

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D0959480	(X3) Date Survey Completed 07/17/2025
Name of Provider or Supplier Northern Region Community Hlth Ctr Lab	Street Address, City, State 520 West Santa Monica Avenue, Dededo, 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 a recertification survey, the following standard level deficiencies were cited:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of patient testing, and interview with testing personnel #1, the laboratory failed to follow their own procedure for reporting White blood counts (WBCs) and red blood cells (RBCs) wet mount microscopic examinations for 2 of 2 patients reviewed as evidenced by: 1. In review of the laboratory's procedures for wet mounts, under 16.5 Interpretation of results states, "Report the following findings as occasional, few, moderate, or Many: RBCs, WBCs, Clue cells, Trichomonas, yeast/Monilia, Epithelial cells, Bacteria." 2. In review of the following patients, they were reported as numerical value for RBCs and WBCs: a. Patient # 37575 reported 3-1-2025 as WBCs = 0-2, RBCs = 0-2. b. Patient # 31006 reported 4-2-2025 as WBCs = 5-10, RBCs 2-5. 3. In an interview with testing personnel #1 at 1323 she confirmed they were not following their own procedures.</p>
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</p>

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:
Based on review of manufacturer's instructions, environmental laboratory charts, and interview with testing personal #1, the laboratory failed to define a humidity criteria for reliable testing operation for the XP-300 hematology analyzer in 2025 as evidenced by: 1. In review of the manufacturer's instructions for the XP-300 hematology analyzer states under 2.2. installation, "use the instruments in place where relative humidity ranges between 30% and 85%." 2. In review of the laboratory's environmental laboratory charts, the laboratory did not monitor humidity. 3. In an interview with testing personnel #1 on 07/17/2025 at 1345 stated they do not monitor humidity in 2025.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on direct observation, and interview with testing personnel #1, the laboratory failed to ensure 200 tubes of BD (Becton Dickinson) BBL saline did not exceed their expiration date and were available for use for wet mount patient testing in July 2025 as evidenced by: 1. In direct observation 1122 on 07/17/2025 the following BD BBL saline tubes were expired and available for use: a. 200-BD BBL Saline tubes Lot #3319162 expiration date 5-14-2025. 2. In an interview with testing personnel #1 at 1122, she stated that saline was used for wet mount testing and they didn't have any other tubes in the clinic to use for wet mounts.