

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0641830	(X3) Date Survey Completed 02/28/2023
Name of Provider or Supplier Camai Community Health Center Inc	Street Address, City, State 2 School Road, Naknek, 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 the lack of documentation and an interview with Testing Person 1 (TP#1) it was determined that the laboratory did not have a policy or procedure for identification, documentation, and notification of imminently life threatening results, or panic or alert values. Findings include: 1. A review of Laboratory Procedures and the Laboratory Quality Manual revealed the laboratory did not establish a policy or process to identify, document, and notify the authorized provider of imminently life threatening results, or panic or alert values. 2. An interview conducted on 2/28/2023 at 1:00 PM with the Laboratory Director and TP#1, confirmed the laboratory did not</p>

have a policy to identify which results would be considered significant and require immediate notification to the authorized provider or individual, and did not have a policy or procedure for documenting and notifying the authorized provider. 3. The laboratory reports performing approximately 5,000 tests annually.

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 Hematology Quality Control (QC) record review for 21 of 21 days in October 2022, and interview with Testing Person 1 (TP#1), the laboratory did not verify the daily background check was within acceptable limits prior to reporting patient Complete Blood Count (CBC) results on the Sysmex Poch-100i analyzer as required by the manufacturer. Findings include: 1. The Sysmex Poch-100i QC for 21 of 21 days in October 2022, did not include a documented review of the instrument background checks for acceptability. 2. The manufacturer's Daily Operating Procedure states "Record the background check on a daily checklist, or keep a copy of the printout for documentation. Compare the results to the acceptable background limits." 3. The laboratory reports performing 277 CBCs annually. 4. The testing person confirmed these findings in an interview on 2/28/2023 at 12:00 PM.