Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 02D1062852	**(X3) Date Survey Completed** 10/23/2024
Name of Provider or Supplier Providence St Elias Specialty Hospital	**Street Address, City, State** 4800 Cordova Street, Anchorage, AK	
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**
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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. This STANDARD is not met as evidenced by: Based on surveyor observation of thermometers, record review, and interview with the Technical Supervisor (TS), the laboratory failed to define, perform, and document function checks on five (5) of six (6) thermometers used by the laboratory to monitor the temperature of refrigerators and freezers used to store patient samples and test reagents, and to monitor the room temperature of the laboratory storage area. Findings include: 1. Observations on 10/23/2024 at 12:00 PM, showed the Streck Temp-Chex thermometers used by the laboratory did not have the expiration dates or function check dates documented. a. Thermometer serial number (S/N) 31300299 i. location: Freezer 1 ii. no date in use or the manufacturer's Certificate of Accuracy on file b. Thermometer S/N 22660550 i: location: Freezer 2 ii. manufacturer's date of certification 7/11/2023 iii. in use 01/10/2022 c. Thermometer S/N 33470268 i. location: Freezer 3 ii. manufacturer's date of certification 10/18/2013 iii. in use 6/18 /2014 d. Thermometer S/N 91790550 i. location: White refrigerator ii. manufacturer's date of certification 4/30/2019 iii. in use 05/29/2020 e. Thermometer S/N 20550269 i. location: small room ii. manufacturer's date of certification 09/08/2011 iii. in use 1/9 /2014 2. A request was made to review the thermometer function checks and none could be provided. 3. In an on-site interview on 10/23/2024 at 12:00 the TS verified

	no function checks had been defined or documented. 4. The laboratory reports performing 12,104 tests annually.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the Technical Supervisor (TS), the laboratory did not have copies of diplomas and or transcripts and or primary source verification for two (2) of fourteen (14) total testing personnel. Findings include: 1. A request was made to review the testing personnel's educational records, and documentation could not be provided for two (2) of the fourteen (14) testing persons. 2. In an on-site interview on 10/23/2024 at 12:00 PM with the TS, verified two testing personnel did not have educational records on file. 3. The laboratory reports performing 12,104 tests annually.