Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0662219	05/04/2023
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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on laboratory personnel interview and chemistry corrective action log record review on May 4, 2023 at 11:00 am, the laboratory's analytic systems quality assessment for chemistry failed to include a review of the effectiveness of corrective actions taken to resolve problems. Findings included: a. In chemistry, it was the practice of the laboratory to perform patient testing using one of three Roche Hitachi Cobas 6000 instruments. b. According to laboratory personnel, when the test results of quality control materials tested on the Roche Hitachi Cobas 6000 instruments failed to met the laboratory's criteria for acceptability, laboratory staff were to document the occurrence in the "DLS - ITC Chemistry Department Action Log." c. As part of the laboratory's analytic systems quality assessment, the "DLS - ITC Chemistry Department Action Log" and chemistry quality control records were to be reviewed monthly. d. On November 6, 2022, laboratory records indicated that the level 1 quality control material test result for potassium failed to meet the laboratory's criteria for acceptability. However, this occurrence of an unacceptable potassium quality control test result was not documented in the "DLS - ITC Chemistry Department Action Log." e. During this survey, laboratory personnel was able to determine that no patient potassium tests were performed and reported on November 6, 2022. f. Laboratory records indicate that the laboratory's November 2022 potassium quality control record and "DLS - ITC Chemistry Department Action Log" were reviewed pursuant to the laboratory's monthly analytic systems quality assessment protocol but

	without any notation as to why the unacceptable potassium quality control test result was not documented in the "DLS - ITC Chemistry Department Action Log" and/or why potassium quality control testing occurred when no patient specimens were tested and reported. The laboratory's analytic systems quality assessment mechanisms were not effective/sufficient in recognizing these issue until it was discovered during the course of this survey. g. According to laboratory survey records, the laboratory performed approximately 2 million patient tests annually using the Roche Hitachi Cobas 6000 instruments.