Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2235419	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
American Testing Solutions Llc	174 Thalia Vilage Shoppes 4101 Bonney Road, Virginia Beach, VA	

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
D0000	An announced CLIA initial survey was conducted at American Testing Solutions, LLC on June 22, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's user guide, lack of documentation, and interviews, the laboratory failed to document monitoring of the molecular lab room humidity for five (5) of the 5 months reviewed (January 2022 to the time of the inspection June 22, 2022). Findings include: 1. During a tour of the laboratory on 6/22 /22 at approximately 10:30 AM, the inspector noted real time Cepheid GeneXpert Polymerase Chain Reaction (PCR) assays were being utilized for SARS-CoV-2 testing on one (1) Infinity 48 analyzer in the facility's single use room designated for COVID-19 molecular testing. 2. Review of the Cepheid Infinity-48s user guide revealed instructions outlined under Environmental Requirements: "Operating temperature 15-30 C, Ambient humidity 20% to 80%, non condensing". 3. Review of

	the molecular laboratory's available environment logs revealed no documentation of monitoring humidity. The inspector requested to review humidity records for the timeframe of January 2022 to 6/22/22. No records were available for review. 4. An exit interview with the Laboratory Director, Clinical Consultant, and the staff testing personnel on 6/22/22 at approximately 2:00 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of procedures, maintenance records, lack of documentation, and interviews, the laboratory failed to document their molecular analyzer's weekly, monthly, and quarterly preventative maintenance according to manufacturer and laboratory log protocols during five (5) of 5 months reviewed (timeframe: January 2022 to the date of the inspection on June 22, 2022). Findings include: 1. Review of the laboratory's procedures revealed "Policy/Procedure Cepheid GeneXpert Infinity System" which outlined the following required maintenance protocols: Weekly - "Clean kiosk table top/keyboard/monitor according to Chapter 9 in Operator Manual, Quick Clean Conveyor Belt, Perform Shutdown according to Chapter 5 Operating Instructions for detailed protocols"; Monthly - "Vacuum rear fan filters, Archive Tests according to Chapter 5 Operating Instructions for detailed protocols"; Quarterly - "Clean Kiosk Scanner, Clean Conveyor Belt according to Chapter 9 in Operator Manual, Clean Cartridge Bays and Plunger Rods, Clean Instrument Surfaces, Replace Fan Filters"; A total of three (3) weekly, two (2) monthly, and five (5) quarterly maintenance activities were outlined as required. 2. Review of the laboratory's GeneXpert Infinity monthly maintenance logs revealed the 3 weekly, 2 monthly, and 5 quarterly maintenance tasks outlined above listed as required and to be "checked once completed according to manufacturer's instructions". The inspector reviewed maintenance logs for timeframe of January 2022 to the date of the survey 6/22/22 and noted: Weekly maintenance was not documented in 2 of four (4) weeks in January, February, April, 3 of 4 weeks in May; Monthly maintenance was not documented for February, March, April, May; Quarterly maintenance was not recorded as performed in the five months reviewed. The inspector requested additional documentation of performance of the maintenance tasks outlined above. No additional records were available to review. 3. An exit interview with the Laboratory Director, Clinical Consultant, and staff testing personnel on 6/22/22 at approximately 2:00 PM confirmed the above findings.