

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0674919	<b>(X3) Date Survey Completed</b> 03/27/2024
<b>Name of Provider or Supplier</b> Old Dominion University Student Health Services	<b>Street Address, City, State</b> 4700 Powhatan Avenue, Suite 1402, Norfolk, 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 Old Dominion University Student Health Services on March 27, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), proficiency testing (PT) records and interviews, the laboratory failed to rotate PT among personnel performing Complete Blood Count (CBC) patient testing for three (3) of 3 PT events in calendar year 2023. Findings include: 1. Review of the CMS Form 209 revealed the laboratory director (LD) identified five testing personnel qualified/responsible for performing patient CBC testing during the review timeframe of 3/16/22 to 3/27/24. 2. Review of the laboratory's Washington State Laboratory of Hygiene (WSLH) 2023 PT documentation, a total of 3 events, revealed that TP #1 signed attestations and performed the following CBC PT: 2023 WSLH Hematology Event 1; 2023 WSLH Hematology Event 2; 2023 WSLH Hematology Event 3. TP #1 performed 3 of 3 PT events in 2023. (See Personnel Code Sheet.) 3. An exit interview with the LD and general supervisor on 3/27/24 at 1:00 PM confirmed the above findings.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a tour, review of the procedure manual, lack of documentation, and interviews, the laboratory's Complete Blood Count (CBC) procedure failed to include protocols for calibration/calibration verification, reportable limits, and normal ranges for CBC test parameters as established/validated for the Beckman Coulter DxH 520 analyzer in use from January 2024 to the date of the inspection on March 27, 2024. Findings include: 1. During a tour of the laboratory on 3/27/24 at 10:00 AM the inspector noted a newly installed Beckman Coulter DxH 520 hematology analyzer (Serial Number BG070428). 2. Review of the laboratory's procedure manual revealed a CBC protocol for the new hematology analyzer outlined above (title of procedure: "DxH 520"). The inspector noted the protocol lacked reportable range limits and reference (normal) ranges for the Beckman Coulter CBC parameters as verified onsite by the laboratory. Additionally, the new procedure did not include instructions regarding calibration protocols. 3. The inspector requested to review the additional procedure protocols outlined above. No addendum was available for review. 4. An exit interview with the Lab Director and general supervisor on 3/27/24 at 1:00 PM confirmed the above findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

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 technical consultant (TC) failed to document performance of semiannual competency assessment for two of four new laboratory testing personnel (TP) during the twenty-four month review timeframe (March 16, 2022 to the inspection date March 27, 2024). Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC and

identified five TP responsible for hematology Complete Blood Count (CBC) analysis /reporting. A discussion with the general supervisor and LD on 3/27/24 at 11:00 AM regarding the CMS 209 revealed that TP #1 - #4 were identified as new TP since the previous inspection on 3/15/22. (See Personnel Code Sheet.) 2. During a review of personnel records, the inspector noted the new staff members' initial hematology training as: TP #1 - September 2022, no semiannual competency documentation; TP #2 - January 2023, semiannual competency dated May 2023; TP #3 - May 2023, no semiannual competency documentation; TP #4 - October 2023, semiannual competency pending. 3. The inspector requested to view semiannual competency assessment records for TP #1 and TP #3 documented in calendar year 2023. The documentation was not available for review. 4. An exit interview with the LD and general supervisor on 3/27/24 at 1:00 PM confirmed the above findings.

**D6055**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), tour, analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and interviews, the technical consultant (TC) failed to ensure that documentation of training/competency evaluations were completed for five (5) of 5 testing personnel (TP) after a hematology instrument change occurred in the laboratory on January 29, 2024. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC and that the LD identified 5 TP responsible for hematology Complete Blood Count (CBC) patient testing. 2. During a tour of the laboratory on 3/27/24 at 10:00 AM, the inspector noted a newly installed Beckman Coulter DxH 520 hematology analyzer (Serial Number BG070428). 3. Review of the laboratory's instrument validation records revealed the new analyzer outlined above was installed by a Beckman Coulter field service technical specialist on 1/29/24 and that the laboratory's information systems had validated the analyzer interface to the facility's computerized medical records. 4. Review of Beckman Coulter User's Guide revealed a five page DxH 520 Competency Technical Training Checklist to be completed for each testing personnel at installation. 5. Review of the laboratory personnel files and installation records revealed that TP #1 - #5 lacked the required DxH 520 Training Competency checklist evaluation. (See Personnel Code Sheet.) The inspector requested to review the training competency evaluation checklists for the 5 TP outlined above. The general supervisor stated on 3/27/24 at 12:30 PM, "The field service representative did not complete the training checklists while onsite. Our lead tech reached out to the company and requested follow up onsite or virtual training so that the checklists can be completed." 6. An exit interview with the LD and general supervisor on 3/27/24 at 1:00 PM confirmed the above findings.