

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0441699	(X3) Date Survey Completed 03/07/2022
Name of Provider or Supplier Putnam County Memorial Hospital	Street Address, City, State 1926 Oak Street, Unionville, MO	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of Ortho Diagnostics Vitros 350 analyzer and quality control (QC) records, Vitros ECiQ analyzer and QC, ACL Elite analyzer, Prothrombin Time (PT) and D-Dimer QC, review of manufacturer's instructions, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory's lack of blood bank alarm check procedure, failed to follow proficiency testing procedure (Refer to D5401); the laboratory failed to perform Vitros 350 calibration verification (Refer to D5439); the laboratory failed to include two control materials of different concentrations each day of patient testing (Refer to D5447); the laboratory failed to perform positive and negative controls each day of patient testing for serum hCG (Refer to D5449); the laboratory failed to follow established criteria for QC (Refer to 5469); the laboratory failed to include two levels of control material each 8 hours of operation for PT and D-Dimer (Refer to D5545); the laboratory failed to perform blood bank QC each day of patient testing (Refer to 5551); and the laboratory failed to perform quarterly blood bank refrigerator alarm checks (Refer to 5555).</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

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:

Based on review of procedures, proficiency testing (PT) and interview with the general supervisor (GS), the laboratory failed to follow "Proficiency Testing" procedure. Findings: 1. Review of "Proficiency Testing" procedure states "The Laboratory Director and all staff performing the testing should sign in the attestation spaces provided on the data sheet". 2. Review of the 2020, 2021 and to date March 1, 2022 PT attestations showed the laboratory director (LD) failed to follow procedure and sign the attestation. 3. Interview with the GS on March 1, 2022 at 11:00 AM confirmed the LD failed to follow "Proficiency Testing" procedure. 44735 Based on interview with the general supervisor (GS) and review of blood bank procedures, the laboratory failed to provide a procedure for quarterly blood bank alarm checks. Findings: 1. Interview with the GS on March 1, 2022 at 2:30 PM, the GS stated that the laboratory was not staffed from 5:30 PM to 6:00 AM daily, and that the blood bank refrigerator would alarm in the laboratory and at the nurse's station. 2. Review of blood bank procedures showed no procedure for performing blood bank alarm checks. 3. Interview with the GS on March 1, 2022 at 2:30 PM confirmed that the laboratory failed to provide a procedure for blood bank alarm checks.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on review of 2020, 2021, and to date March 1, 2022 calibration records for the Ortho Diagnostics Vitros 350 chemistry analyzer and interview with the general supervisor (GS), the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range.

Findings: 1. Review of Vitros 350 calibration records for 2020, 2021, and to date March 1, 2022 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analyte chloride. 2. Interview with the GS on March 1, 2022 at 2:30 PM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for chloride.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on interview with the general supervisor (GS), review of Vitros 350 quality control (QC) package insert, Ortho Diagnostics Vitros 350 analyzer and January 1, 2022 to March 1, 2022 chemistry QC, the laboratory failed to include two control materials of different concentrations for cholesterol for 5 of 60 patient testing days. Findings: 1. Interview with the GS on March 1, 2022 at 1:45 PM, the GS stated that they use package insert ranges for chemistry QC. 2. Review of Vitros 350 package insert showed: PV1 lot # D8955 cholesterol range as 130.4 - 156.4 PV2 lot # C8821 cholesterol range as 228.2 - 260.2 3. Review of Ortho Diagnostics Vitros 350 analyzer showed: PV1 cholesterol range as 141.6 - 170.4 PV2 cholesterol range as 239 - 277 4. Review of Ortho Vitros 350 cholesterol QC showed two acceptable levels of QC were not performed on February 5, 2022, February 10, 2022, February 16, 2022, February 18, 2022, and February 25, 2022. The laboratory reported 15 patient test results while QC was not acceptable. 5. Interview with the GS on March 1, 2022 at 2:00 PM confirmed the laboratory failed to include two control materials each day of patient testing for cholesterol.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of serum human chorionic gonadotropin (hCG) quality control (QC) records for 2020, 2021, and to date March 1, 2022 and interview with the general supervisor (GS), the laboratory failed to perform positive and negative controls for serum hCG for 13 of 13 patient testing days. Findings: 1. Review of serum hCG QC records for 2020, 2021, and to date March 1, 2022 showed the laboratory failed to perform a positive and negative QC each day of patient testing. The laboratory

reported 13 patient tests while QC was not performed. 2. Interview with the GS on March 1, 2022 at 10:30 AM confirmed, the laboratory did not test a positive and negative control each day of patient testing.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on interview with the general supervisor (GS), and review of Ortho Diagnostics Vitros 350 analyzer quality control (QC) records, the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results. Findings: 1. Interview with the GS on March 1, 2022 at 1:45 PM, the GS stated that they use package insert ranges for chemistry QC. 2. Review of Vitros 350 package insert PV1 lot # D8955 showed: cholesterol range as 130.4 - 156.4 alkaline phosphatase as 73 - 124 phosphorus as 3.11 - 3.91 3. Review of Vitros 350 package insert PV2 Lot # C8891 showed: cholesterol range as 228.2 - 260.2 alkaline phosphatase as 308 - 552 phosphorus as 6.53 - 8.13 4. Review of Vitros 350 analyzer showed: PV1 cholesterol range as 141.6 - 170.4 PV2 cholesterol range as 239 - 277 PV1 alkaline phosphatase as 73.4 - 128.6 PV2 alkaline phosphatase as 334 - 586 PV1 phosphorus as 3.03 - 4.15 PV2 phosphorus as 6.39 - 8.79 4. Review of Ortho Vitros 350 cholesterol QC showed two acceptable levels of QC were not performed on February 5, 2022, February 10, 2022, February 16, 2022, February 18, 2022 and February 25, 2022. The laboratory reported 15 patient tests while QC was not acceptable. 5. Interview with the GS on March 1, 2022 at 2:00 PM confirmed the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the "Coagulation" procedure, ACL Elite analyzer quality control (QC) records, and interview with the general supervisor (GS), the laboratory failed to

include two levels of control material each 8 hours of operation for prothrombin time (PT) and D-Dimer for 3 of 60 patient testing days in January, February, and to date March 1, 2022. Findings: 1. Review of the PT and D-Dimer procedure states that "Quality control is usually run once daily but will be repeated if a sample comes in past the 8 hours for the daily run". 2. Review of ACL Elite PT QC showed QC was not performed every 8 hours on January 13, 2022. One patient's PT was reported at 2:47 PM and the last PT QC was performed at 6:23 AM. 3. Review of ACL Elite PT QC showed QC was not performed every 8 hours on January 28, 2022. One patient's PT was reported at 3:39 PM and the last PT QC was performed at 6:46 AM. 4. Review of ACL Elite D-Dimer QC showed QC was not performed every 8 hours on January 24, 2022. One patient's D-Dimer was reported at 9:49 AM and the last QC performed January 23, 2022 at 10:12 AM. 5. Review of ACL Elite D-Dimer QC showed QC was not performed every 8 hours on January 24, 2022. One patient's D-Dimer was reported at 10:30 PM and the last QC was performed 10:49 AM. 6. Interview with the GS on March 1, 2022 at 2:00 PM confirmed the laboratory failed to include two levels of control material each 8 hours of operation for PT and D-Dimer.

D5551

IMMUNOHEMATOLOGY
CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of general laboratory and blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the general supervisor (GS), the laboratory failed to document quality control for six patient testing days in 2021 and failed to provide a procedure for checking patient history in blood bank. Findings: 1. Review of the laboratory's policy "Quality Control" states "Blood Bank: Quality Control will be run at least once per day of use or as required per manufacturer's instructions after maintenance or instrument problems." 2. Review of 2021 blood bank patient testing logs showed patient testing was performed on April 5, 2021, April 16, 2021, April 19, 2021, April 29, 2021, June 1, 2021 and December 14, 2021.. 3. Review of 2021 blood bank QC show no documented QC for April 5, 2021, April 16, 2021, April 19, 2021, April 29, 2021, June 1, 2021 and December 14, 2021. 4. Review of blood bank procedures showed no procedure for checking patient history prior to performing blood bank procedures. 5. Interview with the GS on March 1, 2022 at 2:00 PM confirmed the laboratory failed to document quality control for six patient testing days in 2021 and failed to provide a blood bank procedure for checking patient history.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on lack of blood bank refrigerator alarm checks for 2020, 2021, and to date March 1, 2022 and interview with the general supervisor (GS), the laboratory failed to document quarterly refrigerator alarm inspections. Findings: 1. Lack of blood bank refrigerator alarm checks showed the laboratory did not have documentation for quarterly refrigerator alarm inspections during 2020, 2021, and to date March 1, 2022. 2. Interview with the GS on March 1, 2022 at 10:00 AM confirmed, the laboratory failed to document quarterly refrigerator alarm inspections.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, patient reports, and interview with the general supervisor (GS), the laboratory failed to ensure the procedure reference ranges matched the reference ranges on the patient reports. Findings: 1. Review of the Sysmex XN-350 procedure, "Performance Characteristics: Reference Interval" showed the reference ranges as: Neutrophil (Neut) %: Female 34.0 to 71.1 % Lymphocyte (Lymph) %: Female 19.3 to 51.7 % Monocyte (Mono) %: Female 4.7 to 12.5 % Eosinophil (Eo) %: Female 0.7 to 5.8 % Basophil (Baso) %: Female 0.1 to 1.2 % Male 0.2 to 1.2 % Absolute Neut: Female 1.56 to 6.13 x10³/uL Absolute Lymph: Female 1.18 to 3.74 x10³/uL Absolute Mono: Female 0.24 to 0.36 x10³/uL Absolute Eo: Female 0.04 to 0.36 x10³/uL Red blood cell count (RBC): Female 3.93 to 5.22 x10³/uL Male 4.63 to 6.08 x10³/uL Hemoglobin (Hgb): Male 13.7 to 17.5 g/dL Mean corpuscular volume (MCV): Female 79.4 to 94.8 fL Male 79.0 to 92.2 fL Mean corpuscular hemoglobin (MCH): Female 25.6 to 32.2 pg Male 25.7 to 32.2 pg Mean corpuscular hemoglobin concentration (MCHC): Female 32.2 to 35.5 g/dL Male 32.3 to 36.5 g/dL Red cell distribution width (RDW): Female 11.7 to 14.4 % Mean platelet volume (MPV): Female 9.4 to 12.3 fL 2. Review of "Table of Normal & Critical Values" procedure showed the reference ranges as: ALT (SGPT): 9 - 52 U/L adult/child Chloride: 98 - 110 mmol/L adult Creatinine: 0.0 - 1.2 mg/dL adult Glucose: 65 - 105 mg/dL adult Potassium: 3.6 - 5.0 mmol/L adult PT Normal: 10.9 - 13.9 seconds APTT Normal: 27.4 - 32.4 seconds White Blood Cell (WBC): 4,500 - 11,000/mm³ Hgb: Female 12 - 16 g/dL Hematocrit (Hct): Male 39 - 50 % Female 35 - 45 % Platelet (Plt): 150,000 - 400,000/mm³ RBC: Male 4.0 - 6.2 M/uL Female 4.0 - 6.2 M/uL 3. Review of patient reports showed the reference ranges as: WBC: Female 3.9 - 10.0 x10³/uL Male 4.2 - 9.0 x10³/uL Neut %: Female 34.0 - 67.9 % Lymph %: Female 21.8 - 53.0 % Mono %: Female 5.3 - 12.2% Eo %: Female 0.8 - 7.0 % Baso %: Female 0.0 - 1.2 % Male 0.0 to 1.2 % Absolute Neut: Female 1.78 - 5.38 x10³/uL Absolute Lymph: Female 1.32 - 3.57 x10³/uL Absolute Mono:

Female 0.30 - 0.82 x10³/uL Absolute Eo: Female 0.04 - 0.54 x10³/uL RBC: Female 3.3 - 5.2 x10⁶/uL Male 3.9 - 6.0 x10⁶/uL Hgb: Female 11.2 - 15.7 g/dL Male 14.0 - 18.0 g/dL Hct: Female 34.1 - 44.9 % Male 40.1 - 51.0 % MCV: Female 82.0 - 93.0 fL Male 82.0 - 93.0 fL MCH: Female 26.0 - 34.0 pg Male 26.0 - 34.0 pg MCHC: Female 31.0 - 38.0 g/dL Male 31.0 - 38.0 g/dL RDW: Female 11.6 to 14.4 % Plt: Female 182 - 369 mg/dL Male 163 - 337 mg/dL MPV: Female 9.40 to 12.40 fL ALT (SGPT): 0 - 50 U/L Chloride: 98 - 107 mmol/L Creatinine: 0.6 - 1.2 mg/dL Glucose: 74 - 106 mg/dL Potassium: 3.5 - 5.1 mmol/L PT Normal: 9.92 - 12.80 seconds APTT Normal: 21.62 - 35.78 seconds 4. Interview with the GS on March 1, 2022 at 3:00 PM confirmed that the procedure reference ranges did not match the patient report reference ranges.

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:
Based on review of Ortho Diagnostics Vitros 350, Vitros ECiQ, ACL Elite, blood bank, the laboratory's procedures, proficiency testing and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to review proficiency testing (Refer to D6091); the LD failed to follow procedure for proficiency testing corrective action (Refer to D6092); the LD failed to ensure that the quality control programs are established, and maintained to identify failures in quality as they occur (Refer to D6093); and the LD failed to ensure chemistry and coagulation analyzers were functioning properly (Refer to D6097).

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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.

This STANDARD is not met as evidenced by:
Based on review of "Laboratory Personnel Requirements and Responsibilities" procedure, 2020, 2021, and to date March 1, 2022 proficiency testing (PT) reports and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure all PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of "Laboratory Personnel Requirements and Responsibilities" procedure states "Laboratory director, ensure that PT reports are reviewed by the appropriate staff to evaluate the performance of the laboratory and to identify any problem that requires corrective action. Ensure that an approved corrective action plan is followed when any PT results are found unacceptable or unsatisfactory". 2. Review of 2020 PT results showed no review for events 1, 2 and 3. The laboratory could not provide any corrective action for event 1 for the following analytes: sodium: score of 80% cell I.D. or WBC Diff: score of 60% hematocrit: score of 80% compatibility: score of 80% 3. Review of 2020 PT results showed no corrective action for event 2 for the following

analytes: free thyroxine: score of 60% cell I.D. or WBC Diff: score of 80% 4. Review of 2021 PT results showed no corrective action for event 1 for the following analytes: free thyroxine: score of 80% partial thromboplastin time: score of 60% prothrombin time: score of 60% 5. Review of 2021 PT results showed no corrective action for event 2 for the following analytes: total creatine kinase: score of 20% potassium: score of 0% 6. Interview with the GS on March 1, 2022 confirmed the LD failed to ensure all PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of "Laboratory Personnel Requirements and Responsibilities" procedure, 2020, 2021, and to date March 1, 2022 proficiency testing (PT) reports and interview with the general supervisor (GS), the laboratory director (LD) failed to follow procedure and ensure an approved corrective action plan for any PT results found to be unacceptable. Findings: 1. Review of "Laboratory Personnel Requirements and Responsibilities" procedure states "Laboratory director, ensure that an approved corrective action plan is followed when any PT results are found unacceptable or unsatisfactory". 2. Review of 2020 PT results showed no corrective action for event 1 for the following analytes: sodium: score of 80% cell I.D. or WBC Diff: score of 60% hematocrit: score of 80% compatibility: score of 80% 3. Review of 2020 PT results showed no corrective action for event 2 for the following analytes: free thyroxine: score of 60% cell I.D. or WBC Diff: score of 80% 4. Review of 2021 PT results showed no corrective action for event 1 for the following analytes: free thyroxine: score of 80% partial thromboplastin time: score of 60% prothrombin time: score of 60% 5. Review of 2021 PT results showed no corrective action for event 2 for the following analytes: total creatine kinase: score of 20% potassium: score of 0% 6. Interview with the GS on March 1, 2022 at 11:45 AM confirmed the LD failed to follow procedure to ensure an approved corrective action for any PT results found to be unacceptable.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of blood bank quality control (QC) and interview with the general supervisor (GS), the laboratory director (LD) (whom is also the blood bank technical supervisor) failed to ensure blood bank quality control programs were maintained. Findings: 1. Review of 2021 blood bank QC show no documented QC for April 5, 2021, April 16, 2021, April 19, 2021, April 29, 2021, June 1, 2021 and December 14, 2021 prior to patient testing and patients receiving blood. The laboratory performed blood bank testing on 6 patients while QC was not performed. 2. Review of blood

bank QC for 2020, 2021 and to date March 1, 2022 showed no LD oversight of blood bank QC. 3. Interview with the GS on March 1, 2022 at 10:00 AM confirmed the LD failed to ensure blood bank quality control programs were maintained.

D6097

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(7)

The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Review of Ortho Diagnostics Vitros 350 chemistry analyzer quality control (QC) records, the ACL Elite coagulation analyzer QC records, Vitros ECiQ chemistry analyzer QC records, patient results, and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure the chemistry and coagulation analyzers were functioning properly before patient test results were reported. Findings: 1. Review of the Vitros 350 chemistry analyzer QC records showed on February 5, February 10, February 16, February 18, and February 25, 2022 level 2 control for cholesterol was not within acceptable limits. The laboratory reported 15 cholesterol patient results while QC was not acceptable. 2. Review of the ACL Elite coagulation analyzer QC records showed the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and D-Dimer for 3 patient testing days in January, February, and to date March 1, 2022. The laboratory reported 2 PT and 2 D-Dimer patient results while QC was not performed. 3. Review of Vitros ECiQ chemistry analyzer QC records showed on January 1, 2022 level 3 control for creatine kinase-MB (CKMB) was not within acceptable limits. The laboratory reported one CKMB patient result while QC was not acceptable. 4. Interview with the GS on March 1, 2022 at 2:00 PM confirmed the LD failed to ensure the chemistry analyzer and the coagulation analyzer were functioning properly before patient test results were reported.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of personnel records, 2019/2020/2021 and to date March 1, 2022 personnel performance evaluations and interviews, the technical supervisor (TS) failed to fulfill the technical supervisor responsibilities. The technical supervisor failed to ensure one of two TS's were qualified (Refer to D6111); failed to identify the training needs for one of six laboratory testing personnel (Refer to D6120); failed to evaluate and document semiannual competency for four of six laboratory testing personnel (Refer to D6127); and failed evaluate and document competency for one of six laboratory testing personnel (TP) and four of four blood gas TP (Refer to D6128).

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of

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

subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at

least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following

requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii) (B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (l)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such

certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice

medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
 Based on review of personnel documentation and interview with the general supervisor (GS), the laboratory failed to have the required documentation to qualify one of two technical supervisor's. Findings: 1. The laboratory failed to have academic credentials and laboratory training and/or experience for technical supervisor #11. 2. Interview with the GS on March 1, 2022 at 2:00 PM confirmed, the laboratory failed to have the required documentation to qualify technical supervisor #11.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(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.

This STANDARD is not met as evidenced by:
 Based on review of procedures, 2020, 2021, and to date March 1, 2022 training documents and interview with the general supervisor (GS), the technical supervisor (TS) failed to identify the training needs for one of six laboratory testing personnel. Findings: 1. Review of "Laboratory Personnel Requirements and Responsibilities" procedure states "Technical Supervisor identifies training needs and ensures that testing personnel receive regular in-service training and education appropriate for the type and complexity of the laboratory services performed". 2. Review of 2020 training documents showed no documentation of training for testing personnel #2. 3. Interview with the GS on March 1, 2022 at 11:30 AM confirmed the TS failed to identify the training needs for testing personnel #2.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of procedures, semiannual competencies and interview with the general supervisor (GS), the technical supervisor (TS) failed evaluate and document semiannual competency for four of six laboratory testing personnel (TP). Findings: 1. Review of "Laboratory Personnel Requirements and Responsibilities" procedure states "Technical supervisor evaluates and documents the performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter". 2. Review of 2021 semiannual competencies showed no documentation of semiannual competency for TP #1, TP #2 and TP #4. 3. Review of 2022 semiannual competencies showed no documentation of semiannual competency for TP #5. 3. Interview with the GS on March 1, 2022 at 11:30 AM confirmed the TS failed to evaluate and document semiannual competency for TP #1, TP #2, TP #4 and TP #5.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of procedures, annual competencies and interview with the general supervisor (GS), the technical supervisor (TS) failed to evaluate and document competency for one of six laboratory testing personnel (TP) and four of four blood gas TP. Findings: 1. Review of "Laboratory Personnel Requirements and Responsibilities" procedure states "Technical supervisor evaluates and documents the performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter". 2. Review of 2019, 2020 annual competencies showed no documentation of annual competency for one TP no longer employed at the laboratory. 3. Review of blood gas annual competencies showed no documentation of blood gas annual competency in 2020 and 2021 for TP #7, #8, #9 and #10. 3. Interview with the GS on March 1, 2022 at 11:30 AM confirmed the TS failed to evaluate and document annual competency.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of personnel records and interview with the general supervisor (GS),

one of four testing personnel did not meet the academic qualifications required to perform high complexity testing. (Refer to # 6171)

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have

earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of academic credentials and interview with the general supervisor (GS), the laboratory failed to provide academic credentials to qualify one of four testing personnel. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing personnel #11 was qualified to perform high complexity testing. 2. Interview with the GS on March 1, 2022 at 1:00 PM confirmed the documents needed to qualify the testing person #11 were not available for review.