

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0690783	(X3) Date Survey Completed 12/13/2018
Name of Provider or Supplier Searhc Wrangell Medical Center	Street Address, City, State 232 Wood St, Wrangell, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Procedure Manual Review, the laboratory did not have complete procedures for Reticulocyte Counts and Gram Stains. Findings: 1. The procedure for Reticulocyte Counts did not contain the number and frequency of quality control material. 2. The procedure for Gram Stains did not include standardized or consistent terminology for recording microscopic observations, reporting the relative amounts of observed cells and microorganisms, and reporting organism or cell descriptions. 3. The laboratory</p>

performs approximately 10 reticulocyte counts and 5 gram stains annually. 4. The Laboratory Director and Technical Supervisor confirmed these findings on 12/13/2018 at 6:00 pm.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control records and Technical Supervisor interview, the laboratory did not test the reactivity of staining materials to ensure predictable staining characteristics and accurate reticulocyte enumeration each day of patient testing. Findings: 1. A review of patient reticulocyte counts in 2018 showed quality control records were missing for patients tested on 11/26/2018, 12/5/2018, and 12/12/2018. 2. The laboratory performs approximately 10 reticulocyte counts annually. 3. The technical supervisor confirmed these findings on 12/13/18 at 6:00 pm.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on Personnel Policy Review and Laboratory Director interview, the laboratory did not include the testing patient samples in the Technical Supervisor's Job Description. Findings: 1. The Technical Supervisor's position at the Hospital Facility is entitled Laboratory Services Manager. 2. The Hospital's Position Summary for the Laboratory Services Manager does not include patient testing. 3. The individual in this position routinely performs patient testing in all areas of the laboratory, including the specialties/subspecialties of Microbiology, Chemistry, Hematology, and Immunohematology. 4. The lab performs approximately 35,000 tests annually. 5. The Laboratory Director and Technical Supervisor confirmed these findings on 12/13/2018 at 6:00 pm.