Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0669318	07/18/2025
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
D0000	Federal Surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey. The following condition level and standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on direct observation, manufacturer's instructions and interview with the Technical Supervisor (TS), the laboratory failed to define, monitor and document the room temperature where temperature dependent reagents and supplies were located for 1 of 3 rooms. Findings Included: 1) During a laboratory tour on 7/18/2025 at 9:19 AM, the following reagents and supplies were observed in the supply/storage room without room temperature monitoring or documentation: a. 3 Siemens QuikLYTE Sample Diluent bottles, Lot #4KV635, Manufacturer storage temperature specifications 2 to 30 degrees C. b. 3 DCL Cellpack Boxes, Lot #A5095, Manufacturer storage temperature specifications 2 to 35 degrees C. c. 3 packs of 100 BD Vacutainer SST Tubes, Lot #5063109, Manufacturer storage temperature specifications 4 to 25 degrees C. d. 2 boxes of BD Veritor System for Rapid Detection of Flue A+B, Lot #256045, Manufacturer storage temperature specifications 2 to 30 degrees C. 2) In an interview on 7/18/2025 at 9:20 AM, the TS corroborated the

	findings that the supply/storage room did not have room temperature monitoring or documentation, where reagents and supplies were stored. II. Based on direct observation, manufacturer's instructions and interview with the Technical Supervisor (Ts), the laboratory failed to define temperature ranges consistent with the manufacturer's instructions, for the freezer temperature where 3 of 3 temperature dependent reagents and supplies were stored. Findings Included: 1) In direct observation on 7/18/2025 at 2:05 PM in the laboratory, 3 boxes of Quidel Triage Total 5 Control reagents, Lot #C4083AN, were found with manufacturer storage requirements of -20 degrees C or colder. 2) Review of the freezer temperature range revealed the range to be set at -30 degrees C to -15 degrees C. 3) In an interview on 7 /18/2025 at 2:10 PM in the laboratory, the TS corroborated the improper temperature range settings for the freezer in use.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's procedures, review of Rubella quality control (QC) testing records, and interview with technical consultant #1, the laboratory failed to document the daily rotator speed 3 of 3 months (April through June 2025) reviewed. Findings Included: 1.In review of the manufacturer's instructions for ASI rubella testing states, "rotate at 100 +/- RPM for 5 minutes." 2.In review of the laboratory procedure titled Rubajet Rubella states under 5.5, "place to test card on a flatbed rotator for 100 RPM for 5 minutes ..." 3. In review of the laboratory QC testing records titled Rubella Testing log for April through June 2025, the laboratory did not document the rotator speed for each day of use. 4. In an interview with technical consultant #1 at 1113, she confirmed that they were not documenting rotator speed before testing. 5. The laboratory performed 23 rubella tests between April through June 2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory quality control records, test records and confirmed in interview with the Technical Supervisor, the laboratory failed to take corrective action to ensure the evaluation of all patient test results

	obtained since the last acceptable test run, after 3 of 3 unacceptable quality control (QC) failures requiring recalibration from June 1, 2025 to July 18, 2025 (random review). Findings Included: 1. During a tour of the laboratory on 7/18/2025, 1 Siemens Dimension EXL 200 analyzer (S/N# DR274188) was observed in use in the chemistry section of the laboratory. 2. A review of the laboratory's QC records showed the following repeat control failure dates where recalibration was required, and patient test results since the last acceptable QC run were not evaluated: a. SDAdventist Clinic (S/N# DR274188) Jun 16, 2025 b. SDAdventist Clinic (S/N# DR274188) Jun 27, 2025 c. SDAventist Clinic (S/N# DR274188) June 30, 2025 3. A review of the laboratory's test records labeled "Guam SDA Clinic Laboratory Order Log" showed the following number of patients for whom tests were run for the previous day and not re-evaluated: a. 6/15/2025 - 31 patients, #00472471-00472501 b. 6/26/2025 - 34 patients, #00473011-00473044 c. 6/29/2025 - 52 patients, #00473083-00473138 4. In an interview on 7/18/2025 at 2:45 PM, the TS confirmed that the laboratory did not perform a patient evaluation, post recalibration, due to multiple QC failures.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and interview with staff, the laboratory failed to ensure individuals performing testing met the required qualifications. The laboratory failed to ensure 1 of 5 testing personnel (TP-5) met requirements to perform high complexity testing. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this

	section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS) 209 Form, personnel records, and confirmed in an interview with the Technical Supervisor (TS), the laboratory failed to meet testing personnel (TP) qualifications for 1 of 5 individuals performing high complexity testing. Findings Included: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report (CLIA), provided by the laboratory on 7/18/2025, identified TP-5 performing high complexity testing. 2. Review of the laboratory's TP educational credential records revealed a Bachelor of Science degree and High School diploma from the Philippines, but no foreign degree equivalency to U.S. standards to meet requirements of performing high complexity testing. 3. In an interview on 7/18/2025 at 2:42 PM, the TS confirmed that TP-5 did not have record of foreign degree equivalency, in order to qualify for high complexity testing.