

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  65D2137459	<b>(X3) Date Survey Completed</b>  07/22/2025
<b>Name of Provider or Supplier</b>  Diagnostic Laboratory Services, Inc - Amc-2	<b>Street Address, City, State</b>  263 Vietnam Veterans Hwy, Mangilao, GU	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey on 7/22/2025. The following standard level deficiencies were cited.
<b>D5401</b>	<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 followed its own policy for centrifuge Revolutions Per Minute (RPM) settings for one of one centrifuge. Findings Included: 1. In direct observation on 7/22/25 at 10:01 AM in the laboratory, one Horizon 12 Flex Centrifuge (S/N #230705AB365) was seen in use with the following settings: Blood - 3507 RPM, 6 Mins Coag - 3203 RPM, 13 Mins Urine - 1803 RPM, 4 Mins 2. Review of the laboratory's policies and procedures for 'GUAM-AMC2 HORIZON ELITE URINALYSIS, Urine Centrifuge Spin Time Chart' showed a setting of 1525 RPM for 1 minute for urine specimens. 3. In an interview on 7/22/25 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 preventative maintenance (PM).</p>
<b>D5413</b>	<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 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 one of one reagent. Findings Included: 1. In direct observation on 7/22/25 at 9:53 AM in the laboratory, one Kenmore 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. 1 Box Triage Total 5 Control 1, Lot #C4099AN, Manufacturer storage temperature requirement -20 C and colder. 2. In an interview on 7/22/25 at 10:03 AM in the laboratory, the Technical Consultant confirmed the temperature ranges differed from manufacturer instructions of the reagent(s) stored.