Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	65D0970478	05/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Laboratory Services Inc - Fhp	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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and BD Affirm VPIII Microbial Identification Test quality control record review on May 4, 2023 at 12:30 pm, the laboratory failed to include positive control materials at least once each day patient specimens were assayed. Findings included: a. It was the practice of the laboratory to test patient specimens using the BD Affirm VPIII Microbial Identification Test. According to the manufacturer, this test is intended for use in the detection and identification of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis /vaginosis. b. Laboratory records indicate that each day patient specimens are tested using the BD Affirm VPIII Microbial Identification Test, the laboratory also tests negative and positive control materials using this test system. However, the laboratory uses one positive control material that is known to be positive for Candida species, Gardnerella vaginalis, and Trichomonas vaginalis even though the laboratory reports patient test results for each of these organisms individually. That is, each day patient specimens are tested using the BD Affirm VPIII Microbial Identification Test, the laboratory does not test a positive control control material that includes Candida species only, a positive control material that includes Gardnerella vaginalis only, and a positive control material that includes Trichomonas vaginalis only, even though the

	laboratory reports patient test results for each of these organisms individually. c. According to laboratory survey records, the laboratory tests approximately 1,796 patient specimens annually using the BD Affirm VPIII Microbial Identification Test.