Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1026787	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Md Express Urgent Care Williamsburg	120 Monticello Avenue, Williamsburg, 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 for MD Express Williamsburg on April 20, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview and initial record review conducted remotely on 04/12/21. 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to retain attestations by the testing personnel (TP) performing Hematology, Chemistry, and Cardiac Marker PT testing on two (2) of six (6) events in the twenty-four months reviewed. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) PT documentation (2019 Events A-C, 2020 Events A-C), a total of 6 events, revealed no TP signed attestations for the following 2 hematology and chemistry modules: AAFP 2019 A Hematology, General Chemistry, Cardiac Markers AAFP 2019 B Hematology, General Chemistry, Cardiac Markers The inspector requested to review the TP attestations. The laboratory clinical coordinator stated "Our lab director signed. The testing personnel were assigned but we did not have the personnel sign for those PT reports in 2019." 2. In an interview with the laboratory clinical coordinator on 4/20/21 at 3:30 PM, the above listed findings were confirmed

D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure hematology Complete Blood Count (CBC) PT testing results were returned to American Academy of Family Physicians (AAFP) within the program's deadline for one (1) of six (6) events during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's AAFP hematology PT documentation (2019 Events A-C, 2020 Events A-C), a total of 6 events, revealed that the laboratory failed to submit results and received "failure to participate" scores for the following CBC module: Hematology 2019-C: 0% analyte scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, Platelet Count, Hemoglobin, Hematocrit; 20% for White Blood Count. AAFP noted on forty-nine (49) of the fifty (50) hematology analyte challenges "failed, no results received". 2. In an interview with the laboratory clinical coordinator on 4/20/21 at 3:30 PM, the above listed findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. 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 evaluation taken for two (2) B-type Natriuretic Peptide (BNP) and one (1) Lymphocyte unacceptable analyte results in calendar year 2020. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) PT records (2019 Events A-C, 2020 Events A-C), a total of 6 events, revealed no evidence of remedial action for the following three (3) unacceptable proficiency analyte scores: 2020 AAFP Event A - BNP Cardiac Marker challenge CDM-2N resulted as 3,060 (acceptable range 1,288-3,018); 2020 AAFP Event B - BNP Cardiac Marker challenge sample CDM-10N resulted as 7,121 (acceptable range 364-914) 2020 AAFP Event C- Hematology Lymphocyte percent count challenge HD-11 resulted as 48.70 (acceptable range 49.29-62.10). 2. Review of the laboratory's PT corrective action forms revealed no evaluation action documentation for the unacceptable analyte scores listed above. 3. In an interview with the laboratory clinical coordinator on 4/20/21 at 3:30 PM, the above listed findings were confirmed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interviews, review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), a tour, review of available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to document performance of negative and positive quality control (QC) for SARS-CoV-2 testing on ninety-five (95) of one hundred eleven (111) patient testing days from November 27, 2020 to March 20, 2021. Findings include: 1. In a pre-survey remote entrance interview on 04 /12/21, the inspector noted that the laboratory director (LD) indicated patient COVID-19 testing utilizing Cepheid GeneXpert Xpress System on the laboratory's CMS 116 form. 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 04/12/21 revealed an EUA was granted for the test method outlined above on 09/24/20 (updated on 01/27/21). The FDA listing included the manufacturer's package insert / IFU which outlined External Controls Instructions as: "Testing with the Xpert Xpress SARS-CoV-2/Flu/RSV test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. The Xpert Xpress SARS-CoV-2/Flu/RSV test is only for use under the Food and Drug Administration ' s Emergency Use Authorization. External controls should be used in accordance with local, state, and federal accrediting organizations as applicable". 3. During a tour of the laboratory on 04/20/21 at approximately 1:30 PM the inspector noted one (1) Cepheid GeneXpert Xpress analyzer (Serial Number 841363) in use for COVID-19 testing by Xpert Xpress SARS-CoV-2/Flu/RSV Cartridges. 4. Review of the available Xpert Xpress patient test logs revealed that the facility reported seven hundred ninety-six (796) results on 111 days during the timeframe of 11/27/20 to the date of the inspection, 04/20/21. Review of the patient and QC logs from 11/27/20 to the date of the inspection revealed no record that positive or negative external controls were assayed on the following 95 days while reporting six hundred fifty-six (656) patient results: November 2020: 11/27; December 2020: 12/1, 12/3-12/6, 12/8-12/15, 12/17-12/19 12/22-12/24, 12/26, 12/30-12/31; January 2021: 1/2, 1/4, 1/6- 1/7, 1/9-1/10, 1 /20, 1/22-1/25, 1/27-1/30; February 2021: 2/1, 2/3, 2/5, 2/6, 2/8, 2/9, 2/11- 2/15, 2/17-2/21, 2/23, 2/24, 2/27; March 2021: 3/1, 3/2, 3/4 - 3/8, 3/11, 3/12, 3/14-3/17, 3/19- 3 /23, 3/25, 3/28, 3/29, 3/31; April 2021: 4/1, 4/2, 4/5- 4/13, 4/15, 4/16, 4/18-4/20. The inspector requested to review QC records for the patient testing dates outlined above. No documentation was available for review. The inspector requested to review a LD approved Individualized Quality Control Plan (IQCP). No documentation was available for review. 5. In an interview with the laboratory clinical coordinator on 4/20 /21 at 3:30 PM, the above listed findings were confirmed.