Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0669318	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Guam Seventh Day Adventist Clinic Laboratory	388 Ypao Road, Tamuning, GU	

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 review of the hematology procedure manual and interview with the technical supervisor (TS), the laboratory failed to have a step-by-step procedure for staining of manual white blood cell (WBC) differentials. Findings: 1. Review of the hematology manual showed no procedure for staining of manual WBC differentials. 2. Interview with the TS on September 22, 2021 at 1:00 PM, confirmed the laboratory failed to have a step-by-step procedure for staining of manual WBC differentials.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation of the Sysmex XN 550 hematology analyzer, review of Sysmex manufacturer inserts, temperature logs, and interview with the technical supervisor (TS), the laboratory failed to monitor the humidity to ensure proper operation of the instrumentation. Findings: 1. Observation of the hematology area showed one Sysmex XN 550 hematology analyzer. 2. Review of the temperature logs revealed the laboratory failed to document humidity. 3. Review of Sysmex physical specifications showed "to operate at 10-95 percent relative humidity (no condensation)." 4. Interview with the TS on September 22, 2021 at 11:00 AM confirmed the laboratory failed to monitor the humidity in the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the hematology staining area, three of three opened bottles of Sysmex XN hematology quality control (QC), and interview with the technical supervisor (TS), the laboratory failed to identify the contents and document the preparation and expiration dates of the reagents used in staining white blood cell (WBC) differentials and failed to label the hematology QC with expiration dates. Findings: 1. Observation of the hematology staining area showed two containers with no labeling of identity, preparation, and expiration dates. 2. Observation of the Sysmex XN hematology QC lot #11821401(L), #11831402(N), #11831403(H) showed no expiration date on three of three opened bottles. 3. Interview with the TS on September 22, 2021 at 11:00 AM confirmed the laboratory failed to identify WBC staining material with content, preparation, and expiration dates and failed to document expiration dates of opened hematology QC.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the technical supervisor (TS), the laboratory failed to perform at least a three point calibration (a minimal, mid-point, and maximum) verification every six months. Findings: 1. Review of 2019, 2020, and to date 2021 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TS on September 22, 2021 at 2:00 PM confirmed the laboratory failed to perform at least a three point calibration of sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient reports and interview with Technical Supervisor (TS) on 9/22/21 at 9:15 AM, the laboratory failed to indicate both the name and address of the laboratory where the test was performed for send-out testing. Findings included: 1) Review of the laboratory's Patient Portal result reports for 3 of 3 send-out tests (See Lipase on ACCN# 00388665) showed that send-out test results show the name of the performing laboratory but not the address as required. 2) Interview with Technical Supervisor (TS) on 9/22/21 at 9:15 AM confirmed the laboratory failed to indicate both the name and address of the laboratory where the test was performed for send-out testing.