Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2294162	03/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Acadian Health - Wi Base	1728 Spooner Avenue Suite D, Altoona, WI	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Item 1 Based on surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form CMS-209 (Laboratory Personnel Report), competency evaluation records and interview with the program lead, staff A, the laboratory did not establish and follow written policies and procedures to assess the competence for one of one technical consultant that was not the laboratory director. Findings include: 1. Review of the Form CMS-209 submitted for survey showed one technical consultant, staff B, that was not the laboratory director. 2. Review of the competency evaluation records showed no evidence the laboratory director evaluated the competence of staff B in performing their assigned consultant responsibilities. 3. Interview with staff A on March 10, 2025, at 10:40 AM confirmed the laboratory had not established procedures to evaluate competency for the technical consultants and the laboratory director had not evaluated the competency of the technical consultants for their delegated responsibilities. Item 2 Based on surveyor review laboratory procedures and interview with the program lead, staff A, the laboratory did not establish a procedure defining five of the six elements required to assess competency of testing personnel. Findings include: 1. Review of "Quality Assurance Plan" procedure stated "Must have director observation to be signed off on." Further review of laboratory procedures showed no evidence of a procedures for assessing testing personnel competence that identified the following elements: Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observations of performance of instrument maintenance and function checks; Assessment of test

	performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem-solving skills. 2. Interview with staff A on March 10, 2025, at 11:10 AM confirmed the laboratory had not established a procedure defining the required elements used to assess the competency of testing personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on survey review of laboratory procedures and interview the project lead, staff A, the laboratory director did not sign and date three of six new procedures. Findings include: 1. Review of the laboratory procedures showed the following procedures: Acadian Health Quality Assessment: signed by the laboratory director and technical consultant Quality Assurance Plan: signed by the laboratory director and technical consultant Acadian Health Quality Control Plan: signed by the laboratory director and technical consultant EPOC CLSI Procedure Manual with epoc NXS Host: signed by the technical consultant, not signed by the laboratory director Corrective Action /Preventive Action Procedure: signed by the technical consultant, not signed by the laboratory director EPOC Maintenance: signed by the technical consultant, not signed by the laboratory director 2. Interview with staff A on March 10, 2025, at 11:00 AM confirmed the laboratory director did not sign and date all new procedures prior to patient use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory director did not review and approve the performance specification verification records for one of one new analyzer prior to reporting patient results. Findings include: 1. Review of the validation forms for the Siemens EPOC analyzer showed no documentation that the laboratory director reviewed and signed the performance specification verification records. 2. Interview with the staff A on March 10, 2025, at 11:25 AM confirmed the laboratory director did not review and approve the performance specification verification records prior to reporting patient results.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on competency assessment records and interview with the project lead, staff A, the technical consultant did not document initial competency assessment for ten of ten testing personnel. Findings include: 1. Review of competency assessments for the laboratory showed no documentation of competency assessment for testing personnel after initial training was performed by staff A. 2. Interview with staff A on March 10, 2025, at 10:40 AM, confirmed the technical consultant did not document initial competency assessment for testing personnel.