Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0892728	(X3) Date Survey Completed 04/05/2024
Name of Provider or Supplier Dahl Memorial Clinic	**Street Address, City, State** 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and an interview with the labortory director, the laboratory failed to include instructions for reporting imminently life threatening results, panic, or alert values. Findings include: 1. A review of the test procedures and quality assurance policy revealed that the laboratory failed to establish a policy or procedure to address how imminent life-threatening conditions, panic or alert values are reported and documented. 2. The laboratory director confirmed these findings in an interview on April 5, 2024 at 9:00 AM. 3. The laboratory reports performing approximately 850 patient tests annually.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of patient test records, quality control records, and an interview with the laboratory director, the laboratory failed to perform two control materials each day patients were tested for two (2) out of three (3) patient testing days reviewed. Findings include: 1. A request was made to review QC documentation for three patients tested from July 5, 2023 through November 16, 2023 using the Biosite Triage analyzer, and documentation could not be provided for 2 of the 3 patient testing dates. a. Patient 1: Two Cardiac Panels and 1 B-type natriuretic peptide (BNP), were performed on 7/5/23, no QC was documented for that date. b. Patient 3: One Cardiac panel was performed on 11/16/23, no QC was documented for that date. 2. The laboratory director confirmed these findings in an interview on April 5, 2024 at 9:00 AM. 3. The laboratory reports performing approximately 400 patient tests on the Biosite Triage annually.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of test records and an interview with the laboratory director, the laboratory failed to record the identity of the personnel who performed the testing for twelve (12) of twelve (12) test records reviewed. Findings include: 1. Twelve randomly selected patient test reports for complete blood counts (CBC), Cardiac panels, B-type natriuretic peptide (BNP), and Protime from June 2023 through February 2024 revealed none of the records included the identity of the person who performed the test. 2. The laboratory director confirmed these findings in an interview on April 5, 2024 at 9:00 AM. 3. The laboratory reports performing approximately 850 patient tests annually.