

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2146481	<b>(X3) Date Survey Completed</b> 08/30/2018
<b>Name of Provider or Supplier</b> Vcuh/Mcyp Urgent Care At Tappahannock	<b>Street Address, City, State</b> 300 Mt Clement Park - Suite A, Tappahannock, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA initial survey was conducted at MD Express Urgent Care-Tappahannock on August 30, 2018 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:
<b>D5407</b>	<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> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, patient test logs, and interviews, the laboratory director (LD) failed to sign/date a review and approval of the laboratory's written hematology, chemistry, quality assurance (QA), and quality control (QC) procedures prior to and while patient testing was performed from April 26, 2018 to August 30, 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no record of the LD's approval of the written procedures. The inspector requested to review the LD's approval and to review the QA policies. No documentation was available. The clinical coordinator was interviewed by telephone at approximately 1:00 PM and stated: "We do not have the QA policy ready with our LD's approval. It is in the process of approval. I will have the LD sign all of the procedures as soon as possible and will add the QA policy to our manual". 2. Review of the patient test logs revealed that the lab had reported three hundred twenty-eight (328) complete blood count and two hundred ninety-nine (299) chemistry panel patient reports from 4/26/18 to the date of the survey on 8/30/18. 3. In a telephone interview with the clinical coordinator at approximately 2:30 PM, it was confirmed that the laboratory failed to provide an approved policy and procedure manual prior to reporting patient hematology and chemistry results as outlined above.</p>

**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 initial instrument performance verification documentation, manufacturer's user guide instructions, patient test logs, and an interview, the laboratory failed to evaluate and verify the normal values (reference ranges) for Complete Blood Count (CBC) testing prior to reporting three hundred twenty-eight (328) patient CBC panels from April 26, 2018 to the date of the survey, August 30, 2018. Findings include: 1. Review of the laboratory's instrument validation records revealed the hematology analyzer installation, by a Medonic field service technical specialist, occurred on 4/26/18. The inspector noted that no validation of the CBC patient normal values (reference ranges) for the new Medonic M Series (Serial Number 46122) 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 the following instruction: "The patient Reference Range must be validated by the Lab Director". 3. Review of the patient test logs revealed that the lab had reported three hundred twenty-eight (328) CBC reports from 4/26/18 to the date of the survey on 8/30/18. 4. In a telephone interview with the clinical coordinator at approximately 2:30 PM, it was confirmed that the laboratory failed to evaluate and validate the patient reference range for CBC testing prior to reporting patient results from the new M Series hematology instrument as outlined above.