by the TS for 6/2017 for each analyzer; 3. A review of "Interlaboratory Quality Assurance Program" (IQAP) reports from Beckman Coulter for the "DxH1" analyzer showed that 4 of 7 IQAP reports for the "Retic-x Cell Control" and 3 of 8 for the "Coulter 6C Cell Control" were not reviewed by the TS. Four of these reports were printed in December, 2017 and not reviewed until 3/20/18; 4. A review of available hematology QC records showed that there were no monthly QC or Levey-Jennings reports printed or reviewed to detect shifts and trends in QC by the TS. During an interview on 6/8/18 at 11:30 AM, the hematology supervisor stated that they "don't print monthly QC reports" and that they review the IQAP reports supplied by |

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| | Beckman Coulter. The hematology supervisor stated that they were "going to start reviewing weekly QC." 5. A review of monthly maintenance logs from January through December, 2017 showed that the maintenance logs for "DxH1" for 5/2017 and 7/2017, "DxH2" for 5/2017 through 8/2017, and "DxH3" for 5/2017 through 8 /2017 were not reviewed by the TS; 6. A review of "Corrective Action Documentation Forms" from 2017 which document troubleshooting and instrument service performed showed that 2 of 3 forms for the TOSOH HbA1c analyzer were not reviewed by the TS; and 7. During an interview on 6/8/18 at 1:00 PM, the hematology supervisor confirmed that the TS did not ensure that hematology worksheets were reviewed on a monthly basis as required by the policies and procedures. |