

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1054282	(X3) Date Survey Completed 08/30/2022
Name of Provider or Supplier M D Express Urgent Care - Yorktown	Street Address, City, State 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 Urgent Care-Yorktown on August 30, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) record binders, lack of documentation, and an interview, the laboratory failed to retain copies of the attestation statement signed by the laboratory director/testing personnel and hematology/chemistry instrument printouts for two of six PT testing events during the twenty-one (21) month inspection review timeframe (November 2020 to August 30, 2022). Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) chemistry and hematology PT records(2020 Event C, 2021 Events</p>

A-C, 2022 Events A-B) revealed no signed attestation statements, Medonic hematology instrument print outs, or Alere Triage chemistry print outs retained in the binders for the following events: 2020 AAFP Event C, 2021 AAFP Event A. The inspector requested to review the PT records' documentation outlined above. The lab clinical coordinator located the laboratory's AAFP transmission print outs that were generated on the date of submission. No additional records were available for review for the PT events outlined above. 2. An exit interview with the lab clinical coordinator on 8/30/22 at approximately 3:30 PM, confirmed the above findings.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to document a review/evaluation of two of six chemistry and hematology PT modules during the twenty-one (21) month inspection review timeframe (November 2020 to August 30, 2022). Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) chemistry and hematology PT records (2020 Event C, 2021 Events A-C, 2022 Events A-B) revealed no AAFP retained results or documentation of review/evaluation for: 2020 AAFP Event C: Hematology Module Complete Blood Count (CBC) and Auto Differential for five of five challenge samples HD11 - HD15, Chemistry Module Complete Cardiac Markers for five of five challenge samples CD11-CD15; 2021 AAFP Event A: Hematology Module CBC and Auto Differential for five of five challenge samples HD1 - HD5, Chemistry Module Complete Cardiac Markers for five of five challenge samples CD1-CD5; The inspector requested to review the AAFP results and evaluation documentation for the two hematology and chemistry module events outlined above. No additional documentation was available for review. 2. An interview with the lab clinical coordinator on 8/30/22 at approximately 3:30 PM, confirmed the above findings.