Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1054282	06/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
M D Express Urgent Care - Yorktown	4740 George Washington Memorial Highway, Yorktown, 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 on June 7, 2018 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:
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 hematology analyzer performance verification documentation, manufacturer's user guide instructions, patient test logs, and an interview, the laboratory director failed to evaluate and verify the normal values (reference ranges) for Complete Blood Count (CBC) testing prior to reporting one hundred ten (110) patient CBC panels from March 22, 2018 to the date of the survey, June 7, 2018. Findings include: 1. Review of the laboratory's instrument validation records revealed a new hematology analyzer installation, by a Medonic field service technical specialist, occurred on 3/22/18. The inspector noted that no validation, by the lab director, of the CBC patient normal values for the new Medonic M Series (Serial Number 29611) was documented. The inspector requested to review documentation that the laboratory director validated the Medonic's patient normal value ranges prior to patient testing. No documentation was available for review. 2. Review of the

	Medonic M Series Users Guide for new instrument installation revealed instructions: "The patient Reference Range must be validated by the Lab Director". 3. Review of the patient test log from the laboratory's Electronic Medical Record revealed that the lab had reported one hundred ten (110) CBC reports from 3/22/18 to the date of the survey on 6/7/18. 4. In a telephone interview with the clinical coordinator at approximately 12:30 PM, it was confirmed that the laboratory director failed to evaluate and validate the patient reference range for CBC testing prior to reporting patient results from the new M Series hematology instrument as outlined above.
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 instrument maintenance records, manufacturer's operations manual, quality assurance (QA) logs, and an interview, the laboratory failed to document hematology instrument daily and monthly maintenance from March 22, 2018 to the date of the survey, on June 7, 2018. Findings include: 1. Review of the laboratory's Medonic M Series hematology maintenance logs revealed preventative maintenance procedures for Check Reagent Levels, Verify Background Count, and Aspiration Probe Exterior Cleaning listed as "perform on a daily basis" and Monthly Cleaning (Hypochlorite) and Clot Prevention (Enzymatic) listed as "perform on a monthly basis". The inspector noted that the available hematology maintenance logs from 3/22/18 to 6/7/18 revealed no daily maintenance was documented for seventy-seven (77) of seventy-seven (77) days reviewed and no monthly maintenance was documented in April and May. 2. Review of the Medonic M Series Operations Manual revealed manufacturer's instructions to "perform the following procedures at the scheduled time intervals of ": Check Reagent Levels, Verify Background Count, and Aspiration Probe Exterior Cleaning are scheduled as daily; Cleaning (Hypochlorite) and Clot Prevention (Enzymatic) procedures are scheduled as monthly. 3. Review of the laboratory's QA monthly log revealed no documentation of corrective action regarding the above lapses in maintenance documentation. 4. In a telephone interview with the laboratory clinical coordinator at approximately 12:30 PM, it was confirmed that the laboratory failed to document Medonic M Series hematology daily and monthly preventative maintenance for the days and months outlined above in 2018.
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 and policies, hematology calibration records, and an interview, the laboratory failed to document calibration procedures for hematology Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2017. Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Quality Control (QC) policy that outlined to calibrate CBC testing at a frequency of every six (6) months. 2. Review of the laboratory's Abbott Cell Dyn instrument calibration documentation from June 2016 to the date of the inspection on 6/7/18, a total of twenty-four (24) months, revealed the following lapse in CBC calibration: The inspector noted for 2017, the documentation of calibration procedures on 2/7/17, 4/7/17, and not again until 3/22/18 (the date of an installation of a new Medonic M Series analyzer). The inspector requested to review additional calibration records for the Cell Dyn analyzer during the timeframe of October 2017 to 3/21/18. No additional calibration documentation was available for review. 3. In a telephone interview with the clinical coordinator at approximately 12:30 PM on 6/7 /18, it was confirmed that the laboratory failed to document calibration procedures for CBC testing, in calendar year 2017, according to their written QC policy resulting in a calibration lapse as outlined above.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, new analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and an interview, the technical consultant failed to document training and competency evaluations for thirty-four (34) of thirty-four (34) testing personnel after a hematology instrument change occurred in the laboratory on March 22, 2018. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of technical consultant (TC) and that there are thirty-four (34) testing personnel. 2. Review of hematology procedures revealed the laboratory moved from an Abbott Cell Dyn to a Medonic M Series for Complete Blood Count (CBC) testing in March 2018. 3. Review of the laboratory's instrument validation records revealed a new analyzer installation (M Series Serial Number 29611), was performed by a Medonic field service technical specialist on 3/22/18. 4. Review of the Medonic M Series User's Guide revealed an M Series Training Checklist to be completed prior to patient testing. 5. Review of the laboratory personnel files and installation records revealed that testing personnel Number 1 through Number 34 lacked a Medonic M Series Training Competency checklist and evaluation. The inspector requested the training competency evaluations. No documentation was available for review. (See Personnel Code Sheet.) 6. In a telephone interview with the clinical coordinator at approximately 12:30 PM, it was confirmed that the TC failed to document the Medonic M Series

	hematology training competency evaluations for thirty-four (34) of thirty-four (34) testing personnel prior to utilizing the new instrumentation for patient testing on March 22, 2018 through the date of the survey on June 7, 2018.