

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1015749	<b>(X3) Date Survey Completed</b>  02/14/2023
<b>Name of Provider or Supplier</b>  Acadia-St Landry Hospital	<b>Street Address, City, State</b>  810 South Broadway St, Church Point, 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>	A Recertification survey was performed on February 13, 2023 through February 14, 2023 at Acadia St. Landry Hospital-Respiratory, CLIA ID # 19D1015749. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<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 the laboratory's proficiency test records and interview with the laboratory personnel, the laboratory failed to ensure that proficiency testing attestation statements were signed by the laboratory director for 2 of 3 proficiency testing (PT) events reviewed. The findings are as follows: 1. Review of the College of American Pathologists (CAP) proficiency testing records from the second testing event of 2021 through the second testing event of 2022 for Critical Care Blood Gas with Chemistry proficiency testing revealed no signature present on the attestation form by the laboratory director or designee for the below events: 2021 Critical Care Blood Gas with Chemistry Testing Event 2 2022 Critical Care Blood Gas with Chemistry Testing Event 1 2. In interview on February 13, 2023 at 3:13 PM, Testing Personnel 1 confirmed that the Laboratory Director had not signed the attestation statements identified above.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

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 Director failed to ensure policies and procedures were established for assessing clinical consultant competency. Findings: 1. Review of the laboratory's policy and procedure manual no policy or process specific to competency assessment of the clinical consultant to include, but not limited to, qualification, basis of determination of competency, and frequency of competency assessment required. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel are listed as Clinical Consultant: Personnel 7 3. Review of personnel records revealed no record of competency assessment performed for the duties of Clinical Consultant for Personnel 7. 4. In interview on February 13, 2023 at 3:13 PM, Laboratory Director confirmed a competency assessment was not performed for the duties of Clinical Consultant, and he was unaware that he needed to perform a competency for the Clinical Consultant. II. Based on review of the laboratory's Policy and Procedure manual, personnel files, as well as interviews with laboratory staff, the laboratory failed to follow written policies and procedures to assess employee competency for one (1) of five (5) Testing Personnel. Findings: 1. Review of personnel competency files revealed that a 2022 annual competency assessment was documented for Testing Personnel 2. 2. Further review of the 2022 annual competency assessment completed on June 1, 2022 for Testing Personnel 2 revealed that for the skill "Records/reports test results," the laboratory assessed Testing Personnel 2 as "Needs Improvement." 3. Review of the laboratory's policy "Employee Competency" revealed the following statement: "If evaluation of competency is "needs improvement," the testing personal (sic) shall not continue to perform testing on patients until re-education/training followed by successful reassessment of competency. This shall be initiated by the technical consultant." 4. Review of the laboratory's 2022 Arterial Blood Gas Log revealed the initials of Testing Personnel 2 next to a total of four (4) patients tested on the following dates: a. 7/26/2022 b. 11/01/2022 c. 12/03/2022 d. 12/07/2022 5. In interview on February 14, 2023 at 9:15 am, Testing Personnel 1 confirmed the initials of Testing Personnel 2 next to patients tested after June 1, 2022 on the 2022 Arterial Blood Gas Log. 6. In interview on February 13, 2023 at 2:46 PM, Laboratory Director confirmed that no reeducation or training was initiated after performing the 2022 annual competency for Testing Personnel 2. The Laboratory Director also serves as the Technical Consultant.

**D5221**

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

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure and proficiency testing records, as well as interview with laboratory personnel, the laboratory failed to assess one (1) unacceptable result on one (1) of three (3) testing events. Findings: 1. Review of the laboratory's 2022 College of American Pathologists (CAP) proficiency test results revealed the laboratory received the following unacceptable result: 2nd Event: Sample AQ-07 for PCO<sub>2</sub> 2. Further review of the laboratory's CAP documents revealed no documentation of review or investigation for the identified unacceptable result. 3.

Review of the laboratory's "Proficiency Testing" policy under the "Survey Result Evaluation" section revealed "Unacceptable Challenge--a graded, missed result. An Action Needed Form must be completed for an unacceptable challenge. All related data (QC, maintenance, calibration, lot#/expiration date log, report, raw data printout, etc.) must be reviewed to determine the exact cause for the failure and this data attached to the ANF. Once the problem is identified, appropriate corrective action will be taken to prevent the same problem from recurring." 4. Review of the "Monthly Review of Respiratory Department Blood Gas Laboratory" section "Proficiency Testing Review" revealed the written comment "see comments - successful." Testing Personnel 1 and the Laboratory Director both signed the review. 5. In interview on February 13, 2023 at 4:12 PM, Testing Personnel 1 confirmed an investigation was not performed for the identified unacceptable result.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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;

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 D2009.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.

**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:

I. Based on record review, policy review, and interview, the Laboratory Director serving as Technical Consultant failed to evaluate competency annually in 2022 for five (5) of five (5) Testing Personnel reviewed. Findings: 1. Review of "Testing Personnel Competency Assessment" revealed the initials of Testing Personnel 1 in the column labeled "Evaluator Date Evaluated." 2. Further review of the policy "Technical Consultant" revealed under the section "Responsibilities and Duties," the Technical Consultant is responsible for "Evaluating the competency of all testing personnel and assuring that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently." 3. In interview on February 13, 2023 at 1:30 PM, Laboratory Director stated that Testing Personnel 1 performs the competency and the Laboratory Director initials that Testing Personnel 1 performed it. The Laboratory Director confirmed that he does not actively participate in the competency assessment. II. Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing clinical consultant competency including frequency of performance. Refer to D5209. III. Based on review of the laboratory's Policy and Procedure manual, record review, and personnel interview, the Laboratory Director failed to ensure the laboratory followed written policies and procedures to assess employee competency for one (1) of five (5) Testing Personnel. Refer to D5209. IV. Based on record review and interview with personnel, the Laboratory Director failed to ensure the technical consultant assessed problem solving skills of all testing personnel annually. Refer to D6052.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed for problem solving skills annually. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report ) form revealed the following testing personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's "Employee Competency" policy revealed "Procedures for competency evaluation of testing personnel shall include:...6. Assessment of problem solving skills." 3. Further review of the "Testing Personnel Competency Assessment" form revealed the "Skills/Task/Knowledge" and the associated assessment categories. "Evaluation of problem solving skills" is entered next to each of the following "Skills/Tasks/Knowledge:" a. Read and follows procedure manual. b. Recognizes critical values and places notification calls. c. Performs proficiency testing and records results. 4. In interview with the Laboratory Director on February 13, 2023 at 2:40 PM, the Laboratory Director states that testing personnel have the Laboratory Director's phone number and for problem solving skills the Laboratory Director asks personnel who are they going to call if they have

troubleshooting issues or problems they cannot solve. The Laboratory Director stated they do not have a quiz.