

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D1019114	(X3) Date Survey Completed 02/15/2022
Name of Provider or Supplier Southeast Medical Clinic	Street Address, City, State 641 West Willoughby Ave, Suite 201, Juneau, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert, interview with the laboratory director, and observation, the laboratory failed to follow the manufacturer's instructions to store serum for Direct and Total Bilirubin testing away from fluorescent lights to prevent photodegradation prior to testing. Findings include: 1. The refrigerator used to store Direct and Total Bilirubin specimens has a glass door allowing for room light illumination and internal fluorescent lights that were continuously on. 2. Direct and Total Bilirubin testing is routinely performed three days a week, and the serum samples stored in the refrigerator prior to testing were not protected from the room light or the refrigerator's fluorescent lights. 3. The laboratory performs approximately 3,500 Direct and Total bilirubin tests annually. 4. The laboratory director confirmed these findings 2/15/2022 at 12:30 pm.</p>