

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0395403	<b>(X3) Date Survey Completed</b>  04/28/2026
<b>Name of Provider or Supplier</b>  Aspirus Elcho Clinic	<b>Street Address, City, State</b>  W10618 Clinic Street, Elcho, WI	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory director (Staff A), the current laboratory director failed to document approval of one of one procedure for testing using the i-STAT analyzer. Findings include: 1. Review of the "Chemistry Testing Using the Abbott i-STAT Analyzer" procedure showed no evidence of approval by the current laboratory director. 2. Interview on April 28, 2026, at 1:45 PM confirmed the procedure did not show approval by the current laboratory director.</p>
<b>D6004</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of laboratory records, the Centers for Medicare and Medicaid Services (CMS) Form 209, Laboratory Personnel Report (CLIA), and procedures, and interview with the laboratory director (Staff A), the director failed to delegate in writing technical consultant duties performed by two of two staff members and did not document evaluation of competence for the staff members performing the delegated duties. Findings include: 1a. Review of competence evaluation records showed Staff B performed evaluations of testing personnel in 2025 and 2026. 1b. Review of proficiency testing (PT) records from 2025 and 2026 showed Staff C signed attestation statements as a designee of the laboratory director. 1c. Review of laboratory records showed no documented competence evaluations of Staff B or Staff C in performing technical consultant responsibilities. 2. Review of the CMS Form 209 showed the director had not identified Staff B or C as performing technical consultant responsibilities. 3. Review of the "Aspirus Laboratory Training and Competency Assessment Policy" showed the procedure required assessment of technical consultant responsibilities on an annual basis. 4. Interview with Staff A on April 28, 2026, at 2:15 PM confirmed they had delegated technical consultant responsibilities to Staff B and Staff C without documenting the delegation in writing and confirmed they had not documented evaluation of the staff members' competence to ensure the duties were performed properly.

**D6061**

**CLINICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1419(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:  
Based on surveyor review of one of three i-STAT test reports from 2025 and laboratory procedures and interview with the laboratory director, the clinical consultant failed to ensure the reference range for Total Carbon Dioxide (TCO2) results on the test report was consistent with the reference range included in the test procedure. Findings include: 1. Review of a test report showed the reference range for TCO2 was 20 - 30 mmol/L (millimoles per liter). 2. Review of the "Chemistry Testing Using the Abbott i-STAT Analyzer" procedure showed the TCO2 reference range as 22 - 32 mmol/L. 3. Interview with Staff A on April 28, 2026, at 1:45 PM revealed the laboratory completed three patient tests using the i-STAT analyzer in 2025 and confirmed the reference range for TCO2 on the test report was different from the reference range approved in the procedure.