

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2026696	(X3) Date Survey Completed 09/01/2021
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 September 1, 2021 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:
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services CASPER 0096D report form (CMS CASPER 96), proficiency testing (PT) records, and an interview, the laboratory failed to attain an overall score of at least eighty (80) percent of acceptable responses for Hematology in one (1) out of three (3) 2020 PT testing events. Findings include: 1. During pre-survey duties, the inspector noted that the CMS CASPER 96 report included an overall unsatisfactory PT score for the speciality of Hematology. The pre-survey review revealed the laboratory received 58 % score for 2020 Event 3. 2. During the onsite survey on 09/01/21, the inspector reviewed the laboratory's American Academy of Family Physicians (AAFP) PT records (2020 Events 1-3, 2021 Events 1-2). The review revealed the following unsatisfactory scores: 2020 Event 3: Hematology overall scored at 58% - module breakdown of Cell Identification scored 73%, Red Blood Cell scored 80%, Hematocrit scored 0%, and Platelets scored 0%. 3. An exit interview with the lab/nurse coordinator at approximately 2:30 PM confirmed the above findings.</p>
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 record evaluation of fifteen (15) of 15 unsatisfactory scores for Lymphocyte (LYMP), Monocyte (MONO), Granulocyte (GRAN), Red Blood Cell (RBC), Hematocrit (HCT) and Platelet (PLT) challenges reported on the 2020 Hematology PT Event 3 report. Findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) PT records (2020 Events 1-3, 2021 Events 1-2) revealed no evidence of evaluation for each of the following failed analyte challenge samples: 2020 AAFP Event 3: LYMP % (HD-12, HD-13), MONO % (HD-13), GRAN % (HD-13), RBC (HD-12), HCT (HD-11, 12, 13, 14, 15), and PLT (HD-11, 12, 13, 14, 15). The inspector requested to review documentation that the laboratory evaluated the 15 unacceptable challenge results outlined above. Documentation was not available for review. The lab/nurse coordinator stated at approximately 1 PM: "I have been unable to find the documentation of the review by our previous coordinator or director at the time of this report. I cannot comment on the matter because I was not the coordinator at that time but going forward we will review in a timely manner". 2. An exit interview with the lab/nurse coordinator at approximately 2:30 PM confirmed the above findings

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, patient test logs, two (2) randomly selected patient reports, and interviews, the laboratory failed to ensure that five hundred twenty (520) patient Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and Trichomonas vaginalis (Tv) polymerase chain reaction (PCR) test reports included the performing laboratory address and specimen type during the timeframe of February 3, 2021 to the date of the inspection on September 1, 2021. Findings include: 1. Review of the laboratory's CMS 116 form revealed a laboratory name and physical facility location as follows: MD Express Urgent Care-Hampton 3321 West Mercury Boulevard Hampton, Virginia 23666 and non waived PCR testing for CT, NG, and Tv utilizing Cepheid GeneXpert was added to the test menu on 2/3/21. 2. Review of the patient GeneXpert CT/NG and Tv PCR test logs revealed three hundred six (306) CT/NG and two hundred fourteen (214) Tv patient results were reported from 2/3/21 to 8/31/21 from the Cepheid Serial Number 843965. 3. The inspector requested to review 2 random patient results from the patient test logs. The following selected medical record

number results (MRN #) were printed from the EPIC laboratory information system: MRN # 005962942 (dated 3/17/21) and MRN # 005916263 (dated 9/1/21). The inspector noted that the reports outlined above did not entail the performing laboratory's address or patient specimen type. The inspector inquired regarding the the missing report information. The lab/nurse coordinator stated, on 9/1/21 at approximately 1:30 PM: "We can run urine, endocervical and vaginal swabs but typically only collect urine for male and endocervical for females. I can reach out to our EPIC report builder to add both the source and this site's address information to our reports." 4. An exit interview with the lab/nurse coordinator at approximately 2:30 PM confirmed the above findings