

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D0970478	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Diagnostic Laboratory Services Inc - Fhp	Street Address, City, State 548 S 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of manufacturer's instructions, documentation of freezer temperatures, observation of quality control (QC) material stored in the freezer, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the manufacturer's instructions for storage of control material for 18 of 18 testing days since September 1, 2021 through September 21, 2021. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquid unassayed Multiquel control showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 15 degrees C to minus 30 degrees C. Review of the temperature chart from September 1-21, 2021 showed 18 of 18 days, the temperature failed to meet the required range. 3. Observation of the laboratory freezer showed three sets of Bio-Rad Multiquel unassayed control level I, II, III currently in use in the laboratory. 4. Interview with the TS#1 on September 21, 2021 at 11:00 AM confirmed the laboratory failed to properly monitor the freezer and store QC materials and supplies per manufacturer's instructions.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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 observation of Sysmex XN-L Check hematology controls, review of manufacturer insert, laboratory quality control (QC) procedure, and interview with the technical supervisor (TS) #1, the laboratory failed to use unexpired control. Findings:

1. Observation of the refrigerator located in the laboratory showed one bottle of Sysmex low control (lot #11831401), one bottle of normal control (lot #11831402) and one bottle of high control (lot #11831403) opened on August 16, 2021 and in use for complete blood cell counts. 2. Review of the Sysmex manufacturer insert showed "opened vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." 3. Review of the laboratory's quality control procedure stated "Opened-Stored at 2-8 degrees Centigrade. Stable for 15 days." 4. Interview with TS #1 on September 21, 2021 at 12:00 PM confirmed the laboratory used control material past the expiration date.