Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0892728	08/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dahl Memorial Clinic	350 14th St, Skagway, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) procedures, patient test records, quality control log sheets, and interview with the laboratory director, the laboratory did not follow their written procedure to perform QC each day patients were tested for 2 of 6 patient testing days (11/19/2020 and 4/14/2022) that Abbott i-STAT PT/INR and Biosite Triage D-Dimer, Cardiac Panel, and BNP patient records were reviewed. Findings include: 1. The Quality Control Procedure states '2 controls each day a patient is tested' for the Abbott i-STAT PT/INR and the Biosite Triage D-Dimer, Cardiac Panel, and BNP assays. 2. Review of patient test and QC records revealed the laboratory performed PT/INR and Cardiac panels performed on 11/19/2020 and 4/14 /2022 (2 of 6 dates of patient record review) The QC logsheets were missing QC documentation for these dates. 3. The laboratory director confirmed these findings by interview on 8/23/22 at 14:00.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) 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.

	This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory thermometers and interview with the laboratory director, the laboratory failed to verify the accuracy of 3 of 4 thermometers within the timeframe defined by the manufacturer. Findings include: 1. The Fisher Scientific digital thermometers (serial numbers 130472417 and 130472420) in use in the laboratory's refrigerator and freezer had a calibration due dates of 8/13/15. There was no documentation to indicate a verification of accuracy had been performed. The refrigerator and freezer are used to store reagents and patient samples. 2. The Fisher Scientific digital thermometer (serial number 91265965) used to monitor the laboratory's room temperature and humidity had a calibration due date of 11/30/11. There was no documentation to indicate a verification of accuracy had been performed. 3. The laboratory director confirmed these findings by interview on 8/23 /22 at 14:00.