

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>49D0016288</p>	<p><b>(X3) Date Survey Completed</b></p> <p>12/20/2023</p>
<p><b>Name of Provider or Supplier</b></p> <p>Vpi And Student Health Services Laboratory</p>	<p><b>Street Address, City, State</b></p> <p>Mccomas Hall, Virginia Tech, 895 Washington St, Sw, Blacksburg, VA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>An announced CLIA Recertification survey was conducted at the VPI and Student Health Services Laboratory on 12/20/23 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:</p>
<p><b>D3031</b></p>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of daily quality control (QC) records, lack of documentation, and interview, the lab failed to retain documentation of the daily complete blood count (CBC) QC procedures from 07/06/23 up to 08/29/2023 (49 days). Findings include: 1. Review of the Beckman Coulter DxH520 hematology QC records from 01/01/22 up to the date of survey on 12/20/23 revealed lack of documentation of daily CBC QC procedures from 07/06/23 up to 08/29/2023 (49 days). The inspector inquired about the lack of daily CBC QC documentation in an interview with the laboratory supervisor on 12/20/23 at 12:30. They stated, "we should have those records. We download the old lot number QC documents and print out those files prior to implementing the new lot number of QC materials." The lot number of CBC QC in question was 352315011, 362315012 and 372315013. 2. The laboratory supervisor provided the Beckman Coulter Interlaboratory Quality Assurance Program (IQAP) statistical commutative report for the above-specified lot number. The IQAP statistical commutative report did not include daily CBC QC results. The inspector inquired if the lab printed daily CBC QC results or if another source was available for review from 07/06/23 up to 08/29/2023 on 12/20/23 at 1300. The lab supervisor stated, "no</p>

we do not print out daily CBC QC results. I'm not sure what happened during that timeframe." 3. An exit interview with the lab supervisor and primary testing personnel on 12/20/23 at 1400 confirmed the findings.