

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D2137458	(X3) Date Survey Completed 07/16/2025
Name of Provider or Supplier Diagnostic Laboratory Services - Amc-1	Street Address, City, State 1244 N Marine Corps Dr, 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 a recertification survey on 7/16/2025. 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 direct observation, review of the laboratory's policy and procedures, and interview with the Technical Consultant, the laboratory failed to follow its own policy for centrifuge Revolutions Per Minute (RPM) settings for 1 of 1 centrifuge. Findings Included: 1. In direct observation on 7/16/25 at 10:01 AM in the laboratory, one Centrifuge (642B Brucker, S/N #210238AE285) was seen in use with the following settings: Blood - 3296 RPM, 7 Mins Urine - 3296 RPM, 1 Mins 2. Review of the laboratory's policies and procedures for 'GUAM-AMC1 HORIZON ELITE URINALYSIS, Urine Centrifuge Spin Time Chart' showed a setting of 1983 RPM for 1 minute for urine specimens. 3. In an interview on 7/16/25 at 10:03 AM in the laboratory, the Technical Consultant confirmed the discrepancy between the policy and the centrifuge settings set by the service technician post calibration/preventative maintenance (PM).</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:

I. Based on direct observation, manufacturer's instructions, temperature records, and interview with the Technical Consultant, the laboratory failed to define, monitor and document the room temperature in the Phlebotomy room, where 81 of 81 BD Vacutainer tubes were stored. Findings Included: 1. In direct observation on 7/16/2025 at 8:52 AM, the following supplies were seen in use without temperature monitoring or documentation: a. 41 BD Vacutainer gold-top Serum Separator Tubes (SST), Ref #367986, Manufacturer storage temperature requirements 4 C to 25 C degrees. b. 35 BD Vacutainer K2E lavender-top tubes, Ref #367856, Manufacturer storage temperature requirements 4 C to 25 C degrees. c. 5 BD Vacutainer Trace Element K2 EDTA blue-top tubes, Ref #368381, Manufacturer storage temperature requirements 4 C to 25 C degrees. 2. Review of the laboratory's temperature records revealed no temperature ranges defined, monitored and documented for the phlebotomy section. 3. In an interview, the Technical Consultant confirmed the temperature was not defined, monitored and documented in the phlebotomy area. II. Based on direct observation, review of manufacturer instructions, temperature records, and interview with the Technical Consultant, the laboratory failed to define freezer temperature ranges consistent with the manufacturer's instructions for three of three reagents. Findings Included: 1. In direct observation on 7/16/25 at 2:42 PM in the laboratory, one Vissani Freezer was seen in use monitored by a Fisherbrand Traceable thermometer set to -30 degrees C to -15 degrees C. The following reagent(s) were seen stored within: a. 3 Boxes Quidel Triage Total 5 Control 1, Lot #C4099AN, Manufacturer storage temperature requirement -20 C and colder. 2. In an interview on 7/16/25 at 2:50 PM in the laboratory, the Technical Consultant confirmed the temperature ranges differed from manufacturer instructions of the reagent(s) stored.