Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2201186	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hampton University Clinical Laboratory (Covid-19)	519 E Queens Street #214, Hampton University, 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 Hampton University Clinical Laboratory (COVID-19) on April 12, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of procedures, proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to retain an attestation statement signed by the laboratory director (LD) for one (1) of three (3) events reviewed on April 12, 2022. Findings include: 1. Review of the laboratory procedure manual revealed a Proficiency Testing (HU-ADMIN 113) policy that outlined: "The individual testing/examining the samples and the laboratory director must attest to routine integration of the samples into the patient workload using the laboratory's routine methods". 2. Review of the laboratory's College of American Pathologists (CAP) SARS-CoV-2 proficiency records (3 events: 2021 A, 2021 B, 2022 A) revealed no signed LD attestation statement for the following event: CAP 2022 COV2Q-A, received by the laboratory in February 2022. The inspector requested to review the LD attestation documentation for the event outlined above. No record was retained /available for review. 3. An interview with the Vice President for Research and Clinical Laboratory Manager, on 4/12/22 at approximately 4:30 PM, confirmed the above findings.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, lack of documentation, and interviews, the laboratory failed to label two (2) of five (5) nuclease-free invitrogen reagent bottles utilized for polymerase chain reaction (PCR) SARS-CoV-2 testing with appropriate open-expiration dates at the time of the survey on April 12, 2022. Findings include: 1. During a laboratory tour on 4/12/22 at approximately 1:45 PM, the inspector noted 2 Thermo Fisher Scientific Ambion Nuclease-Free reagent containers (Lot Number 2110477) in use without a revised open-expiration date. The inspector inquired regarding the protocols for storage/handling to maintain purity of the reagent once opened for use. The laboratory manager stated: "We use the Nuclease-Free reagent water in our negative control process. Our reagents should have a receive date and opened stability date on all of those bottles". 2. Review of the laboratory procedures revealed a quality assurance protocol (title: Quality Assessment Plan, HU-PRO)that outlined: "Laboratory reagents, testing kits, control sets and all supplies will be dated upon receipt and when opened for use. The expiration date of all supplies will be noted." The inspector requested to review Thermo Fisher Scientific Ambion Nuclease-Free package insert. No record was retained/available for review. 3. An interview with the Vice President for Research and Clinical Laboratory Manager, on 4/12/22 at approximately 4:30 PM, confirmed the above findings.