

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2043258	<b>(X3) Date Survey Completed</b>  06/19/2018
<b>Name of Provider or Supplier</b>  Walk-In Md	<b>Street Address, City, State</b>  179-B Pine Grove Road, Cartersville, GA	
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>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 19, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Control (QC) document review and an interview with the office manager, the laboratory failed to monitor Quality Control values for the Horiba Micros 60 Hematology Analyzer over time to check the accuracy and precision of test performance. Findings include: 1. No evidence of long term monitoring of Hematology QC available to review (Levy-Jennings charts or eQC) in 2016, 2017 and January to June 2018. 3. An interview with the office manager on June 19, 2018 at approximately 12:20 PM in the break room review desk, confirmed QC for the Horiba Micros 60 Hematology Analyzer was not monitored for accuracy and precision.</p>
<b>D6046</b>	<b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel competency assessment records and an interview with the office manager, the laboratory failed to include the six required competency assessment criteria when evaluating annual competency on testing personnel for the Horiba Micros 60 Hematology analyzer. The findings include: 1. Review of testing personnel (TP #s 2, 3, and 4 on CMS 209) competency assessment records for 2016, 2017 and 2018 revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. An interview with the office manager in the breakroom review desk on June 19, 2018 at approximately 12:40 PM confirmed that annual competency assessment for testing personnel (TP# 2-4, CMS 209) did not contain the six required criteria by CLIA.