

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0717499	<b>(X3) Date Survey Completed</b>  10/25/2024
<b>Name of Provider or Supplier</b>  Harbir S Makin Md	<b>Street Address, City, State</b>  3300 Providence Drive 114, Anchorage, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Quality Control Policy, Quality Control records, and an interview with the Testing Person, the laboratory failed to follow its policy for ensuring Quality Control result acceptability prior to reporting patient test results for Chloride on the Alfa Wasserman Ace Axcel analyzer 62 out of 143 testing days from 5/4/2023 to 10/23/2024. Findings include: 1. The laboratory's Quality Control Policy states that patient results may not be reported unless control results meet quality control acceptability criteria. 2. A review of Quality Control results for Chloride on the Alfa Wasserman Ace Axcel revealed the Level 2 Chemistry Control for Chloride was not within the manufacturer's acceptable range 62 of 143 days patients were tested from 5/4/2023 to 10/23/2024. 3. An interview conducted on 10/25/2024 at 11:30 AM with the testing person confirmed these findings. 4. The laboratory reports running approximately 690 Chloride tests annually.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of the Quality Control Policy, Quality Control records, and an interview with the Testing Person, the laboratory failed to document corrective actions when the Level 2 Chemistry Control was outside the acceptable range for 81 of 167 times the control was run for Chloride from 5/4/2023 to 10/23/2024. Findings include:

1. The laboratory's Quality Control Policy states that all quality control procedures must be documented.
2. A review of Quality Control results for Chloride on the Alfa Wasserman Ace Axcel revealed 81 of the 167 control records from 5/4/2023 to 10/23/2024 were outside the acceptable range with no corrective action documented.
3. An interview conducted on 10/25/2024 at 11:30 AM with the testing person confirmed these findings.
4. The laboratory reports running approximately 690 Chloride tests annually.