

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2026696	(X3) Date Survey Completed 07/26/2023
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 Urgent Care-Hampton on July 26, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of procedures, daily temperature/environment logs, lack of documentation, and an interview, the laboratory failed to retain documentation of monitoring daily relative humidity percent (%) and refrigerator/freezer temperatures according to their procedures for one of twenty-one months reviewed (review timeframe: October 2021 to the date of the inspection, 7/26/23). Findings include: 1. During a tour of the laboratory at approximately 10:00 AM on 7/26/23, the inspector noted: Freezer A - sign stated "Chemistry Biosite and Piccolo Controls are to be stored in this freezer"; Freezer B - sign stated "Patient Send out COVID-19 test swabs are to be stored in this freezer"; Refrigerator A - sign stated "CBC Controls, Cardiac Marker Controls are to be stored in this refrigerator"; Refrigerator B - sign stated "Piccolo, BNP, Cardiac, D-Dimer Reagents are to be stored in this refrigerator". 2. Review of the laboratory's procedures revealed Quality Assurance protocols that outlined daily monitoring of environmental conditions that included laboratory room</p>

temperature/humidity and refrigerator/freezer temperatures. The QA procedure stated, "Record daily and maintain logs of room, refrigerators and freezers' temperatures and humidity." 3. Review of the available laboratory temperature log records for October 2021 up to the date of the inspection revealed no record of laboratory room temperature/humidity or refrigerator/freezer temperature monitoring during the month of November in calendar year 2021. The inspector requested to review documentation of humidity and temperature monitoring in November 2021. No records were available for review. 4. An exit interview with the lab coordinator at approximately 1 PM on 7/26/23 confirmed the above findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of hematology analyzer quality control (QC) records, policies, and interviews, the laboratory failed to follow their QC protocol to verify two (2) levels of acceptable QC for Complete Blood Count (CBC) on 2 days with five (5) patients tested/reported during the twenty-one (21) months reviewed (October 2021 to the date of the inspection on 7/26/23). Findings include: 1. Review of the Medonic hematology analyzer QC records from October 2021 to 7/26/23 revealed that the laboratory failed to verify 2 levels of acceptable hematology QC on the following dates with patient accession numbers (#) tested/reported: 05/30/23 - #848229, #848232; 06/10/23 - #848632, #848636, #848653. The inspector noted that one level of CBC QC (High) was verified on the dates outlined above. The inspector noted that the Low and Normal QC failed on both dates outlined above. The inspector inquired regarding the laboratory's protocol for hematology QC verification. The lab coordinator stated at approximately 11:30 AM on 7/26/23, "Our protocol is to run three levels of hematology QC and at least two of three levels have to be acceptable before we run patients. I will need to look into why the procedures were not followed before CBC testing was done." 2. Review of the laboratory policies revealed a QC protocol that stated, "At a minimum, the lab will run two control specimens every 24 hour period when patient testing is performed. Do not report any patient test result unless the test system has produced adequate control results on the day the patient test has been performed." 3. An exit interview with the lab coordinator at approximately 1 PM on 7/26/23 confirmed the above findings.