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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D2119300 | <b>(X3) Date Survey Completed</b><br><br>06/26/2018 |
| <b>Name of Provider or Supplier</b><br><br>Louisiana Coagulation   | <b>Street Address, City, State</b><br><br>8721 Oak Street, New Orleans, LA |   |
| 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>D0000</b>              | An Initial survey was performed at Louisiana Coagulation-CLIA ID # 19D2119300 on June 26, 2018. Louisiana Coagulation was not in compliance with the following <b>CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing, Testing Personnel</b>   |
| <b>D5024</b>              | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This <b>CONDITION</b> is not met as evidenced by:<br/>Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing for the specialty of Hematology. Findings: 1. The laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Refer to D5217. 2. The laboratory failed to ensure reagents have not exceeded their expiration date. Refer to D5417. 3. The laboratory failed to establish specimen stability for Antibody testing. Refer to D5423 I. 4. The laboratory failed to perform complete performance specification studies for ADAMTS-13 and Platelet Aggregation testing. Refer to D5423 II. 5. The laboratory failed to include on the reports for Platelet Aggregation and ADAMTS-13 tests a disclaimer stating "The performance characteristics for this test were determined by Louisiana Coagulation. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805.</p> |
| <b>D5209</b>              | <b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br>CFR(s): 493.1235   |

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

This STANDARD is not met as evidenced by:

I. Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on June 26, 2018 at 10:00 am, Personnel 3 stated the laboratory's "Personnel Policy" did not include the identified six (6) procedures. II. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for the General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as the laboratory's General Supervisor. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of General Supervisor. 3. Review of personnel records for Personnel 2 revealed a competency assessment for duties as General Supervisor were not performed. 4. In interview on June 26, 2018 at 10:00 am, Personnel 1 stated she did not perform competency assessment for Personnel 2's duties as General Supervisor.

**D5217**

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

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Findings: 1. Review of the laboratory's "Quality Management Program" policy under "Proficiency Testing" revealed the following: a) "The laboratory will participate in the CAP PT program or CAP-acceptable proficiency testing program at least semiannually and authorize the program to release the results to HHS." b) "Analytes not included in the available CAP proficiency testing programs will be monitored semiannually by an external or alternative assessment program to determine the reliability of analytic testing." 2. In interview on June 26, 2018 at 9:00 am, Personnel 2 stated the laboratory began patient testing for Platelet Aggregation October 18, 2016. 3. In further interview on June 26, 2018 at 11:38 am, Personnel 2 stated the laboratory began patient testing for Antiphosphatidylserine on March 15, 2017, ADAMTS-13 Antibody on May 26, 2017, and HIT (PF4) in June 2018. 4. Review of the laboratory's 2017 records revealed the

laboratory did not verify the accuracy of Platelet Aggregation, Antiphosphatidylserine, and ADAMTS-13 Antibody at least twice annually. 5. In interview on June 26, 2018 at 11:15 am, Personnel 4 stated in 2017 a comparison was performed for Platelet Aggregation, Antiphosphatidylserine, and ADAMTS-13 Antibody twice that year. Personnel 4 further stated the laboratory did not have the findings written up. 6. In further interview on June 26, 2018 at 11:15 am, Personnel 4 stated the laboratory began using College of American Pathologists (CAP) proficiency testing (PT) samples for semiannual verification of accuracy. 7. Review of the laboratory's 2018 CAP records revealed ADAMTS-13 Antibody did not have an assessment performed. 8. Further review of the laboratory's 2018 CAP records for ADAMTS-13 revealed a "Proficiency Review Form" that stated " Survey did not contain response for ADAMTS-13 Ab, but instead a Bethesda Inhibitor titer. We are investigating other options for proficiency testing with this analyte. Alternative assessment review will be performed. Report Received: 6 JUN 2018." 9. Review of the laboratory's "Proficiency Review Form" records for ADAMTS-13 revealed an "Alternative Assessment Review" form that was a comparison of positive and negative control performed by two testing personnel on May 15, 2018 and May 21, 2018. 10. In interview on June 26, 2018 at 11:42 am , Personnel 2 stated the control material for the 2018 Alternative Assessment for ADAMTS-13 was not a blinded sample for the testing personnel.

**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 and interview with personnel, the laboratory failed to ensure reagents have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour June 26, 2018 revealed the following expired items: a) BioData Arachidonic Acid, 75 uL, Lot # 0670075, Expiration date: 14 June 2017, Quantity: 1 vial b) BioData Ristocetin, 15 mg/mL, Lot # 06500196, Expiration date: 18 June 2018, Quantity: 25 vials c) ADP Plt Agg, 20 uM, Lot # SLBL1267V, 150 uL, Expiration: 18 June 2018, 11 vials d) ADP Plt Agg, 10 uM, Lot # SLBL1267V, 150 uL, Expiration 18 June 2018, Quantity: 11 vials e) BioData Ristocetin, 1mg/mL, Lot # 06500196, Expiration 18 June 2018, Quantity: 15 vials f) ADP Plt Agg, 50 uM, Lot # SLBL1267V, 150 uL, Expiration 18 June 2018, Quantity: 12 vials g) BioData Ristocetin, 5 mg/mL, Lot #06500196, Expiration 18 June 2018, Quantity: 16 vials 2. In interview on June 26, 2018 at 9:20 am, Personnel 2 confirmed the identified items are expired. Personnel 2 stated it was an oversight that the expired items were not thrown away. 3. In interview on June 26, 2018 at 9:37 am, Personnel 1 stated the last patient for platelet aggregate testing was June 7, 2018.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

I. Based on observation, record review, and interview with personnel, the laboratory failed to establish specimen stability for Antibody testing. Findings: 1. Observation by surveyor during laboratory tour on June 26, 2018 revealed the laboratory utilizes the BioTek ELx800 for ELISA testing of Antiphosphatidylserine, ADAMTS-13, and HIT (PF4) antibodies. 2. Review of the laboratory's "Validation Reports" for the identified antibodies revealed the following: a) "Anti-Heparin Antibody (PF4): Short-term Stability: Repeat freeze-thaw cycles of samples should be limited." b) "ADAMTS-13: Short-term Stability: Repeat freeze-thaw cycles of samples should be limited, but are acceptable. Samples stored at room temperature for up to 7 days are also acceptable." c) "Anti-Phosphatidylserine: Short-term Stability: Repeat freeze-thaw cycles of samples should be limited." 3. Further review of the laboratory's "Validation Reports" revealed the ADAMTS-13 report included a "Figure 5. ADAMTS-13 Antibody Accuracy Study" table. The table included three (3) "refrozen" samples, two (2) "7-Day Room Temp" samples, and one (1) "Frozen" sample. 4. Further review of the "Antibody Accuracy Study" revealed the laboratory did not include the following: a) Biological factors b) Shipping conditions c) Testing throughout seven (7) days for samples stored at room temperature d) Number of freeze thaw cycles evaluated e) Analytes: Antiphosphatidylserine and PF4 Antibodies 5. In interview on June 26, 2018 at 1:02 pm, Personnel 4 stated for ADAMTS-13 the laboratory evaluated one (1) freeze thaw cycle. Personnel 4 further stated the seven (7) day room temperature sample was tested on day one (1) and day seven (7). Personnel 4 at 1:15 pm, stated the laboratory did not have stability study data for PF4 and Antiphosphatidylserine. Personnel 4 confirmed the stability study performed was not complete for Antibody testing. II. Based on observation, record review, and interview with personnel, the laboratory failed to perform complete performance specification studies for ADAMTS-13 and Platelet Aggregation testing. Findings: 1. Observation by surveyor during laboratory tour on June 26, 2018 revealed the laboratory utilizes the BioTek ELx800 for ELISA testing of ADAMTS-13, as well as, the Helena AggRAM and ChronoLog for Platelet Aggregation testing. 2. Review of the laboratory's "Quality Management Program" under "Method Validation" section revealed the following: a) "Validation of a procedure will include verification of the stated performance specifications for accuracy, precision, reportable range (including sensitivity and specificity), and reference ranges." b) "Analytical sensitivity must be verified of a lower detection limit for each assay must be established where applicable. Analytical specificity or interfering substances must be verified or established for each test. Machaon or another entity must perform studies on interfering substances on a suitable number of samples to establish analytical specificity (reagent/instrument manufacturer, other reporting/publishing laboratories). Listing interfering substances identified in the published literature is acceptable." 3. Review of the laboratory's "Validation Reports" for the identified tests revealed the laboratory did not include the following: a) ADAMTS-13: documentation of Specificity study b) Platelet Aggregation: Reportable range, Sensitivity, Specificity to include interfering substances 4. In interview on June 26, 2018 at 12:21 pm, Personnel 4 stated the laboratory listed the interfering substances included in the manufacturers' package

insert. Personnel 4 confirmed the laboratory did not include documentation of literature source and/or data for samples tested for sensitivity studies. Personnel 4 further confirmed the laboratory's performance studies did not include the identified information. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs one hundred fifty (150) Platelet Aggregation and two hundred twenty five (225) ADAMTS-13 tests annually.

**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 observation, record review, and interview with personnel, the laboratory failed to include on the reports for Platelet Aggregation and ADAMTS-13 tests a disclaimer stating "The performance characteristics for this test were determined by Louisiana Coagulation. It has not been cleared or approved by the U.S. Food and Drug Administration." Findings: 1. Observation by surveyor during laboratory tour on June 26, 2018 revealed the laboratory performs the following testing: Platelet Aggregation (BioData with Helena AggRAM and Chrono Log Aggregometer) Antiphosphatidylserine (Method used: ELISA with Corgenix kit) ADAMTS-13 Antibody (Method used ELISA with Technozym ADAMTS-13 INH kit) HIT Antibody (PF4) (Method used: ELISA with Immucor kit) 2. Review of random selection of patient test reports revealed the laboratory did not include the above disclaimer for the following non-FDA approved tests: ADAMTS-13 Antibody (Method used ELISA with Technozym ADAMTS-13 INH kit): Patients 1-4 Platelet Aggregation (BioData with Helena AggRAM and Chrono Log Aggregometer): Patients 5-11 3. In interview on June 26, 2018 at 3:49 pm, Personnel 4 stated the laboratory did not include the above disclaimer on patient final reports. 4. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs one hundred fifty (150) Platelet Aggregation and two hundred twenty five (225) ADAMTS-13 tests annually.

**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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The Laboratory Director failed to establish pertinent performance

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|                     | <p>characteristics for Antibody and Hematology testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D6098. 4. The Laboratory Director failed to ensure all personnel had the appropriate education and experience for performing high complexity testing. Refer to D6102. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6103.</p>                            |
| <p><b>D6086</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, record review, and interview with personnel, the Laboratory Director failed to establish pertinent performance characteristics for Antibody and Hematology testing. Findings: 1. The laboratory failed to establish specimen stability for Antibody testing. Refer to D5423 I. 2. The laboratory failed to perform complete performance specification studies for ADAMTS-13 and Platelet Aggregation testing. Refer to D5423 II.</p> |
| <p><b>D6087</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Refer to D5217. 2. The laboratory failed to ensure reagents have not exceeded their expiration date. Refer to D5417.</p>  |
| <p><b>D6098</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview with personnel, the Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D5805.</p>   |
| <p><b>D6102</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>   |

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 a record review and interview with personnel, the Laboratory Director failed to ensure all personnel had the appropriate education and experience for performing high complexity testing. Findings: 1. The laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow one (1) of two (2) testing personnel to perform high complexity testing. Refer to D6170. 2. The laboratory failed to ensure one (1) of two (2) testing personnel met educational qualification for performing high complexity testing. Refer to D6171.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Refer to D5209 I. 2. The laboratory failed to ensure written policies and procedures to address competency for the General Supervisor were complete. Refer to D5209 II. 3. The Technical Supervisor failed to document the evaluation of competency for one (1) of two (2) testing personnel reviewed. Refer to D6120.

**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 record review and interview with laboratory personnel, the Technical Supervisor failed to document the evaluation of competency for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed Personnel 2 and Personnel 3 served as testing personnel. 2. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following tests: Platelet Aggregation Antiphosphatidylserine (Method used: ELISA) ADAMTS-13 Antibody (Method used: ELISA) HIT Antibody (PF4) (Method used: ELISA) 3. Review of the "Annual Competency Checklist for Technical Laboratory Personnel" forms for Personnel 2 revealed a hire date of September 7, 2016. 4. Further review of the competency assessment forms for Personnel 2 revealed the laboratory did not have documentation of the following: a) Initial Orientation b) Six (6) month evaluation for ELISA testing; due March 2017 c) Annual evaluation for Platelet Aggregation; due September 2017 5. In interview on June 26, 2018 at 10:00 am, Personnel 1 stated an initial orientation was not performed for Personnel 2. Personnel 4 confirmed the laboratory did not perform a six month competency assessment for Personnel 2 for Platelet Aggregation testing. 6. In further interview on June 26, 2018, Personnel 4 stated he was unaware that an initial orientation, six (6) month, and annual competency assessment for each tests performed was required.

**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 record review and interview with personnel, the laboratory failed to ensure testing personnel met licensure and educational requirements to perform high complexity testing. Findings: 1. The laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow one (1) of two (2) testing personnel to perform high complexity testing. Refer to D6170. 2. The laboratory failed to ensure one (1) of two (2) testing personnel met educational qualification for performing high complexity testing. Refer to D6171.

**D6170**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:  
 Based on record review and interview with personnel, the laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow one (1) of two (2) testing personnel to perform high complexity testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 3 was listed as testing personnel. 2. Review of personnel records for Personnel 3 revealed Personnel 3 retained a Laboratory Assistant license. 3. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following tests: Platelet Aggregation

Antiphosphatidylserine (Method used: ELISA) ADAMTS-13 Antibody (Method used: ELISA) HIT Antibody (PF4) (Method used: ELISA) 4. Review of the Food and Drug Administration (FDA) CLIA database revealed the tests performed are high complexity. 5. In interview on June 26, 2018 at 10:45 am, Personnel 4 stated the laboratory thought the Antibody ELISA testing was classified as moderate complexity. Personnel 4, after review of the FDA CLIA database, confirmed the ELISA tests were high complexity. Personnel 3 confirmed she has a Laboratory Assistant license issued by the State of Louisiana.

**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 record review and interview with personnel, the laboratory failed to ensure one (1) of two (2) testing personnel met educational qualification for performing high complexity testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed Personnel 3 served as testing personnel. 2. Review of personnel records for Personnel 3 revealed the following education documents: a) High school diploma b) Medical Laboratory Assistant diploma 3. Further review of personnel records for Personnel 3 revealed no documentation of minimum requirement of an associate's degree in clinical laboratory science or medical technology from an accredited institution or college course transcript to ensure minimum educational requirement was met. 4. In interview on June 26, 2018 at 10:45 am, Personnel 3 confirmed education provided were copies of high school and Medical Laboratory Assistant diplomas.