Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2109497	05/12/2022
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-Mechanicsville on May 12, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of instrument performance verification records, manufacturer's user guide, lack of documentation, and interviews, the laboratory failed to evaluate/verify the reportable range of test parameters after installing and initiating patient Complete Blood Count (CBC) testing on the new Abbott Emerald hematology analyzer on July 21, 2021 and up to the date of the inspection on May 12, 2022. Findings include: 1. Review of the laboratory's instrument validation records revealed a new hematology analyzer installation, by an Abbott field service technical specialist, occurred on 7/21/21. The inspector noted no record of validation for the CBC parameters' reportable range/linearity on the new Abbott Emerald analyzer, Serial Number (SN) 030421-010111. 2. Review of the Abbott Users Guide for new instrument installation revealed instructions "The patient Reference Range and Linearity must be validated by the

	laboratory." 3. The inspector requested to review documentation that the LD validated /approved the Emerald SN 030421-010111 analyzer's reportable ranges prior to patient testing. No documentation was available for review. During the inspection, the practice manager reached out to the field service rep to inquire regarding the linearity study. The manager stated on 5/12/22 at approximately 2:30 PM: "It appears that we never received the linearity study paperwork. It did not get reviewed". 4. An exit interview with the practice site manager on 05/12/22 at approximately 4 PM confirmed the above findings.