

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 64D1048456	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier American Samoa Dept Of Health Clinical Lab	Street Address, City, State 3965 Petesa Rd Tafuna Village, Pago Pago, AS	
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 a recertification survey on 8/14/2025, the following standard level deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, and interview with testing personal #1, the laboratory failed to to define, monitor, and document room temperature where one hundred seventy-five Becton Dickinson (BD) tubes were stored in the phlebotomy area as evidenced by: 1. Based on direct observation at 1420 the laboratory had the following tubes in the phlebotomy room: a. 47- BD 3.5ml SST Lot #435605 expiration date:12-22-2025 b. 104- BD 3.0ml EDTA lot#434405 expiration date: 4-30-2026 c. 24- BD EDTA lot#5036670 expiration date: 6-30-2026 2. In review of the manufacturer's instruction labeled on the package for storage requirements stated, "4-25 degrees C." 3. In interview with testing person #1 at 1421 she stated that they do not monitor room temperature in the phlebotomy area.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p>

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:

Based on manufacturer's instructions, review of the laboratory's maintenance records, and interview with testing person #5, the laboratory failed to perform monthly and quarterly maintenance according to manufacturer's instructions for the Gene Xpert and Sysmex XP-300 for 8 of 8 months reviewed in 2025 as evidenced by: 1. In review of the manufacturer's instructions for the Gene Xpert under 9.1 Maintenance tasks, the following maintenance is due quarterly and monthly: a. Quarterly - Clean plunger rod and cartridge bay b. Quarterly - Clean the instrument surfaces c. Monthly - Archive tests d. Monthly - Purge tests e. Monthly - Replace fan filter 2. In review of the manufacturer's instruction for the Sysmex XP-300 under Cleaning and Maintenance, the following maintenance is due quarterly and monthly: a. Every 3 month - Clean SRV b. Monthly - Clean TD c. Monthly- Clean waste chamber 3. In review of the laboratory's maintenance log (January 2025 through the time of the survey) for Gene Expert the laboratory did not perform the monthly and quarterly maintenance. 4. In review of the laboratory's maintenance log (January 2025 through the time of the survey) for the XP-300 the laboratory did not perform quarterly and monthly maintenance 5. In interview with testing personnel #5 at 1322 she stated that they did not do the monthly or quarterly maintenance, and she didn't know why it hadn't been done.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's individual quality control plan (IQCP) and interview with testing person #1, the laboratory failed to have a risk assessment (RA) for the Biofire GI panel/Respiratory Panel and no RA for the Gene Xpert (Tuberculosis[TB], Gonorrhea /Chylamdia [GC/CT]) assays reviewed for 2024 and 2025 as evidenced by: 1. In review of the laboratory's IQCP the laboratory could not provide documentation for their risk assessments which did not include specimen, test system, reagent, environment, and testing personnel for both the Gene Xpert and Biofire. 2. In an interview with testing person #1 at 1130 she stated that they did not have the risk assessment for either one of the platforms.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control plan, quality control records, patient testing records, and interview with testing person #1, the laboratory failed to follow their quality control plan for running quality control once a month for 1 of 4 months in 2024 reviewed for the Gene Xpert Gonorrhea /Chylamdia [GC/CT]) as evidenced by: 1. In review of the laboratory quality control plan for the Gene Xpert (GC/CT) they were to run the external controls once a month. 2. In review of the laboratory quality control records, for September 2024 to December 2024, the laboratory did not an external control for December 2024. 3. The following patients were ran without a monthly control: a. 12/27/2024 patient #193692 b. 12/27/2024 patient #10007835 c.12/27/2024 patient #197200 3. In an interview with testing person #1 at 1132, she stated the QC bottles expired on the 21st of November so they ran an extra external control on November 21st to cover those patient in all of December.