

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315974	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Crockett Hospital	Street Address, City, State 1607 S Locust Avenue, Lawrenceburg, TN	
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
D0000	During a recertification/validation survey completed on 02/27/25, the laboratory was NOT in compliance with the following conditions: 493.1230 Condition: General laboratory systems. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, a review of manufacturer package inserts, patient instrument printouts, a lack of calibration records, and staff interview, the laboratory failed to retain four of eighteen requested calibration records for the Procalcitonin and fibrin degradation products (D-Dimer) assays performed on the Biomerieux Vidas 3 instrument in 2024. The findings include: 1. During a tour of the laboratory on 02/12/25 at 10:00 a.m., the surveyor observed the Biomerieux Vidas 3 instrument (Serial #VN04233) used for performing patient testing for Procalcitonin and D-Dimer. 2. A review of the manufacturer's package insert for the Procalcitonin assay revealed that "Calibration, using the two calibrators provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data (MLE) has been entered and then every 28 days." 3. A review of the manufacturer's package insert for the D-Dimer assay revealed that "Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 28 days." 4. A review of patient instrument printouts revealed the following: Procalcitonin was performed on 4/10/24 for patient 42202 using reagent lot number 250319-1 with a calibration date of</p>

03/25/24. Procalcitonin was performed on 9/10/24 for patient number 105996 using reagent lot number 250821-0 with a calibration date of 08/23/24. D-Dimer was performed on 03/05/24 for patient 25324 using reagent lot number 250522-0 with a calibration date of 02/07/24. D-Dimer was performed on 06/18/24 for patient 315723 using reagent lot 241210-0 with a calibration date of 06/10/24. 5. The laboratory could not provide the calibration reports for the Procalcitonin assay performed on 03/25/24 for reagent lot 250319-1 and 08/23/24 for reagent lot 250821-0 or the D-dimer assay performed on 02/07/24 for reagent lot 250522-0 and 06/10/24 for reagent lot 241210-0. 6. Electronic mail communication received on 03/05/25 at 9:57 a.m. revealed the following: The manufacturer stated that only the active calibration would be shown on the patient printout. It also noted that any previous calibrations were available from the calibration or history tabs. The general supervisor stated he did not know how to see the previous calibrations. This confirmed the survey findings.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on direct observation, review of the laboratory procedure manual, review of testing personnel competency assessment records, lack of documentation, review of patient test reports, review of the laboratory's American Proficiency Institute (API) proficiency testing records, a review of the Department of Health and Human Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) application for Certification (Form CMS-116), and staff interviews, the laboratory failed to follow the policy for testing personnel competency assessments in 2023 and 2024 (Refer to D5209), failed to evaluate non-graded proficiency testing results in 2024 (Refer to D5211), failed to verify the accuracy of tests not included in subpart I (Refer to D5217).

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on direct observation, review of the laboratory procedure manual, document review, and staff interviews, the laboratory failed to follow the testing personnel competency assessment policy in 2023 and 2024 for eight of eight testing personnel reviewed. The findings include: 1. Laboratory observation on 02/12/25 at 10:00 a.m. revealed the following test systems used for patient testing: Siemens Dimension EXL Chemistry, Endocrinology, and Toxicology instruments (serial #s DE272522 and DE272534). Instrumentation Labs Gem 3500 Blood Gas Instruments (serial #s

16127510 and 1617509). Biomerieux Vidas 3 instrument used for performing Procalcitonin and fibrin degradation products (D-Dimer). Genexpert (serial number 724142) used for performing testing for Chlamydia trachomatis, Neisseria gonorrhoea, Group B Streptococcus, Methicillin Resistant Staphylococcus aureus, and Clostridium difficile. Quick view serum pregnancy test kit. Qiagen AmniSure rupture of membranes test kit. Sysmex CA 600 Series coagulation instrument used to perform Prothrombin Time (PT), Activated Partial Thromboplastin Time (aPTT), and Fibrinogen. Alcor MiniSed was used for performing Erythrocyte Sedimentation Rate (ESR). Biofire Film Array (Serial # 2FAA95D1) used for performing Blood Culture Identification, Gastrointestinal Panel, and Respiratory Viral Panel. A microscope used for urine microscopy, vaginal wet prep, and manual white blood cell differential. Sysmex XN 550 (serial # 17980) used for performing Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff), Reticulocyte Count, and Body Fluid Cell Counts. Bactec 9240 (Serial # DB6929) used for pathogen detection in blood. Beckman Coulter MicroScan Walk Away (Serial # 44010274) used for performing microorganism identification and sensitivity. Becton Dickinson Gram Stain kit. Plates for growth and isolation of organisms from urine, wound, sputum, blood cultures, body fluids, and throat swabs. Immunocard Stat! Mononucleosis Test (Mono). Ortho Clinical Diagnostics system and reagents used for performing ABO type, Rhesus type (Rh), Antibody Screen, and Compatibility Testing (Gel method was used as the primary system, Tube Method was used for backup). Ortho Clinical Diagnostics Fetal Screen kit. Sure-View Rheumatoid Factor test kit. 2. During observation on 02/12/25 at 10:00 a.m., the general supervisor stated that testing personnel are cross-trained to perform testing in every laboratory section, except night shift personnel (testing persons seven and eight), who did not read plates and perform organism identification and sensitivity in the microbiology section of the laboratory. He also stated that the laboratory used the Ortho tube method as a backup method to the Ortho Gel system for transfusion medicine testing. 3. A review of the laboratory procedure manual revealed procedures for both the Ortho Gel and Ortho tube methods for transfusion medicine testing. 4. A review of the laboratory's policy titled "Laboratory Competency Evaluation 736-1518" revealed that testing personnel competency evaluation would include (when applicable) direct observation of routine patient test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records, direct observation of performance of instrument maintenance and function checks, assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing sample, and assessment of problem-solving skills. 5. A review of the policy titled "Personnel 736-9106" revealed that personnel are evaluated for competency 90 days of successful employment and then yearly. 6. A review of testing personnel competency assessment records revealed the following: Testing Person One (General Supervisor) Hire date = 03/06/24 The six-month competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The six-month competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not

include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing Person Two: Hire date = 11/24/98 2023 annual competency assessment was not documented/performed for any test system. The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing person three: Hire date = 10/20/14 2023 annual competency assessment was not documented/performed for any test system. The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing person four: Hire date=05 /21/18 The 2023 annual competency assessment was not documented/performed for any test system. The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing person five: Hire date=09/08/20 The 2023 annual competency assessment was not

documented/performed for any test system. The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing person six: Hire date = 06/20/16 The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Testing person seven: Hire date = 08/07/23. The initial competency assessment was documented on 12/8/23. The document did not include training and assessment of test performance for the Sysmex XN 550 hematology instrument, the Biomerieux Vidas 3 instrument used for Procalcitonin and D-Dimer testing, the GeneXpert instrument, the Biofire Film Array instrument, or wet prep. No interim competency assessment for 2024 was available on the survey date (02/13/25). The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented /performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of patient testing, direct observation of maintenance, monitoring the recording and reporting of test results, blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of patient testing, direct observation of maintenance, monitoring the recording and reporting of test results, blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of patient testing, direct observation of maintenance, monitoring the recording and reporting of test results, blind testing, and assessment of problem-solving skills. Testing person eight: Hire date = 07/30/17 The 2023 annual competency assessment was not documented/performed for any test system. The 2024 annual competency assessment did not include the Qiagen AmniSure ROM, wet prep, Gram Stain, or the ABO, Rh, Antibody Screen and Crossmatch performed using the tube method. The 2024 annual competency assessment was not documented

/performed using the six required elements for the following test systems: Urine microscopy did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. Manual differential did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. The BacTec Blood Culture instrument did not include direct observation of maintenance, monitoring the recording and reporting of test results, record review (worksheets, quality control, proficiency testing results, and preventive maintenance records), blind testing, and assessment of problem-solving skills. 7. A review of patient test reports revealed the following: Wet prep reported for patient # 0539299 on 04/11/24 by testing person three, and on patient #0579595 on 02/11/25 by testing person eight. Urine microscopic reported for patient # 0537892 by testing person two on 04/01/24, and for patient # 0579490 on 02/11/25 by testing person four. Manual white blood cell differential reported for patient #0537495 on 04/02/24 by testing person seven and for patient # 0579304 on 02/11/25 by testing person four. Quigen AmniSure ROM reported on patient # 0538730 by testing person seven on 04/06/24, and patient # 0562173 by testing person seven on 10/06/24. Gram stain reported on patient #0527230 by testing person four on 01/03/24. Blood culture reported on patient # 0526990 by testing person four on 01/07/24. 8. The general supervisor confirmed the survey findings during an interview on 02/13/25 at 6:15 p.m.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of records, and staff interviews, the laboratory failed to evaluate results that were not graded by the PT program for two of three Microbiology events reviewed from 2024. The findings include: 1. A review of the laboratory's API PT Performance Evaluation records revealed the following: 2024 Microbiology-Event Two Urine Culture MIC/Zone Diameter Value: 10 of 10 results for sample UR-06 were "Not Graded" with a notation of "3" in the Performance column. Urine Culture Susceptibility Interpretation for the sample UR-06: One of Seven results was "Unacceptable," One of seven results was "Not Graded" with a notation of "2", and One of seven results was "Not Graded" with a notation of "3" in the Performance column. The notation key on page 11 of the Performance Evaluation indicated the following: 2- No Consensus, 3- See Data Summary 2024 Microbiology-Event Three Blood Culture MIC/Zone Diameter Value: 20 of 20 results for sample BLD-03 were "Not Graded" with a notation of "3" in the Performance column. Blood Culture Susceptibility Interpretation: 14 of 14 results for sample BLD-03 were "Not Graded" with a notation of "6" in the Performance column. Urine Culture MIC/Zone Diameter Value: 14 of 14 results for sample UR-11 were "Not Graded" with a notation of "3" in the Performance column. The notation key on page 11 of the Performance Evaluation indicated the following: 2- No Consensus, 3- See Data Summary, and 6- Educational Sample 2. Documentation for evaluation of the "Not Graded" results was unavailable on the survey date (02/13/25). 3. An interview with

the technical supervisor on 02/13/25 at 6:15 p.m. confirmed that the laboratory failed to evaluate results that were not graded by the API PT program in 2024. Word Key: MIC- Minimum Inhibitory Concentration

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on direct observation, lack of documentation, review of the laboratory's American Proficiency Institute (API) PT reports, final patient test reports, and staff interviews, the laboratory failed to verify the accuracy of the Vitamin D, the Placental alpha macroglobulin-1(PAMG-1), and the Erythrocyte Sedimentation Rate (ESR) analytes twice a year in 2024. The findings include: 1. Observation of the laboratory on 02/12/25 at 10:00 a.m. revealed the Siemens Dimension EXL used for performing Vitamin D, the Qiagen AmniSure Rupture of Membranes test kit used for PAMG-1, and the Alcor MiniSed ESR instrument used for ESR patient testing. 2. On the survey date (02/13/2025), documentation for twice-a-year verification of accuracy for 2024 for the Vitamin D and Amnisure ROM analytes was unavailable. 3. A review of the laboratory's API PT performance evaluation reports revealed that in 2024, the laboratory was enrolled in and participating in the wrong PT module for the ESR analyte. 4. A review of final patient test reports revealed the following: Vitamin D was reported on patient 0538815 reported on 04/08/24 at 10:05 am and patient 0562481 on 10/07/24 at 5:49 pm. Amnisure ROM was reported on patient 0538730 on 04/06/24 at 11:20 pm and patient 0562173 on 10/06/24 at 8:00 pm. The first ESR for the Alcor Mini-Sed instrument was reported on 02/08/24 for patient 0530125. 5. An interview with the general supervisor on 02/13/25 at 6:15 pm confirmed the laboratory failed to verify the accuracy of the Vitamin D, PAMG-1 ROM, and ESR analytes twice a year in 2024.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) 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.

This STANDARD is not met as evidenced by:
CITATION NUMBER ONE: Based on direct observation, a review of the laboratory procedure manual, a review of the Alcor MiniSed equipment validation protocol, a review of the Alcor MiniSed validation documentation, a review of a patient test report, staff interview, and review of electronic mail (email) communication, the laboratory failed to follow its' equipment qualification procedure for the Alcor MiniSed Erythrocyte Sedimentation Rate (ESR) instrument. The findings include: 1. Laboratory observation on 02/12/25 at 10:15 a.m. revealed the Alcor MiniSed ESR instrument used for patient testing. 2. A review of the procedure titled "Equipment Qualification Protocol, 736-8219" revealed the following: "Once the piece of equipment is installed, defined manufacturer system checks are performed." "After the

equipment standard operating procedure has been written and approved, staff participate in equipment training. All laboratory staff are trained and competency evaluated." "Documentation of training exists in the form of checklists, sign-off sheets, competency evaluation forms, etc., which are retained by the lab supervisor. 3. A review of the manufacturer's guide for validation of the Alcor MiniSed ESR instrument under the section for "Sample Requirements for Analysis" revealed that sixty samples with a value between 15 to 105 mm/hr, with at least 40% of the samples with a result over 35 mm/hr, from both males and female were to be included in the validation. "HCT and MCV data must be collected for each sample to aide in data analysis." When testing was complete, the data was to be sent to the manufacturer for analysis. 4. A review of the Alcor MiniSed validation documents revealed the following lacking documentation: Sixty samples were not included as part of the validation study. No values greater than or equal to 105 mm/hr were included in the study. 40% of the samples included in the study were not over 35 mm/hr. Hematocrit and Mean Corpuscular Volume data were not available. The data had not been sent to the manufacturer for data analysis. Training and competency of testing personnel were not documented. Precision had not been evaluated. The reportable range was not verified according to manufacturer protocol. 5. A review of a patient test report revealed that the first ESR patient from the Alcor MiniSed was reported on 02/08/24 for patient # 0530125. 6. The survey findings were confirmed during an interview with the general supervisor on 02/13/25 at 6:15 p.m. 7. A review of the email communication received on 02/27/25 at 9:29 a.m. revealed that the laboratory had reported approximately 246 ESR patients from the first patient testing date on 02/08/24 until 02/13/25 (the onsite survey date). CITATION NUMBER TWO: Based on direct observation, review of laboratory policy, quality controls (QC) records, lack of records, and staff interview, the laboratory failed to follow its policy when it failed to retain the manufacturer QC package inserts for nine of nine QC lots reviewed from 2024. The findings include: 1. Observation of the laboratory on 02/12/25 at 10:00 a.m. revealed the Alcor MiniSed ESR (Serial 02738) instrument used for ESR patient testing and two Dimension EXL (Primary Serial DE272522/Backup Serial DE272534) instruments used for chemistry, endocrinology, and toxicology patient testing. 2. A review of the laboratory policy titled "Package Insert Review and Retention" revealed the laboratory was required to maintain package inserts for two years in an electronic shared drive or in binders. 3. A review of the laboratory quality control data revealed the following: In January 2024, Biorad Cardiac Marker control lots 67673 and 67675, Immunoassay Plus lots 85341, 85342, and 85343, and Specialty Immunoassay lots 64942 and 64943 were in use. In July 2024, Sed Rate (Seditrol) control lots C143 and C243 were in use. 4. The manufacturer's QC package inserts were not available on the date of the survey for any of the nine lots reviewed. 5. An interview with the general supervisor on 02/13/25 at 6:15 p.m. confirmed the survey findings.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(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.

This STANDARD is not met as evidenced by:
Based on direct observation, review of the laboratory procedure manual, review of

comparison studies for the transfusion medicine testing, and staff interviews, the laboratory failed to compare the ABO and Rhesus (Rh) blood typing performed using the Ortho Gel method to the Ortho tube (backup) method in 2023 and 2024. The findings include: 1. Laboratory observation on 02/12/25 at 10:15 a.m. revealed Ortho Blood Bank system reagents and equipment used for performing transfusion medicine testing, including ABO type, Rh type, Antibody Detection, Direct Antiglobulin Testing, and Compatibility testing. During observation, the general supervisor stated that the primary method for the laboratory was the Ortho Gel technique, but the laboratory also used the Ortho tube method as a backup procedure. 2. A review of the laboratory procedure manual revealed procedures for both the Ortho Gel and tube methods. 3. A review of comparison studies for the transfusion medicine testing area revealed no documentation that the ABO/Rh type performed by the Gel method had been compared to the ABO/Rh performed by the tube (backup) method in 2023 or 2024. 4. The general supervisor confirmed the survey findings during interview on 02/13/25 at 1:30 p.m.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(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. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory policies, quality control (QC) records, lack of records, review of a patient activity report, and staff interviews, the quality assessment process failed to document effective corrective action to resolve and prevent errors in hematology QC (one of three lots reviewed) for the Reticulocyte percent (Retic %) analyte in 2024. The findings include: 1. Observation of the laboratory on 02/12/25 at 10:00 a.m. revealed the Sysmex XN 550 (Serial 17980) used for patient Retic % testing. 2. A review of the laboratory policies titled "Quality Assurance" and "Sysmex Quality Control Schedule & Corrective Action, 736-5031.HEM" revealed the following: The "Quality Assurance" policy stated that QC review was included in the quality assessment process, and "The lab must also initiate corrective action when problems occur and document all quality assurance activities." The "Sysmex Quality Control Schedule & Corrective Action, 736-5031.HEM" policy section "Quality Control" stated that controls were performed every eight hours with low and normal controls at 7:00 am, normal and high controls at 3:00 pm, and low and high controls at 11:00 pm. Section "Corrective Action" stated " When Quality Results fall outside expected ranges the QC specimen is remixed and repeated, If results are still outside expected ranges then a Corrective Action measure is initiated and actions taken to correct instrument malfunction is documented on the Hematology corrective QC Action Log...." 3. A review of the laboratory's hematology QC records for level one (lot 42651401) for the Retic % analyte revealed the following: Sysmex Insight Quality Control Peer data reports for Parent lot 4265 (42651401, 42651402, and 42651403): Period One (09/25/24-10/26/24) was reviewed on 11/04/24 by the laboratory technical consultant/general supervisor and 11/21/24 by the laboratory director. Cumulative QC data printed from the Sysmex XN 550 analyzer with a date range from 09/29/24 to 12/31/24: QC results were outside of the laboratory's expected ranges for 72 of 138 runs. QC results that were not repeated for failed runs on nine of

41 days. The Sysmex Insight report (used for reviewing QC data generated from the Sysmex XN 550 instrument), when compared to the results printed from the Sysmex XN 550, revealed that the Insight report did not flag results that were outside the laboratory's acceptable quality control limit range. Discrepancies were noted between the Sysmex instrument cumulative QC data and the Hematology Quality Control Log: Level one QC results outside the laboratory's expected range in the cumulative QC data printed from the Sysmex XN 550 instrument did not have documented corrective action on the hematology log for five of 41 days (10/03/24 at 2:36 and 2:43 p.m., 10/16/24 at 6:29 and 6:33 a.m., 10/22/24 at 10:29 p.m., 10/25/24 at 3:39 p.m. and 10:26 at 7:06 a.m.). Corrective action was documented on the hematology log for runs that were not in the cumulative QC data for seven of 41 days (09/30/24 for 3 p.m. run, 10/1/24 for 7 a.m. and 11 p.m. run, 10/2/24 for 7 a.m. run, 10/3/24 for 7 a.m., 10/6/24 for the 11 p.m. run, 10/7/24 at 11 p.m. run, 10/8/24 for the 7 a.m. run.) 4. Documentation for corrective action to resolve the repeated QC failures for level one (lot 42651401) for the Retic % analyte was not available during the period of QC failures from 09/29/24 through 10/27/24. Documentation that the laboratory contacted technical service was noted on the hematology log on 10/28/24. 5. A review of a patient activity report revealed one patient was tested on a date with QC failures for level one QC (patient 562165 on 10/05/24). 6. An interview with the laboratory technical consultant on 02/13/25 at 6:15 p.m. confirmed the laboratory's quality assessment process did not include effective corrective action to resolve or prevent QC failures for the Retic % analyte in 2024.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
The laboratory director failed to ensure instrument validations were performed according to established procedure (Refer to D6086), failed to ensure proficiency testing reports were evaluated to determine the laboratory's performance and identify problems (Refer to D6091), failed to ensure the quality control and quality assessment procedures were effective (Refer to D6093), and failed to ensure testing personnel competency assessment policies were followed (Refer to D6103).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on laboratory observation, procedure manual review, a patient test report, staff interview and review of an electronic mail communication, the laboratory director failed to ensure that the verifications performed on the Alcor Mini-Sed Erythrocyte Sedimentation Rate (ESR) instrument were performed according to established procedure (Refer to D5401, Citation One).

<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of records, the Form CMS-116, and staff interviews, the laboratory director failed to ensure non-graded proficiency testing results were evaluated to determine laboratory performance (Refer to D5211), and failed to ensure the laboratory verified the accuracy of non-waived test methods (Refer to D5217).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory procedure manual, review of comparison studies, review of a patient activity report, and staff interviews, the laboratory director failed to ensure the laboratory compared the results of analytes performed using different test methodologies (Refer to D5775) and failed to ensure the laboratory's review process was effective in correcting problems with Retic % quality control (Refer to D5793).</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: The laboratory director failed to ensure testing personnel competency assessment policies and procedures were followed and failed to ensure eight of eight testing personnel had documented competency assessment for use of the Ortho tube (backup) method for transfusion medicine testing (Refer to D5209).</p>