

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 02D0641048	<b>(X3) Date Survey Completed</b> 04/28/2025
<b>Name of Provider or Supplier</b> Providence Seward Medical Center	<b>Street Address, City, State</b> 417 1st Ave, Seward, 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>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the cell washer maintenance log, patient testing log, and an interview with the general supervisor, the laboratory failed to perform cell washer function checks to ensure the cell washer is performing accurately and reliably 27 of 73 days patients were tested for ABO and Rh determinations, antibody screens, and compatibility testing in 2024 and up to 4/28/2025. Findings include: 1. A review of the cell washer maintenance logs and Immunohematology patient testing logs revealed that cell washer function checks were not documented on the following dates patients were tested. (1/26/24, 2/11/24, 3/8/24, 5/10/24, 5/14/24, 5/16/24, 5/26/24, 6/15/24, 7/12/24, 7/20/24, 7/24/24, 7/27/24, 8/4/24, 8/13/24, 8/23/24, 8/24/24, 9/16/24, 11/19/24, 11/20/24, 11/22/24, 11/23/24, 12/12/24, 1/4/25, 1/12/25, 2/27/25, 4/16/25, 4/23/25) 2. The general supervisor confirmed these findings in an on-site interview on 4/28/25 at 4:00 PM. 3. The laboratory reports performing approximately 250 Immunohematology tests annually.</p>
<b>D5555</b>	<p><b>IMMUNOHEMATOLOGY</b> CFR(s): 493.1271(c)(f)</p> <p>(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must</p>

be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented.

This STANDARD is not met as evidenced by:

Based on a review of Immunohematology alarm system records and an interview with the general supervisor, the laboratory failed to document alarm system checks for the Immunohematology refrigerator where blood products are stored in 2023 and 2024. Findings include: 1. A request was made to review documentation of the Immunohematology refrigerator high and low temperature alarm checks and documentation could not be provided for 2023 and 2024. 2. The laboratory receives and stores approximately 120 units of packed red blood cells per year. 3. On an on-site interview on 4/28/25 at 4:00 PM, the general supervisor confirmed the alarm system testing for the Immunohematology refrigerator was not documented in 2023 and 2024.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on an interview with the general supervisor and lack of records, the laboratory failed to perform a comparison of test results in 2024 for Chloride, Creatinine, Glucose, Hematocrit, Hemoglobin, Potassium, Sodium, and Urea Nitrogen using the Abbott i-STAT Chem8+ cartridges and the Siemens Dimension chemistry and the Sysmex XN 550 Hematology analyzers. Findings include: 1. A request was made to review documentation of the comparison of test results for analytes run on the Abbott i-STAT Chem8+ cartridges, the Siemens Dimension, and the Sysmex XN 550 for 2024, and documentation could not be provided. 2. The general supervisor confirmed the test comparisons were not performed, in an on-site interview on 4/28/25 at 4:00 PM. 3. The laboratory reports performing approximately 51,000 routine chemistry and 17,000 hematology tests annually.