Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1103778	12/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
M D Express Urgent Care - Newport News	12997 Warwick Boulevard, Newport News, 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 MD Express Urgent Care-Newport News on December 8, 2021 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 was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of procedures, hematology calibration records, lack of documentation, and an interview, the laboratory failed to document calibration procedures every six (6) months for hematology Complete Blood Count (CBC) testing according to their written procedure in calendar year 2020. Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Quality Control (QC) policy that outlined to calibrate the CBC testing on the Medonic M Series hematology analyzer at a frequency of every 6 months. 2. Review of the hematology instrument calibration documentation for calendar year 2020 revealed calibration

	procedures were documented on 04/23/20. The inspector requested to review additional calibration records for calendar year 2020. No additional documentation was available. 3. In an exit interview with the Lab and X-ray Coordinator on 12/08/21 at approximately 1:00 PM, the above findings were confirmed.