

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1032460	<b>(X3) Date Survey Completed</b> 01/12/2023
<b>Name of Provider or Supplier</b> Cvfp-Walk In-Amherst	<b>Street Address, City, State</b> 816 S Main Street, Amherst, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at the Physicians Treatment Center of Amherst on 01/12/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
<b>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the CASPER 0096D CLIA Application and Survey Summary Report, proficiency testing (PT) records and an interview, the laboratory failed to participate in one of four Complete Blood Count (CBC) events reviewed. Record review included second and third PT events in 2021 and the first two events in 2022. Findings include: 1. Review of the CASPER 0096D CLIA Application and Survey Summary Report and the American Proficiency Institute (API) PT records for the second and third events in 2021 and the first two events in 2022 revealed the</p>

laboratory received a score of 0% for the following event: 2022 Event 2- 0%- for the CBC module (Notation by API-failure to participate). 2. An exit interview with the testing personnel and lab consultants on 01/12/23 at 1310 confirmed the findings.

**D3031**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on a review of quality control (QC) records, lack of documentation, and interview, the laboratory failed to retain the "Boule Con-Diff Hematology Control " manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for ten of ten lot numbers utilized from 04/01/21 up to 12/22/22. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from 04/01/21 up to 12/22/22 revealed the laboratory received and utilized ten lot numbers of the "Boule Con-Diff Hematology Control". The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 1013, 1043, 1053, 1073, 1103, 1093, 0101, 0401, 0701, and 0933. The inspector requested to review the aforementioned package inserts. The documentation was not available for review. 2. An exit interview with the testing personnel and lab consultants on 01/12/23 at 1310 confirmed the findings.

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on observation of hematology procedures, review of policy and procedures (P&P), lack of documentation, and interviews, the lab failed to implement a mechanism to verify the accuracy of manually transcribed patient results from the Medonic hematology analyzer printout into the Athena electronic health record (EHR) at the date of survey on 01/12/23. Findings include: 1. An observation and interview with the testing personnel (TP) on 01/12/23 at approximately 1245 revealed the TP print the patient's complete blood count (CBC) results from the Medonic hematology analyzer. The results are manually transcribed into the Athena EHR. A barcode label is placed on the printed CBC result and then later scanned into the patient's chart. In addition, the TP stated that either the manually transcribed CBC results in Athena or the scanned copy of the CBC results would be provided to patients upon request. 2. Review of the P&P revealed a lack of documentation of a procedure to verify the accuracy of the manually transcribed CBC results into the Athena EHR. 3. An exit

interview with the lab consultants on 01/12/23 at 1310 confirmed the lab did not have a mechanism to ensure accuracy of manually transcribed patient CBC results into the Athena EHR.