Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2077175	07/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Md Express Urgent Care - Gloucester	6567 George Washington Memorial Highway, Gloucester, 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 on July 11, 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 fifty-one (151) patient CBC panels from March 20, 2018 to the date of the survey, July 11, 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 3/20/18. The inspector noted that no validation, by the lab director, of the CBC patient normal values for the new Medonic M Series (Serial Number 29693) 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 logs revealed that the lab had reported one hundred fifty-one (151) CBC reports from 3/20/18 to the date of the survey on 7/11/18. 4. In an 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.
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 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 hematology instrument calibration documentation from July 2016 to the date of the inspection on 7/11/18, a total of twenty-four (24) months, revealed the following seven (7) month lapse in CBC calibration: The inspector noted documentation of calibration procedures on 2/7/17 in calendar year 2017. The laboratory documented the next hematology calibration on 3/20/18 (the installation date of a new Medonic M Series analyzer). The inspector requested to review additional calibration records for the previously installed analyzer (Abbott Cell-Dyn) during the timeframe of August 2017 to 3/20/18. No additional calibration documentation was available for review. 3. In an interview with the clinical coordinator at approximately 12:30 PM, 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 of seven (7) months as outlined above.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory director failed to document evaluation of and corrective action for two (2) of five (5) PT events reviewed. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) hematology and chemistry PT documentation, a total of five (5) events, revealed no evidence of evaluation for the following failed analyte scores: 2017 AAFP Event 3: Creatine Kinase Isoenzyme CK (CKMB) 13-N, White Blood Cell (WBC) HD-13; 2018 AAFP Event 1: Red Blood Cell (RBC) HD-1, Hematocrit (HCT) HD-1, Hemoglobin (HGB) HD-1, WBC HD-1. The inspector requested to review documentation that the laboratory evaluated the CKMB, WBC, RBC, HCT, and HGB challenge failures outlined above. Documentation was not available for review. 2. In an interview with the clinical coordinator at approximately 12:30 PM, it was confirmed that the laboratory director failed to document evaluation for the PT performance scores in the two (2) proficiency testing events listed above in 2017 and 2018.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, monthly Quality checklists, instrument validation records, calibration records, personnel records, and an interview, the laboratory director failed to assure the quality of lab services and failed to ensure that the quality assurance (QA) policies were maintained in 2017 and up to the date of the survey on 7/11/18. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written and approved QA policy that included laboratory director review of monthly quality checklists. The monthly quality checklists include the areas of calibration, maintenance, quality control and personnel. 2. Review of the signed monthly Quality checklists for 2017 up to the date of the survey, 7/11/18, revealed that the lab director did not identify the following: - no evaluation of the normal values (reference ranges) for Complete Blood Count (CBC) testing on the Medonic M analyzer (See D 5421), - a seven (7) month lapse in CBC calibration (See D 5437), - failure to document training and competency evaluations for thirty-four (34) testing personnel for the Medonic M Series hematology instrument (See D 6055). 3. In an interview with the clinical coordinator at approximately 12:30 PM, it was confirmed that the laboratory director failed to assure lab quality by failing to ensure that the QA policies were maintained for the timeframe 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 CMS 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 20, 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 laboratory's hematology procedures and instrument validation records revealed the laboratory moved from an Abbott Cell Dyn to a Medonic M Series for Complete Blood Count (CBC) testing in March 2018. The new instrument (M Series Serial Number 29693) installation was documented on 3/20/18 by a Medonic field service technical specialist. 3. Review of the Medonic M Series User's Guide revealed manufacturer's instructions that the "M Series Training Checklist is to be completed prior to patient testing". 4. Review of the laboratory personnel files and instrument installation records revealed that testing personnel # 1 through # 34 lacked a Medonic M Series Training Competency checklist and evaluation. The inspector requested to review the training competency evaluations. No documentation was available for review. (See Personnel Code Sheet.) 5. In an 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 20, 2018 through the date of the survey on July 11, 2018.