

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 02D0641826	<b>(X3) Date Survey Completed</b> 09/26/2024
<b>Name of Provider or Supplier</b> Cordova Community Medical Center	<b>Street Address, City, State</b> 602 Chase Avenue, Cordova, AK	
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>D5421</b>	<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) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the laboratory director, the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and reference range for the Protime (PT)/INR test on the Abbott i-STAT, Serial Number 43707, in use on 2/27/2023, prior to testing patient samples. Findings include: 1. A request was made to review the verification of performance specifications for the PT/INR test on the Abbott i-STAT analyzer and documentation could not be provided. 2. An interview conducted on 9/26/2024 at 3:00 PM with the laboratory director confirmed the laboratory did not have the verification studies for accuracy, precision, reportable range, and reference range for PT/INR on the Abbott i-STAT. 3. The laboratory reports performing approximately six (6) PT/INRs annually.</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:

Based on observation of digital thermometers, lack of documentation, and an interview with Testing Person 1 (TP1), the laboratory failed to verify the accuracy of four (4) of four (4) thermometers used by the laboratory to monitor the temperature of the refrigerators and freezer used to store patient samples and test reagents, within the timeframe defined by the manufacturer. Findings include: 1. The Sensoscientific digital thermometers (serial numbers SRS7-36810, SRS7-36811, SRS7-36841, SRS7-36801) used in the laboratory's refrigerators and freezer had calibration due dates of 3 /10/2022. 2. A request was made to review the documentation verifying the accuracy of the Sensoscientific thermometers, and documentation could not be provided. 3. The testing person 1 confirmed these findings by interview on 9/26/2024 at 3:00 PM. 4. The laboratory reports performing 11,196 tests annually.