

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2123858	<b>(X3) Date Survey Completed</b>  10/17/2018
<b>Name of Provider or Supplier</b>  Northern Virginia Carenow Urgent Care Llc	<b>Street Address, City, State</b>  10004 Southpoint Parkway (22676 601), Fredericksburg, 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 BetterMed Urgent Care on October 17, 2018 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:
<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 proficiency testing (PT) records, Laboratory Personnel Report form (CMS 209), and interviews, the laboratory failed to test proficiency testing specimens in the same manner as it tested patient specimens for five (5) of eleven (11) events participated in from May 2017 until October 2018. Findings include: 1. Review of the CMS 209 and American Proficiency Institute (API) Chemistry and Hematology PT records (a total of 11 events) revealed that two testing personnel tested the same PT specimens in the following PT events: 2017 Hematology/Coagulation Event 3 attestation signed by TP J and TP K, 2018 Hematology/Coagulation Event 1 attestation signed by TP B and TP L, 2018 Hematology/Coagulation Event 2 attestation signed by TP B and TP G, 2018 Chemistry Event 2 attestation signed by TP B and TP C, 2018 Chemistry Event 3 attestation signed by TP B and TP G, a total of 5 PT events ran in duplicate. (See attached Personnel Code Sheet.) 2. In an interview with the Testing Personnel A (TP A)/Site Manager at approximately 12:00 PM, TP A stated that the individual who draws the blood performs the testing on the specimen. They do not have another individual repeat the testing on the specimen prior to reporting. 3. In an exit interview with TP A and TP L at approximately 1:00</p>

PM, it was confirmed that the laboratory failed to test PT specimens in the same manner as patient specimens by running the events above in duplicate.

**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, and interviews, the laboratory failed to retain the Cell Dyn manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for seven (7) of eight (8) QC lot numbers utilized from May 2017 until October 2018. Findings include: 1. Review of the laboratory's QC for the Cell Dyn Emerald May 2017 until October 2018 revealed 8 lot numbers of "Cell Dyn 18+" QC material were utilized to document and evaluate patient testing on the Cell Dyn Emerald analyzer. The following 7 QC lot numbers had no acceptable range documentation or manufacturer's package inserts retained: 7128 exp 8/25/18, 7156 exp 9/22/17, 7212 exp 11/17/17, 7296 exp 2/9/18, 8015 exp 5/4/18, 8099 exp 7/27/18, and 8127 exp 8/24/18. 2. The inspector requested to review the package inserts for the 7 lot numbers of QC listed above. Testing Personnel A (TP A) stated the laboratory failed to retain the "Cell Dyn 18 +" inserts. No documentation was provided. 3. In an exit interview with TP A and TP L at approximately 1:00 PM, it was confirmed that the laboratory failed to retain the manufacturer's assay information package inserts for the "Cell Dyn 18+" QC for the lot numbers outlined above.