

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2169551	(X3) Date Survey Completed 09/15/2020
Name of Provider or Supplier Northern Virginia Carenow Urgent Care Llc	Street Address, City, State 11380 Iron Creek Road, Chester, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on a laboratory tour, interviews, review of manufacturer's package insert, patient and quality control (QC) logs, the laboratory failed to label two (2) of 2 SARS-CoV-2 QC vials (positive and negative, open/ in use) with appropriate expiration date noted during an unannounced follow up survey on September 15, 2020. Findings include: 1. During a laboratory tour at approximately 11:45 AM, the inspector noted 2 quality control (QC) vials of ACCURUN SARS-CoV-2 (Lot Number 10496538 Negative, Lot Number 10496539 Positive) stored in the refrigerator. The vials were not labeled with an open date or a revised expiration date. The inspector inquired if the QC was in use for COVID-19 patient testing and what date the vials were opened. The site manager stated "Yes, this is the last set of QC that we opened to use with our Healgen COVID antibody cassette tests. I am not sure what date they were opened. I can give you an approximate date around August 10, 2020. The QC expiration date printed on the label is May 2022". 2. Review of the ACCURUN Reference Material Kit Series 1000 package insert revealed a manufacturer's defined open vial stability of thirty (30) days. The package insert stated: Storage and Stability instructions: "Store at 2-8 degrees C, once opened, vials should be stored at 2-8 degrees C and discarded after 30 days. After opening, record the date opened and the expiration date on the vial." Limitations of the Procedure instructions: "Deviations from the procedures and instructions recommended by test kit manufacturer may produce unreliable results." The inspector reviewed the open stability limitations with the site manager. The site</p>

manager stated at approximately 12:30 PM, "I will order new QC today. This is the last vials that we have to use." 3. Review of the Healgen COVID patient/QC logs during the timeframe of 8/1/20 to 9/15/20 revealed documentation of QC results utilizing the ACCURUN (Lot Number 10496538 Negative, Lot Number 10496539 Positive) outlined above with thirteen (13) patient results reported from 9/1/15 to 9/15/20. 4. During an interview with the site manager at approximately 1:15 PM, it was confirmed that the laboratory failed to label opened SARS-CoV-2 QC vials in use for patient testing with the appropriate expiration date.