

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2128479	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Chp-Cvfp Liberty University Student Health	Street Address, City, State 1606 Regents Pkwy, Lynchburg, 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 recertification survey was conducted at CVFP-Liberty University Student Health on June 8, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that 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:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), manufacturer's instructions for use (IFU), and lack of documentation, the laboratory failed to follow the manufacturer's instructions for test verification protocols for Xpert Xpress SARS-CoV-2 and Xpress SARS-CoV2-/Flu /RSV Cassettes from December 20, 2021 to the date of the inspection on June 8, 2021. Findings include: 1. During a tour of the laboratory on 6/8/21 at approximately 1:00 PM, the inspector noted three (3) Cepheid Xpert Xpress analyzers (Serial Numbers: 843966, 843963, 844201) were in use for rapid, real-time polymerase chain reaction (PCR) testing by with SARS-CoV-2 and SARS-CoV2-/Flu/RSV test cassettes. 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 06/08/21 revealed an EUA was granted for the two Cepheid test methods outlined above. 3. Review of the EUA documentation package insert for the test cassettes outlined above revealed manufacturer's instructions: "For use under the Emergency Use Authorization only. EUA documentation and product resources are available</p>

online at Cepheid.com/coronavirus." The inspector reviewed the manufacturer's EUA online documents and product instructions for both test methods which included: Xpert Xpress SARS-CoV-2 Verification Protocol: "Please consult guidance from CMS regarding Emergency Use Authorized diagnostic tests. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. The Xpert Xpress SARS-CoV-2 Verification Protocol guide is an example of verification for accuracy, reportable, and reference ranges and may be modified to meet site-specific criteria. The Laboratory Director is ultimately responsible for ensuring that verification procedures are in accordance with local, state, and federal accrediting organizations. For further guidance on appropriate quality control practices, refer to 42 CFR 493.1256." Xpert Xpress SARS-CoV-2/Flu/RSV Verification Guide: "This test has not been FDA cleared or approved. This protocol was developed by Cepheid Medical/Scientific Affairs, to provide assistance with verification studies of the Xpert Xpress SARS-CoV-2/Flu/RSV test. It concerns one aspect of the verification process, which is testing of known positive and negative samples. It is the laboratory director's responsibility to ensure that a complete and adequate verification study is performed in accordance with federal, state, and local laws". The inspector requested to review the LD's approved verification or validation study for the SARS-CoV-2 and SARS-CoV2-/Flu/RSV testing. No records were available for review. 4. An interview with the primary testing personnel and Ancillary Services Manager on 06/08/21 at approximately 3:30 PM, confirmed the above findings.

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:
A. Based on a tour, interviews, review of manufacturer's package inserts, policies/procedures, temperature logs, and lack of documentation, the laboratory failed to monitor room temperature of Cepheid SARS-CoV-2 and SARS-CoV2-/Flu/RSV reagent storage area according to the manufacturer's requirement and an approved quality assurance (QA) policy during the six months reviewed (December 2020 to the date of the inspection on June 8, 2021). Findings include: 1. During a survey of the laboratory's reagent storage on 6/8/21 at approximately 2:00 PM, the inspector inquired regarding the storage area for the Cepheid SARS-CoV-2 and SARS-CoV2-/Flu/RSV test cassettes. The primary testing personnel (TP) stated: "We are storing them in an exam room because we do not have room for them here in the lab". The inspector toured the storage area with the primary TP and noted forty-six (46) cases of Cepheid SARS-CoV-2 and SARS-CoV2-/Flu/RSV test kits, sixty (60) tests per case (lot numbers 242802, 244308, 254359, 264531). The inspector noted the varied lot numbered boxes were marked as received from December 2020 up to May 2021. 2. Review of the package insert for the test cassette methods outlined above revealed manufacturer's storage and stability instructions: "Store kits 2-28 C". 3. Review of the laboratory's temperature log sheets for calendar year 2020 and up to the June 8, 2021

revealed no documentation of the exam room reagent storage area. The inspector requested to review room temperature monitoring logs for the Cepheid SARS-CoV-2 and SARS-CoV2-/Flu/RSV test kits (lot numbers outlined above) stored in the exam room storage area. No records were available for review. The Ancillary Services Manager stated at approximately 2:30 PM: "I have ordered extra thermometers and we will start recording the storage area temperature. I stored the boxes in my office up until a short while ago. I moved them here because I ran out of room and it is easier to oversee stock. " 4. Review of the laboratory's procedure manual revealed a quality assurance policy that stated "Our quality assurance plan addresses the entire laboratory process, from the time a patient or sample arrives in our facility, to the moment results are recorded on patient charts and reported to the appropriate health care provider. QA Forms for each monitor which are suitable for documenting the review are part of this plan." The inspector noted that the QA checklist included a review of "temperature records for temperature fluctuations for instruments and all test methods". Cepheid Xpress systems and reagents were listed for temperature monitoring. 5. An interview with the primary testing personnel and Ancillary Services Manager on 06/08/21 at approximately 3:30 PM, confirmed the above findings. B. Based on a tour, review of manufacturer's package inserts, temperature logs, and lack of documentation, the laboratory failed to monitor room temperature/humidity of an adjacent exam room where one (1) of three (3) Cepheid Xpert Xpress analyzers (Instrument B) was utilized for patient testing according to the manufacturer's requirement during the six months reviewed (December 2020 to the date of the inspection on June 8, 2021). Findings include: 1. During a tour of the laboratory on 6/8/21 at approximately 1:00 PM, the inspector noted three (3) Cepheid Xpert Xpress analyzers (Serial Numbers SN: 843966, 843963, 844201) were in use for rapid, real-time polymerase chain reaction (PCR) testing by SARS-CoV-2 and SARS-CoV2-/Flu/RSV test cassettes. Instrument B (SN 843963) was located in an adjacent exam room testing area. 2. Review of the package insert for the test cassette methods outlined above revealed manufacturer's guidelines: "The recommended environmental operating conditions are 15-30C (59-86F), 20-80% relative humidity, noncondensing." 3. Review of the laboratory's temperature log sheets for calendar year 2020 and up to the June 8, 2021 revealed no documentation of the adjacent exam room test area's temperature or humidity. The inspector requested to review additional room temperature/humidity monitoring logs for Instrument B. No records were available for review. 4. An interview with the primary testing personnel and Ancillary Services Manager on 06/08/21 at approximately 3:30 PM, confirmed the above findings.

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 a tour, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), quality control (QC) and patient logs, and lack of documentation, the laboratory failed to document performance of negative and positive quality control (QC) for Cepheid SARS-CoV-2

Cassette testing on thirty-two (32) of 33 days and SARS-CoV2-/Flu/RSV Cassettes for one hundred four (104) of one hundred nine (109) days while reporting one thousand one hundred seventy-nine (1,179) patient results from December 20, 2020 to June 8, 2021. Findings include: 1. During a tour of the laboratory on 6/8/21 at approximately 1:00 PM, the inspector noted three (3) Cepheid Xpert Xpress analyzers (Serial Numbers: 843966, 843963, 844201) were in use for rapid, real-time polymerase chain reaction (PCR) COVID-19 testing by Cepheid SARS-CoV-2 and SARS-CoV2-/Flu/RSV test cassettes. The Ancillary Services Manager stated "We use the multi test if students present sick, if they are with the athletic department, traveling, or pre surgery they will get a COVID only. They run the analyzers everyday, Monday through Friday " 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 06/08/21 revealed an EUA was granted for the test methods outlined above. The FDA listing included the manufacturer's package insert / IFU which outlined (on page 29 under Quality Control, External Controls) instructions as: "External controls should be used in accordance with local, state, and federal accrediting organizations as applicable". 3. Review of the Cepheid QC logs revealed positive and negative external controls were assayed on the following dates: 12/2/20, 02/01/21, 04/07/21, 04/11/21, 04/21/21. The inspector requested to review additional QC records. No documentation was available for review. The inspector requested to review a lab director approved Individualized Quality Control Plan (IQCP). No documentation was available for review. 4. Review of the available Xpert Xpress patient test logs from the timeframe of 12/20/20 to 06/08/21 revealed that the facility reported: SARS-CoV-2/Flu/RSV - eight hundred twelve (812) tests; SARS-CoV-2 - three hundred sixty seven (367); a total of 1,179 results. 5. In an exit interview with the primary testing personnel and Ancillary Services Manager on 06/08/21 at approximately 3:30 PM, the above findings were confirmed.