

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2162379	<b>(X3) Date Survey Completed</b> 02/14/2023
<b>Name of Provider or Supplier</b> Northern Virginia Carenow Urgent Care Llc	<b>Street Address, City, State</b> 12214 W Broad Street, Richmond, 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 Northern Virginia Carenow Urgent Care on 02/14/23 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 was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the review of policy and procedures (P&amp;P), instrument test data, daily patient test data, and interview, the laboratory failed to follow the established P&amp;P ensuring that the SARS-CoV-2 (COVID-19) positive and negative quality control (QC) materials provided expected results on 08/03/22 and 08/29/22 while reporting 46 and 24 patients respectively. Refer to D5401.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the review of policy and procedures (P&P), instrument test data, daily patient testing data, and interview, the laboratory failed to follow the established P&P ensuring that the SARS-CoV-2 (COVID-19) positive and negative quality control (QC) materials provided expected results on 08/03/22 and 08/29/22 while reporting 46 and 24 patients respectively. Findings include: 1. An interview with the general supervisor on 02/14/23 at noon revealed the laboratory utilized the BioRad CFX 96 C1000 Touch Thermal Cycler (serial number 785BR28340) and the Assurance SARS-CoV-2 Real-Time polymerase chain reaction (RT-PCR) test panels to perform COVID-19 patient testing. 2. Review of the P&P, "BetterMed Urgent Care SARS-COV-2 Laboratory Protocol" (signed by the lab director 03/23/21), "6.0 Data Analysis and Interpretation" revealed the following statements: "6.2 Positive controls are run for each PCR experiment and must amplify to report patient results. 6.3 Negative controls are run for each PCR experiment and must be negative to report patient results." 3. Review of the BioRad CFX 96 C1000 Touch Thermal Cycler Maestro instrument positive/negative QC and patient test data and the Ignite laboratory information system (LIS) patient result data revealed the following: 08/03/22- the positive control failed to amplify for the assay run. A total of 46 patients performed on the assay run. 21 of the 46 patients reported as positive for COVID-19. 08/29/23- the negative control amplified as positive for COVID-19 for the assay run. A total of 24 patient performed on the assay run. 20 of the 24 patients reported as negative for COVID-19. There was no documentation available for review of a repeat of patient samples with positive and negative QC materials providing expected results on 08/03/22 and 08/29/22. 4. An exit interview with the general supervisor on 02/14/23 at 1400 confirmed the findings.