

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D2138833	<b>(X3) Date Survey Completed</b> 10/18/2019
<b>Name of Provider or Supplier</b> Doctors Care Mauldin	<b>Street Address, City, State</b> 793 East Butler Rd, Mauldin, SC	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review and testing personnel interview, the laboratory director failed to sign the attestation statement for two of five proficiency testing events reviewed (2019, Events 1 and 2). Findings include: 1. Review of proficiency testing records from American Proficiency Institute (API) revealed that the attestation statements for the following were not signed by the laboratory director: a. 2019, Event 1 and 2019, Event 2 2. During the exit interview at 12:45 pm on 10/18 /2019, testing personnel confirmed that the attestation statement was not signed by the laboratory director.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on direct observation, lack of documentation, and testing personnel interview, the laboratory failed to document the performance specifications (accuracy, precision, reportable range) for the Medonic hematology analyzer before use. Findings include: 1. During the laboratory tour on 10/18/2019 at 10:15 am, the Medonic hematology analyzer was observed in the laboratory. Testing personnel stated during interview at 10:15 am that laboratory testing began December 17, 2017. 2. There were no performance specifications documentation available for review during the survey. The surveyor did find documentation of preventative maintenance performed on December 16, 2017. 3. Testing personnel was asked about the Medonic performance specifications at 12:24 pm. Testing personnel replied that the analyzer came from a center that had closed, and that preventative maintenance was performed before testing began.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on hematology data log review and testing personnel interview, the laboratory failed to perform and document at least two levels of acceptable hematology quality control (QC) before patient testing on 6 random test days reviewed from January and February 2018. Findings include: 1. Review of the hematology data log revealed that patient complete blood count (CBC) testing was performed on the following days before having two levels of acceptable controls: a. 1/16/2018--one level of acceptable QC (normal); 4 patients tested b. 1/24/2018--one level of acceptable QC (high); 1 patient tested c. 1/25/2018--one level of acceptable QC (high); 1 patient tested d. 1/29/2018--one level of acceptable QC (high); 7 patients tested e. 2/11/2018--one level of acceptable QC (low); 2 patients tested f. 2/15/2018--one level of acceptable QC (low); 1 patient tested. 2. Testing personnel confirmed during an interview on 10/18/2019 at 12:45 pm that the laboratory failed to perform and document at least two levels of acceptable hematology QC on these days.