

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D0662186	<b>(X3) Date Survey Completed</b>  07/21/2021
<b>Name of Provider or Supplier</b>  Hot Springs County Memorial Hospital Laboratory	<b>Street Address, City, State</b>  150 E Arapahoe St, Thermopolis, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 19 of 19 proficiency testing events reviewed from January 2020 to July 2021. The findings were: 1. Review of the API proficiency testing records failed to include the attestation statements signed by the laboratory director for the following events: a. 2020 Core Chemistry event #1, #2, and #3. b. 2020 Hematology and Coagulation event #1, #2, and #3. c. 2020 Microbiology event #1, #2, and #3. d. 2020 Immunology event #1, #2, and #3. e. 2021 Miscellaneous Chemistry event #1. f. 2021 Microbiology event #1, and #2. g. 2021 Immunology event #1. h. 2021 Hematology and Coagulation event #1. i. 2021 Core Chemistry event #1, and #2. 2. Interview with the technical consultant on 7/21/21 at 5:15 PM revealed the laboratory director had not delegated his responsibility for signing the attestation statement, however a policy was currently being developed.</p>
<b>D5002</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p>

	<p>This CONDITION is not met as evidenced by: Based on review of new instrument verification studies, review of quality control (QC) records, lack of documentation, review of patient testing logs, and staff interview, the laboratory failed to ensure the BioFire respiratory panel 2.1 was verified for accuracy prior to testing patient samples (D5421); and failed to ensure QC was performed each day of patient testing for the BioFire respiratory panel 2.1 (D5449).</p>
<p><b>D5010</b></p>	<p><b>VIROLOGY</b> CFR(s): 493.1205</p> <p>If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of new instrument verification studies, review of quality control (QC) records, lack of documentation, review of patient testing logs, and staff interview, the laboratory failed to ensure the BioFire respiratory panel 2.1 was verified for accuracy prior to testing patient samples (D5421); and failed to ensure QC was performed each day of patient testing for the BioFire respiratory panel 2.1 (D5449).</p>
<p><b>D5016</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on observation, review of manufacturer's instructions, lack of documentation, review of the i-STAT Blood Gas Log, review of quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), review of patient testing logs, and staff interview, the laboratory failed to ensure reagents were not used beyond their expiration date (D5417); failed to ensure manufacturer's instructions were followed to perform function checks every 8 hours on the Abbott i-STAT instrument for blood gas analysis (D5431); failed to ensure calibration verification was performed on the Abbott i-STAT instrument every 6 months (D5439); and failed to ensure QC was performed as outlined in the IQCP for blood gas analysis (D5445).</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT)</p>

records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 12 of 19 testing events reviewed from January 2020 to July 2021. The findings were: 1. Review of the API proficiency testing reports failed to include documentation the laboratory had evaluated testing results. The following concerns were identified: a. Review of the 2020 Core Chemistry event #1 and #2 showed no documentation the laboratory director (LD) had reviewed the results. b. Review of the 2020 Hematology and Coagulation event #1 showed no documentation the LD had reviewed the results. c. Review of the 2020 Microbiology event #1, #2, and #3 showed no documentation the LD had reviewed the results. d. Review of the 2020 Immunology event #1, #2, and #3 showed no documentation the LD had reviewed the results. e. Review of the 2021 Miscellaneous Chemistry event #1 showed no documentation the LD had reviewed the results. f. Review of the 2021 Microbiology event #1 showed no documentation the LD had reviewed the results. g. Review of the 2021 Immunology event #1 showed no documentation the LD had reviewed the results. h. Review of the 2021 Core Chemistry event #1 and #2 showed no documentation the LD had reviewed the results. 2. Interview with the technical consultant on 7/21/21 at 5:15 PM revealed the laboratory director had not delegated his responsibility for reviewing PT results; however a policy was currently being developed.

**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 lack of documentation and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence a policy and procedure had been developed in regard to reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 2. Interview with the laboratory manager on 7/21/21 at 5:15 PM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 test results.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation, review of the manufacturer's instructions, and staff interview, the laboratory failed to ensure the Abbott i-STAT CG4+ cartridges for performing blood gases (arterial and cord blood) pH, partial pressure of carbon dioxide, partial pressure of oxygen, and lactic acid tests were not used past their expiration date as the laboratory failed to record the date the cartridges were removed from refrigerated storage. In addition the laboratory failed to ensure blood collection tubes were not

used beyond their expiration date in 3 of 3 blood collections sites (blood collection room #1, blood collection room #2, and the mobile blood collection tray).The laboratory performed approximately 52 blood gases per year and approximately 487 immunohematology procedures per year. The findings were: Related to the Abbott i-STAT CG4+ cartridges; 1. Observation on 7/21/21 at 2:30 PM showed 6 CG4+ test cartridges (lot number D21080 with an expiration date of 11/18/21) were stored at room temperature next to the Abbott i-STAT analyzer. The test cartridges failed to include a revised expiration date for room temperature storage. 2. Review of the Abbott i-STAT manufacturer's instructions showed the expiration date for the CG4+ reagent cartridges changed from the printed expiration date to 14 days at room temperature. 3. Interview with the respiratory therapy director and the laboratory manager on 7/21/21 at 2:45 PM confirmed there was not a revised expiration date on the cartridges. THIS IS A REPEAT DEFICIENCY, previously cited on 8/27/19. Related to blood collection tubes: 1. Observation of blood collection room #1, blood collection room #2, and the mobile blood collection tray on 7/21/21 at 9:30 AM showed the following concerns: a. Blood collection room #1 showed 15 K2EDTA (used for immunohematology) blood collection tubes with an expiration date of 7/14/21 were available for use. b. Blood collection room #2 showed 19 heparinized blood collection tubes with an expiration date of 7/1/21, 2 serum separator tubes with an expiration date of 7/11/21, and 5 K2EDTA tubes with an expiration date of 7/14/21 were available for use. c. The mobile blood collection tray showed 5 K2EDTA blood collection tubes with an expiration date of 7/14/21 were available for use. 2. Interview with phlebotomist #1 on 7/21/21 at 9:50 AM confirmed the blood collection tubes had expired and discarded them at that time.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of the BioFire new instrumentation verification study and staff interview, the laboratory failed to verify accuracy for 21 of 22 tests included in the BioFire 2.1 respiratory panel (4 bacteria and 17 viruses). The findings were: 1. Review of the BioFire new instrumentation study, initiated on 11/30/20, showed precision studies for all the analytes and an accuracy study for SARS-CoV-2 had been completed, however an accuracy study had not been completed for the 4 bacteria and 17 remaining viruses. 2. Interview with the laboratory director on 7/21/21 at 11:15 AM revealed it was his understanding since the test method had been given an Emergency Use Authorization by the FDA, the verification study was not required.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with

at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on lack of documentation, review of the laboratory's "i-STAT Blood Gas Log", review of the Abbott i-STAT operator's manual, and staff interview, the facility failed to follow the i-STAT manufacturer's instructions to perform a function check every 8 hours, as required, for blood gases for 7 of 7 months reviewed (1/1/21 through 7/19/21). The laboratory tested approximately 52 blood gas samples per year. The findings were: 1. Review of the i-STAT Blood Gas Log showed no documentation the laboratory had verified the performance of the i-STAT instrument by using the internal or external Electronic Simulator every 8 hours. 2. Interview with the respiratory therapy director and the laboratory manager on 7/21/21 at 2:50 PM confirmed the laboratory did not perform the function checks as required. 3. Review of the Abbott i-STAT operator's manual showed "Verify the performance of each handheld in the i-Stat System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit..."

**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 lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for pH, partial pressure of oxygen (PO<sub>2</sub>), partial pressure of carbon dioxide (PCO<sub>2</sub>), and lactate analyzed on the Abbott i-STAT instrument for 2 of 2 years reviewed (2019, 2020). The laboratory performed approximately 52 blood gases per year. The findings were: 1. Review of the laboratory's records showed no documentation the laboratory had verified the reportable range every 6 months for pH, PO<sub>2</sub>, PCO<sub>2</sub>, and lactate on

the Abbott i-STAT instrument. 2. Interview with the technical consultant on 7/21/21 at 5:15 PM confirmed the reportable range had not been verified as required.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(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--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of patient testing logs, review of quality control (QC) records, lack of documentation, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to perform two levels of control once a week for blood gas testing on the Abbott i-STAT instrument for 1 of 25 weeks reviewed. The failure affected 2 patient samples (#30041924 and #113715). The findings were: 1. Review of the QC records showed 2 levels of control were performed on 6/28/21 and again on 7/12/21. An arterial blood gas (ABG) was run on patient #30041924 on 7/6/21 (8 days after the last QC) and an ABG was run on patient #1137519 on 7/10/21 (12 days after the last QC). 2. Review of the laboratory's IQCP, last revised 9/15/18, showed "...external QC with each new lot number and weekly." 3. Interview with the technical consultant on 7/21/21 at 5:15 PM confirmed the QC had not been performed as required.

**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 quality control (QC) record review, review of the patient testing log, lack of documentation, and staff interview, the laboratory failed to perform two levels of QC each day of testing from 4/15/21 to 6/30/21 for the bioMerieux Biofire respiratory panel 2.1 which included 18 viruses (including SARs-CoV-2), and 4 bacteria. This failure affected 20 patient samples. The findings were: 1. Review of the QC records showed the laboratory performed a positive and a negative control for the Biofire respiratory panel 2.1 on 3/26/21, 4/28/21, 5/3/21, and 6/25/21. Review of the patient testing log showed patient samples were run on 4/15, 2 on 4/27, 4/29, 5/4, 5/6, 5/12, 5/13, 6/2, 2 on 6/3, 6/4, 6/8, 6/15, 6/16, 6/19, 6/22, 2 on 6/24, and 6/30. There was no documentation a positive and negative control had been run on each day of patient testing. 2. Interview with the laboratory manager on 7/21/21 at 5:15 PM revealed it was his understanding since the test method had been given an Emergency Use

	<p>Authorization by the FDA a risk assessment for an Individualized Quality Control Plan was not necessary and the laboratory was only required to perform quality control once per lot number or shipment. The laboratory manager confirmed the laboratory had failed to perform positive and negative control materials each day of respiratory panel testing.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure testing personnel were qualified to perform moderate complexity testing on the Abbott i-STAT analyzer (D6065) for 2 consecutive survey cycles (2019, 2021).</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, staff interview, and lack of documentation, the laboratory failed to ensure testing personnel had the appropriate education required prior to testing patient specimens for 2 of 3 testing personnel (#1, #2) that performed arterial and cord blood gas testing. The findings were; 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory employed 3 testing personnel that performed arterial and cord blood gas testing. Review of the laboratory's personnel files showed no evidence of the required qualifications for testing personnel (TP) #1 and TP #2. 2. Interview with the laboratory manager on 7/21/21 at 5:15 PM revealed the testing personnel were respiratory therapists which performed testing on the Abbott i-STAT analyzer. In addition the laboratory manager stated the hospital's human resource department did not require transcripts or a diploma upon hire. THIS IS A REPEAT DEFICIENCY, previously cited on 8/27/21.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p>

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 the BioFire respiratory panel 2.1 verification documentation, lack of documentation, review of proficiency testing records, and staff interview, the laboratory director failed to ensure the test verification study was complete for the BioFire respiratory panel 2.1 (D5421); failed to sign the API proficiency testing attestation statements (D6089); and failed to review and evaluate proficiency testing results (D6091).

**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 the BioFire respiratory panel 2.1 test verification documentation, lack of documentation, and staff interview, the laboratory director failed to ensure the test verifications of accuracy, precision, analytic specificity, and analytic sensitivity was complete and met the laboratory's performance characteristics specified by the manufacturer. Refer to D5421.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of American Proficiency Institute (API) proficiency tests into the patient workload for 19 of 19 proficiency testing events reviewed from January 2020 to July 2021. Refer to D2009.

**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 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director failed to

	<p>review and evaluate PT testing results for 12 of 19 testing events reviewed from January 2020 to July 2021. Refer to D5211.</p>
<p><b>D6108</b></p>	<p><b>LABORATORY TECHNICAL SUPERVISOR</b> CFR(s): 493.1447</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel files, lack of documentation, and staff interview, the technical supervisor failed to ensure annual competency assessments had been completed for testing personnel (D6120) performing moderately complexity testing for two consecutive survey cycles (2019, 2021).</p>
<p><b>D6120</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel files, lack of documentation, and staff interview, the technical supervisor failed to complete a competency assessment for one testing personnel (respiratory therapy director) performing arterial blood gas and cord blood venous pH (moderate complexity ) for 2 years of testing (2019, 2020). The findings were: 1. Review of the personnel file for the respiratory therapy director showed no documentation an annual competency assessment had been completed in 2019 or 2020. 2. Interview with the laboratory manager on 7/21/21 at 5:20 PM revealed the laboratory did not complete competency assessments on the respiratory therapists performing arterial blood gases and cord blood venous pH. THIS IS A REPEAT DEFICIENCY, previously cited on 8/27/19.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure 1 of 3</p>

testing personnel was qualified to perform high complexity testing in the specialties of immunohematology and hematology for two consecutive survey cycles (2019, 2021). Refer to D6171.

**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 the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure 1 of 3 testing personnel (TP #3) was qualified to perform high complexity testing in the areas of immunohematology and hematology. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed TP #3 performed high complexity testing. 2. Review of the personnel files showed no evidence of the documentation required to show TP #3 was qualified to perform high complexity testing. 3. Interview with the laboratory manager on 7/21/21 at 5:15 PM revealed TP #3 was a temporary employee supplied by an agency. In addition, the laboratory manager confirmed the documentation to show the required qualifications was unavailable. THIS IS A REPEAT DEFICIENCY, previously cited on 8/27/19.