Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0662219	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Lab Services, Inc - Itc	590 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: Based on review of procedure "Chemistry Roche 6000 /311/411 G100.1 COBAS CHEM" interview with Technical Supervisor #2 (TS2), and review of QC records on September 23rd, 2021 at 2:25 PM, laboratory personnel failed to follow established written Quality Control procedures. Findings included: 1. "Chemistry Roche 6000 /311 /411 G100.1 COBAS CHEM procedure Section 3 Frequency of Use" indicates that QC is tested "Daily after startup maintenance procedures - 2 levels in the morning and 1 level in PM". Per review of QC and interview with TS2, laboratory is running 3 levels of QC in the morning and no QC in the evening. 2. "Chemistry Roche 6000 /311 /411 G100.1 COBAS CHEM procedure Section 5 "QC Review" states the interpretation of acceptable QC is based on 2 levels of QC being run at a time, not 3. There is not clear guidance about what acceptable QC is. 3. For assay HDL, the laboratory is running alternate Roche QC if all levels of Biorad QC have failed, but it is not clear per procedure if that is acceptable. 4. Interview with TS2 on September 23rd, 2021 at 2:25 PM confirmed that laboratory personnel failed to follow established written Quality Control procedures. 5. At the time of the survey on September 23rd, 2021, the laboratory performed 1,581,231 Chemistry tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedures "Safety Precautions for Microbiology Dept G401. 90.10.1", "BacT/ALERT 3D Operating Procedure (MIC-SH-EQP-3D-10)", and "Blood Culture Workup and Reporting MIC-SH-CUL-BC-12", and interviews with Technical Supervisor #2 (TS2) on September 23, 2021, at 11:45 AM and 2:25 PM, the laboratory procedure manuals failed to include laboratory-specific instructions for step-by-step performance of the procedures, including test calculations and interpretation of results. Findings included: 1. The procedure "Safety Precautions for Microbiology Dept G401.90.10.1" Section 2 states "Process specimens or cultures with possibility of aerosol contamination in a biological safety cabinet (BSC) or vertical laminar flow hood ...". The procedure does not reflect the laboratory practice which is plating urine cultures on open bench in main lab, by the lab door, next to a functioning centrifuge, in heavy traffic area. 2. The procedure "BacT/ALERT 3D Operating Procedure (MIC-SH-EQP-3D-10)" states "Test Frequency (24hr/7days per week)" but the lab is not staffed 24 hours. Current operating hours are M-Sa 6:30 AM to Midnight. On Sun 1 PM-6 PM. This leaves both a 13-hour period then another 12-hour period on Saturday-Sunday where staff would not be available to detect a positive. 3. The procedure "Blood Culture Workup and Reporting MIC-SH-CUL-BC-12" Section 1.3 includes instructions on how to load MycoF/Lytic bottles, but this lab does not perform this assay. 4. Interview with TS2 on September 23, 2021, at 11:45 AM confirmed that the laboratory is using procedures that are also used by other laboratories. 5. Interviews with the TS2 on September 23, 2021, at 2:25 PM confirmed the laboratory failed to include laboratory-specific instructions for step-by-step performance of the procedures, including test calculations and interpretation of results. 6. At the time of the survey on September 23, 2021, the laboratory performed 1,969,171 tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on review of 3 of 3 patient reports (see YE10325362 7yr F), Critical Result SpreadSheet, T-Bili Age-Specific Range print out from Laboratory Information System (LIS), procedure "CHEM-SH-TBIL-02 Total Bilirubin: Cobas 6000", and interview with Technical Supervisors (TS) TS1 and TS2 on September 23, 2021, at 12: 30 PM; the laboratory failed to provide "reference intervals" or "normal" values that accurately reflected the patient population. 1. Age-specific ranges are not clear/the same between Critical Result SpreadSheet, T-Bili Age-Specific Range print out from LIS, procedure "CHEM-SH-TBIL-02 Total Bilirubin: Cobas 6000" procedure, and the LIS. Additionally, the nomenclature for age range break-downs is different between them. 2. Nomenclature for different tests with age-specific ranges are different (TSH, ALP, Phos) with the ranges not clearly defined and "Adult" being used but not defined. 3. Interview with TS1 and TS2 on September 23, 2021, at 12:30 PM confirmed that laboratory personnel failed to provide "reference intervals" or "normal" values that accurately reflected the patient population. 4. At the time of the survey on September, 23rd 2021, the laboratory performed 1,969,171 tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, blood culture procedures, and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure the quality assessment program was maintained to identify failures. Findings: 1. Review of the blood cultures procedure, "MIC-SH-CUL-BC-12 Blood Culture Workup and Reporting", section 3 states "Contact client immediately with all positive blood culture results: treat as critical result." 2. Interview with TS #1 revealed "the laboratory is closed from 12 AM to 6 AM Monday-Saturday. On Sunday, a testing personnel comes in for four hours starting at 1 PM. Laboratory is not staffed from midnight Saturday night to approximately 1pm Sunday afternoon and then again not staffed from 6pm Sunday evening to 6am Monday morning. Lab is also closed midnight to 6am Mon-Sat." TS #1 confirmed the laboratory director failed to have a system to detect positive blood cultures and identify failures from the Bactec blood culture analyzer when the laboratory is closed.