

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1015596	(X3) Date Survey Completed 07/27/2021
Name of Provider or Supplier Sterling Surgical Hospital	Street Address, City, State 989 Robert Boulevard, Slidell, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An Initial survey was performed at Sterling Surgical Hospital Lab, CLIA ID # 19D1015596, on July 27, 2021. Sterling Surgical Hospital Lab was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories Performing Moderate Complexity Testing, Testing Personnel
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, proficiency testing (PT) records, policies, and interview with personnel, the laboratory failed to ensure that proficiency testing for Hematology and Chemistry testing was performed by personnel who routinely perform laboratory testing for three (3) of three (3) events reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director also serves as Technical Consultant. 2. Review of the laboratory's "Proficiency Testing" policy stated "The samples will be run along with the routine work by lab personnel and treated the same as patients. The testing personnel testing the PT specimens and the laboratory director or designee will sign the attestation statement that the PT specimens are tested under the same conditions as patient specimens." 3. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the Laboratory Director performed the testing, not Testing Personnel, for the following events: a) 2020 Chemistry Core 3rd Event b) 2020 Hematology/Coagulation 3rd Event c) 2021 Chemistry Core 1st Event</p>

d) 2021 Hematology/Coagulation 1st Event e) 2021 Chemistry Core 2nd Event 4. In interview on July 27, 2021 at 12:28 pm, the Laboratory Director stated she performed the identified PT testing.

D3021

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(c)(1)

Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have policies related to blood products storage. Findings: 1. In interview on July 27, 2021 at 12:41 pm, the Laboratory Director stated the hospital has a contract with the Blood Center and nursing staff issues the blood that is stored at the hospital . The Blood Center performs all testing for the blood products. The Laboratory Director further stated the refrigerator is monitored by the Blood Center. 2. Review of laboratory policies revealed the laboratory did not include the following: a) length of storage of blood products b) monitoring of refrigerator temperature, to include but not limited to who is responsible c) laboratory's responsibilities 3. In interview on July 27, 2021 at 12:41 pm, the Laboratory Director confirmed the laboratory did not include the identified items in their policies.

D3025

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(d)

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, nursing policies, and interview with personnel, the laboratory failed to ensure the laboratory included a policy for transfusion reactions. Findings: 1. In interview on July 27, 2021 at 12:41 pm the Laboratory Director stated the hospital has a contract with the blood center and the nursing staff administers blood units. The laboratory does not perform blood bank testing. 2. Review of the laboratory's policies revealed the laboratory did not include a policy related to transfusion reaction investigations. 3. Review of nursing services' "Blood Transfusion" policy revealed the hospital "will ensure that nurses be educated on the following standards of care guidelines: acute hemolytic reaction, febrile reactions (increase of 1 degree F or more from pre-transfusion vitals), allergic reactions (hives, SOB, rash, urticaria, etc.), circulatory overload, and sepsis. Refer to Attachment for contracted blood bank transfusion reaction protocol." 4. The attachment "Contracted blood transfusion reaction protocol" and example of the "Reference Laboratory Transfusion Reaction Report" were not included in the nursing services "Blood Transfusion" policy. 5. Further review of the nursing services "Blood Transfusion" policy revealed the frequency of monitoring the patient's vital signs, including the specific readings taken, were not detailed. 6. In interview on July 27,

	<p>2021 at 3:00 pm, the Lab Services Manager confirmed the nursing policy for blood transfusion did not include the identified information.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Findings: 1. Review of the laboratory's "Point of Care Competency" policy revealed the laboratory did not include competency of the Clinical Consultant, including frequency of performance. 2. Review of personnel records for the Clinical Consultant revealed a competency assessment for duties as Clinical Consultant was not performed. 3. In interview on July 27, 2021 at 10:32 am, the Laboratory Director stated she did not perform a competency assessment for the Clinical Consultant.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have complete performance verification studies for the i-Stat analyzer. Refer to D5421. 2. The laboratory failed to have in house data to support the reduction in frequency of quality control for the i-Stat Individualized Quality Control Plan (IQCP). Refer to D5445. 3. The laboratory failed to perform quality control (QC) as required by laboratory policy on the i-Stat analyzer for Chemistry testing for two (2) of ten (10) months reviewed. Refer to D5447. 4. The laboratory failed to establish complete procedures to monitor, assess, and correct problems identified with the analytic system. Refer to D5791.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

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 observation by surveyor, review of performance verification studies, policies, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the i-Stat analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 27, 2021 at 9:40 am revealed the laboratory utilizes the i-Stat 1 for testing of the following analytes: pCO₂, pH, pO₂, lactate, Chem 8 + panel (sodium, potassium, chloride, TCO₂, glucose, BUN, creatinine, hematocrit, ICA), and PT/INR testing. 2. Review of the laboratory's "New Test Method Verification" policy revealed the following: a) Precision: "Start with PRECISION, 20 data points is a standard but minimum is two samples with two different known values, five repetitions. To access PRECISION, calculate the mean (X), standard deviation (SD), and coefficient of variation (CV) for each set of results. Compare the CV obtained to that stated in the manufacturer's literature regarding performance specifications." b) Accuracy: "Determine the difference between the two values and compare to the limits of acceptability stated in the package insert for known samples or use the allowable Proficiency Testing scoring limits found in PT Summary Report. Another simple way to evaluate the results is to calculate the ratio of means for comparison." c) Reportable Range: "If samples with very low and very high values were used for precision and accuracy and the results were acceptable, then the reportable range has been verified. If not, use a sample at the low end, one in the middle and one on the higher end of linearity." d) Reference Range: "Collect specimens from a minimum of 10 normal patients. Test each specimen only once, and spread the testing over a minimum of three days. Add up the values obtained for each sample and divide by 10 to calculate the normal patient 'mean'. Calculate the standard deviation (SD). Establish the range of plus and minus two SD from the mean. Compare this range to the manufacturer's range. If the lab's range falls within the manufacturer's range, the manufacturer range can be accepted." e) "Document all activities involved in verifying performance specifications." f) "Retain this documentation for as long as the test method is in use and for 2 years after discontinuation of the method." 3. Review of the laboratory's "Prothrombin Time (PT/INR)" policy under "Reference Interval" section revealed "Due to the variables that may affect PT/INR results, each laboratory should establish its own reference interval." 4. Review of the laboratory's performance verification (validation) records for the i-Stat revealed the laboratory did not include the following: a) Accuracy: acceptability criteria b) Precision: acceptability criteria c) Reportable range studies including acceptability criteria d) Reference range studies to include but not limited to documentation of normal donors used 5. In interview on July 27, 2021 at 12:11 pm, the Laboratory Director stated the laboratory did not include the specific acceptability criteria for the studies, acceptability was less than or equal to the manufacturer's CV. 6. In further interview on July 27, 2021 at 12:21 pm, the Laboratory Director stated donor questionnaires for normal donors were not included for reference range for PT/INR test. The Laboratory Director further stated she did not know the reportable ranges for tests performed on the i-Stat. 7. In further interview on July 27, 2021 at 12:32 pm, the Laboratory Director stated she did not perform reference range studies as indicated by the laboratory's procedure for the chemistry tests for the i-Stat. 8. Review of the laboratory's test menu revealed the laboratory performs two (2) pCO₂, two (2) pH, two (2) pO₂, two (2) lactate, 282 sodium, 282 potassium, 282 chloride, 282 TCO₂, 282 glucose, 282 BUN, 282 creatinine, 282 hematocrit, 282 ICA, and two PT/INR tests annually.

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 observation by surveyor, review of the laboratory's policies, quality control records, and interview with personnel, the laboratory failed to have in house data to support the reduction in frequency of quality control for the i-Stat Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyor during laboratory tour July 27, 2021 at 9:40 am revealed the laboratory utilizes the i-Stat 1 for testing of the following analytes: pCO₂, pH, pO₂, lactate, sodium, potassium, chloride, TCO₂, glucose, BUN, creatinine, hematocrit, ICA, and PT testing. 2. Review of the laboratory's "QC Plan" revealed "Perform liquid Quality Control on each lot new lot number of reagent and once a month." 3. Review of the laboratory's IQCP records revealed the laboratory did not include in-house quality control data to support the reduction of external controls to monthly. 4. In interview on July 27, 2021 at 12:10 pm, the Laboratory Director confirmed she did not run QC to support the reduction of external controls to monthly.

D5447

CONTROL PROCEDURES

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

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of policies, quality control records, patient test records, and interview with personnel, the laboratory failed to perform quality control (QC) as required by laboratory policy on the i-Stat analyzer for Chemistry testing for two (2) of ten (10) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 27, 2021 at 9:40 am revealed the laboratory utilizes the i-Stat 1 for testing of the following analytes: pCO₂, pH, pO₂, lactate, Chem 8 + panel (sodium, potassium, chloride, TCO₂, glucose, BUN, creatinine, hematocrit, ICA), and PT/INR testing. 2. Review of the laboratory's "QC Plan" revealed "Perform liquid Quality Control on each lot new lot number of reagent and once a month." 3. Review of monthly QC records for the i-Stat for September 2020 through June 2021 revealed the laboratory failed to perform two (2) levels of external controls for the following months: a) October 2020 b) February 2021 4. In interview on July 27, 2021 at 10:34 am, the Laboratory Director stated she did not realize monthly quality control was not performed in October 2020. 5. In in further interview on July 27, 2021 at 12:

11 pm, the Laboratory Director stated she could not find the quality control for February 2021. 6. Review of the laboratory's patient test records revealed the following patients were reported for Chem 8+ analytes without quality control performed: a) October 2, 2020 : Patient 10049895 b) October 7, 2020: Patient 10050141 c) October 8, 2020: Patient 10050114 d) October 12, 2020: Patient 10049945, Patient 10050097, Patient 10050091 e) February 2, 2021: Patient 10051973, Patient 10051956, f) February 5, 2021: Patient 10052013, Patient 10051906, Patient 10051974

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 observation by surveyor, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems identified with the analytic system. Findings: 1. The laboratory failed to have complete performance verification studies for the i-Stat analyzer. Refer to D5421. 2. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control for the i-Stat. Refer to D5445. 3. The laboratory failed to perform quality control (QC) as required by laboratory policy on the i-Stat analyzer for Chemistry testing for two (2) of ten (10) months reviewed. Refer to D5447.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6016. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6029. 6. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.

<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2007.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control for the i-Stat. Refer to D5445. 2. The laboratory failed to perform quality control (QC) as required by laboratory policy on the i-Stat analyzer for Chemistry testing for two (2) of ten (10) months reviewed. Refer to D5447.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6065.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Refer to

D5209. 2. The Technical Consultant failed to evaluate the competency of nineteen (19) of nineteen (19) nursing staff performing laboratory testing. Refer to D6046.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have policies related to blood products storage. Refer to D3021. 2. The laboratory failed to ensure the laboratory included policy for transfusion reactions. Refer to D3025.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of random selection of personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency of nineteen (19) of nineteen (19) nursing staff performing laboratory testing. Findings: 1. Review of personnel records for random selection of nineteen (19) nursing staff serving as Testing Personnel revealed the Lab Services/Pre-Admin Manager, not the Technical Consultant, performed the competency assessments for the Testing Personnel. 2. Further review of the Lab Services Manager personnel records revealed she did not meet the state licensure requirement to qualify as a Technical Consultant. 3. In interview on July 27, 2021 at 3:30 pm, the Laboratory Director (who serves as Technical Consultant) stated she was not aware that the Technical Consultant was required to perform the competency assessments.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met education requirements. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation that one (1) of nineteen (19) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for Testing Personnel 19. 2. In interview on July 27, 2021 at 1:44 pm, the Lab Services Manager stated the laboratory did not have documentation of education for Testing Personnel 19 who works PRN.