

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2293472	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Acadian Health- Ga Base	Street Address, City, State 325 Hammond Drive, Sandy Springs, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 8, 2025. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following standard level deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 Wisconsin State Laboratory of Hygiene (WLSH) proficiency test (PT) records and staff interview , the laboratory testing personnel (TP) and/or lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings: 1. Review of the WLSH 2024 PT records revealed event #2 and #3 attestations were not signed by the TP or the LD. 2. Review of the WLSH 2025 PT records revealed the event #1 attestation was not signed by the TP or the LD and event #2 attestation was not signed by the LD. 3. Interview with TP #6 (CMS 209) on 10/08/25 at 1:08 pm in the front office confirmed the aforementioned findings.</p>
D5209	<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>

This STANDARD is not met as evidenced by:
Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow a policy and procedure to assess testing personnel (TP) competency as required. Findings include: 1. SOP review revealed there was no policy and procedure to assess (TP) competency available at the time of survey. 2. Review of TP competency documents revealed the lack of the 6 required criteria. 3. Interview with TP #6 (CMS 209) in the front office on 10/8/25 at 12:37 p. m. confirmed the lack of a TP competency policy and procedure in the SOP and the competency documents/forms lacked the 6 required criteria.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on SOP review and staff interview, the laboratory failed to include all required policy & procedures. Findings include: 1. SOP review reveals the lack of policy & procedure for critical values, specimen collections, and a procedure for action to take if a test system becomes inoperable. 2. Interview with TP #6 (CMS 209) on 10/08/25 at 12:37 p.m. confirmed the lack of the aforementioned policy and procedures.

D6019

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

(e)(4)(iv) 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 review of the laboratory's 2024 WSLH PT evaluation reports, the laboratory director failed to ensure the laboratory followed the corrective action plan when PT results are found to be unacceptable or unsatisfactory. The findings include: 1. Review of the PT evaluation report for 2024 Chemistry event #3 revealed the following

unsatisfactory/unacceptable results : Chloride 20%, CO2 60%, Creatinine 40%, Glucose 0%, Ionized Calcium 20%, Lactate 0%, pCO2 20%, pH 20%, pO2 60%, Potassium 20%, Sodium 20%, and BUN 0%. 2. Review of the PT evaluation report for 2024 Hematology event #3 revealed the following unsatisfactory/unacceptable results : Hematocrit 0% & Hemoglobin 0%. 3. Interview with TP #6 (CMS 209) on 10/08/25 at 1:27 PM in the front office confirmed the aforementioned PT scores.