

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1097178	(X3) Date Survey Completed 09/09/2022
Name of Provider or Supplier Chp-Walk In Care Airport	Street Address, City, State 14005 Wards Road, 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	<p>An announced CLIA recertification survey was conducted at CVFP Walk-In Care Airport on September 8, 2022 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 is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's package insert, tour, and interviews, the laboratory failed to label three of three hematology quality control (QC) vials with appropriate expiration date, observed in use to monitor patient Complete Blood Count (CBC) performance, on the date of the survey September 8, 2022. Findings include: 1. Review of the laboratory's procedure manual revealed a protocol (Titled: Quality Control Procedure) that stated "The CBC machine controls consist of three levels (low, normal, high). Controls are viable 14 days after opening. Once the control vials have been opened the date will be written on each vial along with the expiration date." 2. Review of the Boule Con-Diff Tri-Level QC package insert revealed a manufacturers defined open vial stability of fourteen (14) days. 3. A laboratory tour at approximately 11:00 AM revealed three vials of CDS Boule Con-Diff QC (Low-Lot</p>

Number # 22205-31, Normal- Lot # 22205-32, High- Lot # 22205-33) were stored in the refrigerator in a specimen cup outside of the manufacturer's package. The inspector noted the three vials did not have an open date with revised expiration date. 4. The inspector inquired if the identified control materials, outlined above, were currently in use for the monitoring the Medonic hematology analyzer. The facility's Clinical Lead stated on 09/08/22 at approximately 11:30 AM, "Yes, we put the CBC QC tubes in that specimen cup when they are the opened to use. The inspector inquired regarding a protocol description for labeling in use/opened hematology QC. The facility's Clinical Lead responded on 09/08/22 at approximately 11:35 AM, "The QC tubes should have been labeled with the date they were opened and expiration date. The staff may have written the dates on our lab calendar. I can check the calendar and then write the dates on the tubes." 5. An exit interview with the Ancillary Services Manager and Clinical Lead on 09/08/22 at approximately 1:30 PM confirmed the findings above.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for one of eleven testing personnel responsible for reporting moderate complexity Complete Blood Count and Food and Drug Administration Emergency Use Authorized Cepheid Polymerase Chain Reaction COVID-19 patient testing during the timeframe of September 2021 to the date of the inspection on September 8, 2022. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interviews, the laboratory failed to retain documentation of education qualifications for one of eleven (11) testing personnel (TP) from September 2021 to the date of the

inspection on September 8, 2022. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the LD identified 11 TP as qualified to perform moderate complexity Complete Blood Count (CBC) and Food and Drug Administration (FDA) Emergency Use Authorized (EUA) Cepheid Quad Real-Time Polymerase Chain Reaction (RT-PCR) COVID-19 patient testing. 2. Review of the available laboratory personnel records for evaluation of education documentation revealed no record for TP A. TP A's personnel record indicated initial laboratory training with patient testing began September 2021. (See Personnel Code Sheet.) 3. The inspector requested to review education documentation for TP A. The records were not available for review on the date of the inspection, 09/08/22. The Clinical Lead stated on 09/08/22 at approximately 1 PM, "We will request the education records from our human resource department and we can send them to you later today. We do require education documentation for laboratory staff." 4. An email correspondence with the Ancillary Services Manager on 09/09/22 at 12 PM revealed that the laboratory could not provide the requested education records for TP A. The Ancillary Services Manager stated in the 09/09/22 email, "This employee has a note in her human resource employee folder that she had recently moved and was getting transcript sent to her." 5. An exit interview with the Ancillary Services Manager on 09/09/22 at approximately 12:30 PM confirmed the above findings.