

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2169551	(X3) Date Survey Completed 10/21/2020
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert instructions, and interviews, the laboratory failed to follow Quidel cardiac chemistry quality control (QC) storage requirements for one (1) of five (5) kits on the date of the unannounced follow up inspection on October 21, 2020. Findings include: 1. During a tour of the laboratory, the inspector noted one box of Quidel Triage Total 5 Level 2 (Lot C3664AN) stored in the upright refrigerator. The inspector noted that the package had no label of a received or open date. The inspector noted the refrigerator temperature recorded by the FisherBrand Traceable thermometer as 2 degrees Celsius (C). 2. Review of the Quidel outer package revealed storage temperature instructions as - 20 C. The package insert stated: "The Quidel Triage Total 5 Controls are assayed materials to be used with Quidel Triage Cardiac Panel for Triage Meters to assist the laboratory in monitoring patient test performance. Store frozen at -20 C or colder in non-defrosting freezer. Do not store near the freezer door. Controls should not be used if thawed upon receipt. Controls should not be refrozen." 3. The inspector inquired of the testing personnel (TP) to describe the process for handling storage of the Triage control materials. The TP stated, on 10/21/20 at approximately 1:30 PM: "I usually work at one of our other sites. I am not sure why that QC is in the refrigerator". The inspector and TP noted four (4) additional boxes of the Quidel Triage Total 5 Level 2 stored in the laboratory's bench top freezer at -24 degrees C. The inspector inquired of the site manager, approximately 1:55 PM, to describe the policy regarding the storage of Triage control materials. The site manager stated: "I will instructed this site to destroy</p>

the box of controls that were stored in the refrigerator. I will remind staff of the proper storage when putting supplies away". 4. In an interview with the site manager, on 10/21/20 at approximately 3:00 PM, the above findings were confirmed.