Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1026787	02/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Md Express Urgent Care Williamsburg	120 Monticello Avenue, Williamsburg, 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 the Med Express Williamsburg on February 5, 2019 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:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of the manufacturer user's guide and interview, the lab director failed to review and approve the policy and procedures for the new hematology analyzer installed on March 21, 2018. Dates of record review included March 1, 2017 and up to the date of survey on February 5, 2019. Findings include: 1. An interview with the clinical coordinator at approximately 4:00 PM revealed that the laboratory utilizes the Medonic M-series User's Guide as their policy and procedures for operating the hematology analyzer. 2. Review of the Medonic M Series Users Guide revealed the lab director failed to review and sign the User's Guide upon installation on March 21, 2018.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the review of initial verification records, manufacturer user's guide, and interview, the lab director failed to review and approve the accuracy, precision, reportable and reference range documentation for the new hematology instrument installed on March 21, 2018. Dates of record review included March 1, 2017 and up to the date of survey on February 5, 2019. Findings include: 1. Review of the initial verification records for the Medonic M-series hematology analyzer (serial number 29686) revealed the analyzer was installed and put in use on March 21, 2018 by a Medonic technical specialist. There was no documentation by the lab director of review or approval of the accuracy, precision, reportable range study or reference range. 2. Review of the Medonic M Series Users Guide for new instrument installation revealed the instruction: "The patient Reference Range must be validated by the Lab Director". 3. An interview with the clinical coordinator at approximately 4: 00 PM confirmed the above-specified findings.