Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1061170	06/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Iron County Medical Center	301 N Hwy 21, Pilot Knob, 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	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of "Laboratory Manager Duties" procedure, "Routine Analysis, Clinical Microscopic" procedure, centrifuge maintenance, Nova Stat Profile Prime Plus procedure, temperature logs, humidity logs, 2019/2020 and to date June 1, 2021 calibration verification for the Beckman Coulter AU480 chemistry analyzer, Ortho workstation manufacturer's instructions, immunohematology records, blood bank procedure manual, "ICMC Laboratory QA Manual" procedure, blood bank quality control (QC), "Quality Assurance Program" procedure, observation of Beckman Coulter DxH 900 hematology analyzer, Nova Stat Prime Plus blood gas analyzer, lack of instrument comparisons and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow written procedures (Refer to D5401); failed to document room temperature and humidity in the blood gas laboratory (Refer to D5413); 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 (Refer to D5439); failed to follow manufacturer's instructions for incubator temperature verification (Refer to D5551); failed to correctly perform refrigerator alarm inspections according to the laboratory's established policy (Refer to D5555);

	failed to have a system that twice a year evaluates and defines the relationship between test results using the different instruments (Refer to D5775); and failed to follow quality assurance (QA) policy for blood bank (Refer to D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on review of procedures, centrifuge maintenance, and interview with technical supervisor (TS) #2, the laboratory failed to follow written procedures for "Laboratory Manager Duties" and "Routine Analysis, Clinical Microscopy". Findings: 1. Review of procedure "Laboratory Manager Duties" stated "Review daily quality control results to determine appropriate frequency and to look for shifts in QC data". Interview with the TS #2 stated they did not monitor shifts in QC data for the Beckman Coulter AU480 and Beckman Coulter Access 2. 2. Review of the procedure "Routine Analysis, Clinical Microscopy" stated "Centrifuge the urine specimen in the urine centrifuge tube at 1600 RPM's for 5 minutes". Review of centrifuge maintenance showed the centrifuge was checked at 2500 RPM's. Interview with the TS #2 stated they spun urine specimens at 2500 RPM's for 5 minutes. 3. Interview with TS #2 on June 1, 2021 at 1:30 PM confirmed the laboratory failed to follow written procedures for "Laboratory Manager Duties" and "Routine Analysis, Clinical Microscopic".
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Nova Stat Profile Prime Plus procedure, temperature logs, humidity logs, and interview with the technical supervisor (TS) #2, the laboratory failed to document room temperature and humidity in the blood gas laboratory. Findings: 1. Review of Nova Stat Profile Prime Plus blood gas analyzer procedure stated "ambient operating temperature 15 degrees Celsius to 32 degrees Celsius" and "operate at humidity 20% to 85% without condensation". 2. Review of temperature logs showed no documentation of room temperature in the blood gas laboratory. 3. Review of humidity logs showed no documentation of humidity in the blood gas laboratory. 4. Interview with TS #2 on June 1, 2021 at 2:00 PM confirmed the laboratory failed to document room temperature and humidity in the blood gas laboratory.

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 2019/2020 and to date June 1, 2021 calibration verification for the Beckman Coulter AU480 chemistry analyzer and interview with the technical supervisor (TS) #2, 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 calibration records for 2019, 2020 and to date June 1, 2021 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 analytes: hemoglobin A1C, albumin, alcohol, alkaline phosphatase, alanine aminotransferase, amylase, asparate aminotransferase, blood urea nitrogen, calcium, cholesterol, creatinine kinase, chloride, bicarbonate, creatinine, c-reactive protein, direct bilirubin, high density lipoprotein, potassium, lactic acid, lipase, magnesium, sodium, phosphorous, rheumatoid factor, total bilirubin, total protein, triglyceride, uric acid, glucose, acetaminophen, salicylate, valproic acid, vancomycin, digoxin, and phenytoin. 2. Interview with TS #2 on June 1, 2021 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 on the Beckman Coulter AU480 chemistry analyzer.
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 Ortho workstation manufacturer's instructions, immunohematology records, and interview with the technical supervisor (TS) #2, the laboratory failed to follow manufacturer's instructions for incubator temperature verification during 2019, 2020, and to date June 1, 2021. Findings: 1. The manufacturer's instructions for incubator temperature verification states,"Fluid temperature measurements should be made with an unused card and a calibrated thin wire digital meter. Temperature must read 37 degrees C. +/- 2 degrees C." 2. Review of immunohematology records showed the laboratory failed to verify the temperature of the incubator used for antibody detection and extended crossmatch procedures. 3. Interview with TS #2 on June 1, 2021 at 10:00 AM confirmed the laboratory failed to verify the temperature of the incubator as stated in the manufacturer's instructions.
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 review of the blood bank procedure manual and interview with technical supervisor (TS) #2, the laboratory failed to correctly perform refrigerator alarm checks according to the laboratory's established policy for 2019/2020 and to date June 1, 2021. Findings: 1. Review of blood bank procedure, "Maintenance and Quality Control- Alarm Check" states,"Slowly add crushed ice at the proper rate to provide a temperature drop of no more than 0.5 C per minute." and "Slowly add warm water to the ice slurry (refrigerator) or a container of pre-cooled (-30 C) antifreeze solution (freezer) at the proper rate to provide a temperature rise of no more than 0.5 C per minute." 2. Interview with TS #2 on June 1, 2021 at 10:30 AM, TS stated that, "she lowers the temperature on the monitor screen until the alarm sounds and does not use ice." 3. Interview with the TS #2 on June 1, 2021 at 10:30 AM confirmed, the laboratory failed to correctly perform refrigerator alarm inspections according to the laboratory's established policy.
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. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of "Quality Assurance Program" procedure, observation of Beckman Coulter DxH 900 hematology analyzer, Nova Stat Prime Plus blood gas analyzer, lack of instrument comparisons, and interview with the technical supervisor (TS) #2, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2020 and to date June 1, 2021. Findings: 1. Review of "Quality Assurance Program" procedure states "comparison studies are performed every 6 months between instruments or methodologies if required." 2. Observation of the laboratory revealed a Beckman Coulter DxH hematology analyzer and observation of the blood gas laboratory revealed a Nova Stat Prime Plus blood gas analyzer. Both analyzers perform hemoglobin (hgb) testing. The laboratory and the blood gas laboratory both report hemoglobin results. 3. Lack of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the Beckman Coulter DxH 900 hematology analyzer and Nova Stat Prime Plus blood gas analyzer twice a year in 2020 and to date June 1, 2021. 4. Interview with the TS #2 on June 1, 2021 at 2:00 PM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between the Beckman Coulter DxH 900 hematology analyzer and Nova Stat Prime Plus blood gas analyzer in 2020 and to date June 1, 2021.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of "ICMC Laboratory QA Manual", blood bank quality control (QC), and interview with the technical supervisor (TS) #2 the laboratory failed to follow the quality assurance (QA) policy for blood bank. Findings: 1. Review of "ICMC Laboratory QA Manual" stated "Blood Bank: QC must be run every 24 hours". 2. Review of blood bank QC showed blood bank QC is performed only on days of patient testing. Interview with TS #2 stated blood bank QC is performed only on days of patient testing. 3. Interview with the TS #2 on June 1, 2021 at 2:00 PM confirmed the laboratory failed to follow QA policy for blood bank.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on review of Nova Stat Profile Prime Plus blood gas patient test report and interview with technical supervisor (TS) #2, the laboratory failed ensure the patient test report included address of the laboratory. Findings: 1. Review of the Nova Stat Profile Prime Plus blood gas patient test report showed the test report did not include the address of the laboratory location where the test was performed. 2. Interview with TS #2 on June 1, 2021 at 1:00 PM confirmed the laboratory failed to ensure the blood gas patient test report included the address of the laboratory.
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 verification procedures, 2019/2020/2021 proficiency testing (PT) records, "Quality Assurance Program" procedure, blood gas quality control (QC) log, blood bank QC records, Beckman Coulter DxH 900 hematology analyzer, 2019 blood gas procedure, patient reports, personnel records, lack of initial training documentation, lack of procedures and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that verification procedures for the Nova Stat Profile Prime Plus, Beckman Coulter DxH 900 and Beckman Coulter AU480 are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (Refer to D6086); failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6091); failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory (Refer to D6092); failed to ensure the QC programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (Refer to D6093); failed to ensure that patient blood gas results were reported only when the system is functioning properly (Refer to D6097); failed to ensure eight of twelve testing personnel (TP) received appropriate training prior to testing patient specimens in the laboratory and in the blood gas laboratory (Refer to D6102); and failed to ensure that an approved procedure manual is available to all personnel for blood gas testing and blood bank Ortho workstation testing (Refer to D6106).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by:

	Based on review of verification procedures and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure that verification procedures for the Nova Stat Profile Prime Plus, Beckman Coulter DxH 900, and Beckman Coulter AU480 are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Findings: 1. Review of the Nova Stat Profile Prime Plus blood gas analyzer verification procedures showed no accuracy, precision, reportable range of test results, and verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes: pCO2, pO2, pH, SO2, total hemoglobin (tHB), carboxy-hemoglobin (COHB), meth-hemoglobin (MetHb) and deoxyhemoglobin (HHb) in May 2020 when patient testing started. 2. Review of the Beckman Coulter DxH 900 verification procedures showed no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes: white blood cell count (WBC), red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin (MCHC) and platelet (PLT) in June 2019 when patient testing started. 3. Review of the Beckman Coulter AU480 chemistry analyzer verification procedures showed no reportable range for the analytes: hemoglobin A1C, albumin, alcohol, alkaline phosphatase, alanine aminotransferase, amylase, asparate aminotransferase, blood urea nitrogen, calcium, cholesterol, creatinine kinase, chloride, bicarbonate, creatinine, c-reactive protein, direct bilirubin, high density lipoprotein, potassium, lactic acid, lipase, magnesium, sodium, phosphorous, rheumatoid factor, total bilirubin, total protein, triglyceride, uric acid, glucose, acetaminophen, salicylate, valproic acid, vancomycin, digoxin and phenytoin in June 2019 when patient testing started. 4. Interview with the TS #2 on June 1, 2021 at 2:00 PM confirmed the LD failed to ensure that verification procedures for the Nova Stat Profile Prime Plus, Beckman Coulter DxH 900, and Beckman Coulter AU480 are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.
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 the 2019/2020/2021 proficiency testing (PT) records and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of 2019 PT records showed the laboratory director failed to document review of the evaluation report obtained for chemistry core - second event, chemistry core - third event, immunology/immunohematology - first event, and chemistry miscellaneous - first event. 2. Review of 2020 PT records showed the laboratory director failed to document review of the evaluation report obtained for chemistry core - third event. 3. Review of the hematology/coagulation PT records for the first, second, and third PT testing events of 2020 showed the laboratory obtained "not graded" results for blood cell identification. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 4. Review of the chemistry

	core PT records for the second event in 2020 showed the laboratory obtained "not graded" results for blood oximetry. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 5. Review of the hematology/coagulation PT records for the first event in 2021 showed the laboratory obtained "not graded" results for blood cell identification. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 6. Interview with TS #2 on June 1, 2021 at 1:00 PM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to 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 the 2020/2021 proficiency testing (PT) records and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings: 1. Review of 2020 chemistry core- second event PT record showed the laboratory obtained an unacceptable result for specimens: BG-09 analytes partial pressure of carbon dioxide (pCO2), and pH 2. Review of 2021 chemistry core-first event PT record showed the laboratory obtained an unacceptable result for specimens: BG-01 analyte pCO2 BLX-01 analyte oxyhemoglobin BLX-02 analyte oxyhemoglobin BLX-03 analyte oxyhemoglobin BLX-04 analyte oxyhemoglobin BLX-05 analyte oxyhemoglobin 3. No corrective action documentation was available to show the laboratory investigated the unacceptable PT results. 4. Interview with the TS #2 on June 1, 2021 at 1:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
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 the "Quality Assurance Program" procedure, blood gas quality control (QC) log, blood bank QC records, Beckman Coulter DxH 900 hematology analyzer, and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure the quality control (QC) programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur in 2019/2020 and to date June 1, 2021. Findings: 1. Review of the laboratory's "Quality Assurance Program" procedure stated that "the total quality assurance program will be monitored by the laboratory manager and medical director" and quality measures for quality control include "daily review of QC, correct intervals

	of QC performed and monthly evaluation of QC ranges." 2. Review of 2020 and to date June 1, 2021 blood gas QC log showed no review by the laboratory director to assure the quality of the testing and to identify failures in quality. 3. Review of the 2019/2020 and to date June 1, 2021 blood bank QC log showed no review by the laboratory director to assure the quality of the testing and to identify failures in quality. 4. Review of the 2019/2020 and to date June 1, 2021 Beckman Coulter DxH 900 hematology analyzer QC log showed no review by the laboratory director to assure the quality of the testing and to identify failures in quality. 5. Interview with the TS #2 on June 1, 2021 at 1:00 PM confirmed, the laboratory director failed to ensure the QC programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.
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: Based on review of 2019 blood gas procedure, quality control (QC), patient reports and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure that patient blood gas results were reported only when the system is functioning properly. Findings: 1. Review of i-Stat blood gas procedure states "QC performed every 30 days". 2. Review 2019 i-Stat QC showed in February QC was performed at 36 days. Five i-Stat blood gas patients were performed from February 18, 2019 to February 24, 2019. 3. Review of 2019 i-Stat QC showed in May QC was performed at 38 days. Four i-Stat blood gas patients were performed from May 6, 2019 to May 14, 2019. 4. Interview with TS #2 on June 1, 2021 at 2:00 PM confirmed the LD failed to ensure that patient i-Stat blood gas results were reported only when the system is functioning properly.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of initial training documentation, and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure eight of twelve testing personnel (TP) received appropriate training prior to testing patient specimens in the laboratory and in the blood gas laboratory. Findings: 1. Review of personnel records showed the laboratory could not provide documentation for initial training prior to testing patient specimens for TP #2, #3, and #5 in the laboratory and TP #8, #9, #10, #11 and #12 in the blood gas laboratory. 2. Interview with the TS #2 on June 1, 2021 at 1:00 PM confirmed the laboratory director failed to ensure all testing personnel received appropriate training prior to testing patient specimens in the laboratory and in the blood gas laboratory.

D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of procedures and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure that an approved procedure manual is available to all personnel for blood gases and blood bank Ortho workstation. Findings: 1. Review of procedures showed no approved procedure for the Nova Stat Profile Prime Plus blood gas analyzer. 2. Review of procedures showed no approved procedure for the blood bank Ortho workstation. 3. Interview with the TS #2 on June 1, 2021 at 2:00 PM confirmed the LD failed to ensure that an approved procedure manual for the Nova Stat Profile Plus analyzer and the Ortho workstation was available to all personnel.
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 personnel performance evaluations and interviews, the technical supervisor (TS) failed to fulfill the technical supervisor responsibilities. The technical supervisor failed to evaluate and document the performance of six of twelve TP at least semiannually during the first year the individual tests patient specimens (Refer to D6127); failed to document annual competency evaluations for 2019, 2020, and to date June 2, 2021 (Refer to D6128).
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 personnel records and interview with the technical supervisor (TS) #2, the TS failed to evaluate and document the performance of six of twelve testing personnel (TP) at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of 2019/2020/2021 performance evaluations showed the TS failed to perform semi-annual competency evaluations for TP #5 in the laboratory and TP #8, #9, #10, #11 and #12 in the blood gas laboratory. 2. Interview with TS #2 on June 1, 2021 at 1:00 PM confirmed, the TS failed to evaluate and document the performance of six of twelve TP at least semiannually during the first year the individual tests patient specimens.

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 2019/2020/2021 personnel competency assessments and interview with the technical supervisor (TS) #2, the technical supervisor failed to document annual competency assessments for 2019, 2020 and to date June 2, 2021. Findings: 1. Review of 2019 personnel competency evaluations showed the TS failed to document annual competency assessments for testing personnel (TP) #1, #6 and #7 in the laboratory. 2. Review of 2020 personnel competency assessments showed the TS failed to document annual competency assessments for TP #1 and #7 in the laboratory. 3. Review of 2021 personnel competency assessments showed the TS failed to document annual competency assessments for TP #2, #3, and #4 in the laboratory and TP #8, #9, #10, #11, and #12 in the blood gas laboratory. 4. Interview with the TS #2 on June 1, 2021 at 1:00 PM confirmed the technical supervisor failed to document annual competency assessments.