Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2162379	09/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Northern Virginia Carenow Urgent Care Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, review of manufacturer package insert (PI) and product sheet, daily patient and quality control logs (QC) and an interview with the site manager, the laboratory failed to ensure that the positive and negative Anti-SARS-CoV-2 QC materials were not utilized beyond the manufacture's open-vial stability from 9/1/20 - 9/15/20 while reporting a total of thirty (30) patients. Findings include: 1. A tour of the laboratory at approximately 10:10 AM on 9/15/20 revealed that the laboratory utilized the Sera Care Accurun Anti-SARS-CoV-2 Reference Materials Kit 1000 positive (lot number 10496539) and negative (lot number 1046938) controls to perform daily external QC procedures for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. The QC material vials had a hand-written in use date as 8/01/20. 2. Review of the manufacturer PI revealed the following statement: "Storage Instructions- After opening, the vials should be stored at 2-8 degrees Celsius and discarded after 30 days." Review of the manufacturer's product sheet revealed the following statement: "Open Vial Stability: Once opened, stable for 30 days." 3. Review of the daily patient and QC logs for the COVID-19 Antibody testing revealed that the above-specified QC materials were utilized from 9/1/20-9/15/20 while reporting a total of 30 patients. 4. An interview with the site manager on September 15, 2020 at approximately 10:30 AM confirmed utilization of the above-specified QC materials beyond the manufacture's open-vial stability from 9/1-15/20.