Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0662216	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Guam Dept Public Hlth & Soc Svcs Central Lab	761 South Marine Corps Drive, 3rd Floor, 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	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey on July 17, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations, and the following standard level deficiencies were cited.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation of the molecular laboratory, and interview with the laboratory supervisor, the laboratory failed to ensure a unidirectional work flow for the molecular clean room, extraction rooms and PCR room from July 2023 to July 2025. Findings Included: 1. Observation of the molecular laboratory in July 17, 2025, revealed the molecular clean room, extraction rooms and PCR rooms were all attached to a central room in a cross pattern and did not have a unidirectional work flow. 2. By interview, the laboratory supervisor confirmed on July 17, 2025, at 5:00 pm the molecular laboratory did not have a unidirectional workflow.
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 observation of the laboratory storage areas, lack of monitored temperature records, and an interview with the laboratory supervisor the laboratory failed to monitor and document room temperatures for areas outside the laboratory where laboratory reagents and testing kits were stored from 2023 to 2025 (2 of 2 years). Findings Included: 1. On July 17, 2025, at 2:15 pm., while on a tour of the laboratory, the following testing kits were observed being stored outside of the laboratory from 2023 to 2025 with the following temperature requirements: a. 35 bottles of Reagent through 170 ml, Catalog #990556, Store at 15 - 25 degrees Celsius. b. Six boxes of DNA tissue Kits, E2 1&2, Store at 15 - 25 degrees Celsius. c. Eight boxes of QIAamp 96 Virus QiaCube HT Kits, Lot#58101681, Store at 15 - 25 degrees Celsius. 2. On July 17, 2025, at 5:00 p.m., the laboratory supervisor confirmed, by interview, temperatures were not being monitored outside of the laboratory. II. Based on observation of the laboratory, review of storage room temperature records, and interview with the laboratory supervisor, the laboratory failed to define room temperature ranges consistent with the manufacturer's storage requirements for 28 out of 28 Blood Collection tubes containers stored in a storage room. Findings Included: 1. Observation of the laboratory on July 17, 2025 at 11:30 am revealed a storage room where, the following BD Vacutainer Blood Collection tube containers were stored with storage requirements of 4 to 25 degrees Celsius: a. Twelve BD Vacutainer Blood Collection tubes - Yellow Top - Lot#4236591. b. Five BD Vacutainer Blood Collection tubes - Red Top - Lot#4236618. c. Eleven BD Vacutainer Blood Collection tubes - Orange/Gray Top - Lot#4233264. 2. Review of the storage room temperature log on the wall showed temperature ranges of 20 - 38 degrees Celsius were being monitored. 3. By interview with the laboratory supervisor on July 17, 2025 at 12:00 pm, the laboratory supervisor confirmed the temperature ranges differed from the manufacturer's storage requirements for the collection tubes. III. Based on observation of the laboratory, review of TB room temperature records (Room B-2), and interview with the laboratory supervisor, the laboratory failed to define room temperature ranges consistent with the manufacturer's storage requirements for one of one box of Fisherbrand AFB check slides were being stored. Findings Included: 1. Observation of the laboratory on July 17, 2025 at 1:00 pm revealed one box of Fisherbrand AFB check slides with a storage requirement of 20 - 30 degrees Celsius. 2. Review of the TB laboratory room temperature log on the wall showed temperature ranges for Room B-2 were set at 18 - 28 degrees Celsius. 3. Further review of room B-2 temperature records revealed the following days the room temperature fell below the manufacturer's storage requirements (19 degrees Celsius) in 2025: a. February - 7 out of 28 days. b. April - 4 out of 30 days c. May - 10 out of 31 day. d. June - 10 out of 30 days. e. July - 5 out of 17 days. 4. By interview with the laboratory supervisor on July 17, 2025 at 5:00 pm, the laboratory supervisor confirmed the temperature ranges differed from the manufacturer's storage requirements for the Fisherbrand AFB check slides.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory reagent safety data sheets, and interview with the laboratory supervisor, the laboratory failed to include expiration dates for 56 of 56 bottles of chemicals. Findings Included: 1. Observation of the laboratory on July 17, 2025 at 1:15 pm revealed the following chemicals without expiration dates: a. 53 bottles of Spectrum Pheol Loose Crystals, Received June 21, 2005, Lot#AD501. b. 02 bottles of EKI Basic Fuchin Powder, no received date lot#1612516. c. 01 bottle of Methylyene Blue, Received December 1, 2011, lot#106583. 2. The laboratory SDS did not include expiration dates for the above chemicals used for clinical testing. 3. The laboratory did not have a procedure for assess expiration dates for chemicals received without one or a retest date. 4. By interview, the laboratory supervisor confirmed the above finding on July 17, 2025, at 5:00 pm.