Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2109497	02/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Northern Virginia Carenow Urgent Care Llc	6296 Mechanicsville Turnpike, Mechanicsville, 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
D0000	An announced CLIA recertification survey was conducted at BetterMed Urgent Care on February 13, 2020 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:
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, patient test logs, procedures, lack of documentation, and interviews, the laboratory failed to retain manufacturer's assay information inserts documenting Troponin and D Dimer acceptable ranges for thirteen (13) of nineteen (19) QC lot numbers utilized in the twenty-three (23) months reviewed. Findings include: 1. Review of the laboratory's QC and patient test logs for Troponin and D Dimer from March 2018 to the date of the inspection on 2/13/20 revealed 19 lot numbers of "Quidel Triage Total 5" QC material were utilized to document and evaluate patient testing on the Triage instrument. The following 13 utilized QC lot numbers had no manufacturer's package inserts with acceptable ranges documented: 03349, 03353, 03356, 03364, 03367, 03370, 03371, 03399, 03403, 03407, 03408, 03429, 03434. 2. Review of the policy and procedure manual revealed an approved Troponin and D Dimer Individualized Quality Control Plan (IQCP) with instructions to "retain all control lot inserts". 3. During an interview, at approximately 12:00 PM on 02/13/2020, the inspector requested to review the package inserts with acceptable ranges for the 13 lot numbers listed above. The site manager stated: "I assumed the role as manager in 2019 and realized that the staff was not remembering to retain all of the QC inserts at this site. I have tried to make sure that we are keeping

	them with the QC print outs." 4. In an exit interview with the site manager at approximately 2:30 PM on 02/13/2020, the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, manufacturer's operations manual, instrument maintenance records, field service maintenance records, lack of documentation, and interviews, the laboratory failed to document performance of required Abbott Emerald Cell-Dyn hematology analyzer maintenance (twice annually) in calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's procedure manual revealed that the laboratory utilized a copy from the Abbott Emerald Cell-Dyn User Guide as their hematology maintenance procedure. The maintenance protocol stated: "Every 6 months perform syringe piston lubrication". 2. Review of the Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 3. Review of the laboratory's hematology maintenance logs from March 2018 through the date of the survey on 2/13/20, revealed no semiannual piston syringe maintenance was recorded as performed during the twenty-three (23) months reviewed. The inspector requested to review additional documentation of the piston syringe maintenance in 2018 and 2019. No other records were available. The site manager stated, at approximately 1:00 PM on 02/13/2020, "I assumed the role as manager in 2019 and thought that our Peaks Service field representative was completing the required maintenance. We have not been doing this in the lab." 4. The inspector requested to review the Peaks Service record reports for 2018 and 2019. Review of the field service reports revealed no semiannual piston syringe maintenance was recorded as performed by the vendor in calendar years 2018 or 2019. 5. In an exit interview with the site manager at approximately 2:30 PM on 02/13/2020, the above findings were confirmed.