

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2026696	(X3) Date Survey Completed 05/07/2019
Name of Provider or Supplier M D Express Urgent Care- Hampton	Street Address, City, State 3321 West Mercury Boulevard, Hampton, 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-Hampton on May 7, 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:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology and chemistry proficiency testing (PT) records and an interview, the laboratory failed to retain attestations by the personnel performing the PT testing on seven (7) of the 7 events reviewed from calendar year 2017 up to the date of the inspection on 5/7/19. Findings include: 1. Review of the laboratory's 2017 (three events), 2018 (three events), and year to date 2019 (one event) American Proficiency Institute (API) PT documentation revealed no testing personnel (TP) signed attestations for the hematology and chemistry PT modules. The inspector requested to review the TP attestations. The primary testing personnel stated, "We have the lab director sign but did not have the personnel sign the attestations at this location". 2. In an interview with the clinical coordinator, at approximately 12:30 PM, the above findings were confirmed.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
 Based on a tour, review of analyzer maintenance records, policies and procedures, and an interview, the laboratory director (LD) failed to document approval and review of procedures for Complete Blood Count (CBC) patient testing on the Medonic M Series analyzer from the date of installation on March 22, 2018 and up to the date of the inspection on May 7, 2019. Findings include: 1. During a tour of the laboratory, the inspector noted a Medonic M Series hematology analyzer in use for patient CBC testing. The primary testing personnel stated, "We replaced our Abbott Cell Dyn with the Medonic instrument in 2018". 2. Review of the laboratory's hematology analyzer maintenance documentation revealed that a field service representative installed the Medonic M Series analyzer on March 22, 2018. 3. Review of the laboratory's policy and procedure manual revealed a procedure for Abbott Cell Dyn 1800 Operation, Quality Control, Maintenance, Troubleshooting and CBC testing. The policies were approved by the LD on 6/2/15. The laboratory inspector requested to review approved procedures for the Medonic hematology analyzer. The primary testing personnel stated, "We have not updated all of our procedure manuals yet". 4. In an interview with the clinical coordinator, at approximately 12:30 PM, the above findings were confirmed.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on a tour, a review of manufacturer's analyzer user guides, daily temperature logs, and an interview, the laboratory failed to monitor the daily relative humidity percent (RH%) for two (2) analyzers (Alere Biosite Meter and Medonic M Series) to ensure manufacturer's operating requirements were followed from June 2017 to April 2019. Findings include: 1. During a tour of the laboratory, the inspector noted a Medonic M Series hematology analyzer in use for patient hematology Complete Blood Count (CBC) testing and an Alere Biosite Meter in use for patient chemistry Creatine Phosphokinase MB (CK-MB), Troponin, Myoglobin, D-dimer, and B Type natriuretic peptide (BNP) testing. 2. Review of the manufacturer's users guides for ambient operating requirements revealed: Medonic M Series humidity requirement less than or equal to 80%, Biosite humidity requirement 10-85%. Review of the 2 manufacturers users guides also revealed maintenance instructions with daily humidity listed as "record daily". 3. Review of the daily temperature logs from June 2017 to April 2019 revealed no record of laboratory humidity monitoring. 4. In an exit interview with the clinical coordinator at approximately 12:30 PM, the above findings were confirmed.

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 eight hundred ninety-one (891) patient CBC panels from March 22, 2018 to the date of the survey, May 7, 2019. 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 29666) 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 reported 891 CBC reports from 3/22/18 to the date of the survey on 5/7/19. 4. In an interview with the clinical coordinator at approximately 12:30 PM, the above findings were confirmed.

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 hematology instrument maintenance logs, manufacturer's operations manual, and an interview, the laboratory failed to document required monthly Medonic M Series hematology analyzer preventative maintenance procedures for three (3) of thirteen (13) months reviewed from March 2018 to April 2019. Findings include: 1. Review of the laboratory's Medonic M Series hematology analyzer maintenance logs and manufacturer's Clinical Diagnostic Solutions User Manual revealed the following two (2) required preventative maintenance procedures listed as "perform monthly": Monthly Cleaning with Hypochlorite, Clot Prevention (Enzymatic Cleaning). 2. Review of the laboratory's Medonic instrument maintenance logs from 3/22/18 to 4/30/19 revealed that the laboratory failed to document performance of the 2 monthly maintenance procedures listed above in: August 2018, October 2018, February 2019. 3. In an exit interview with the clinical coordinator at approximately 12:30 PM, the above findings were confirmed.

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), new analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and an interview, the technical consultant (TC) failed to document training and competency evaluations for thirty-two (32) 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 TC and that there are thirty-four (34) testing personnel. 2. Review of the laboratory's instrument validation records revealed a new hematology analyzer installation (Medonic M Series - Serial Number 29682) was performed by a Medonic field service technical specialist on 3/22/18. 3. Review of the Medonic M Series User's Guide revealed an M Series Training Checklist to be completed prior to patient testing. 4. Review of the laboratory personnel files and installation records revealed that testing personnel # 1 through # 32 lacked a Medonic M Series Training Competency checklist and evaluation. The inspector requested the training competency evaluations. No documentation was available for review. The clinical coordinator stated, "the field service representative trained two of us in March 2018 and we have trained the other personnel. I do not have those records at this time". (See Personnel Code Sheet) 5. In an exit interview with the clinical coordinator at approximately 12:30 PM, the above findings were confirmed.