

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0257012	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Woodall, Wilson & Manley Md Llp	Street Address, City, State 101 Houston St, Barnesville, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 16, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and staff interview, the lab failed to rotate PT samples among all testing personnel (TP). Findings include: 1. Review of the PT documents: 2016 testing event #3 through 2018 testing event #1 revealed the same TP (#2 CMS 209 form) performed all PT testing. 2. Interview with testing personnel #2 (CMS 209 form) on 5/16/18 at approximately 10:30 AM in the nurses' office, confirmed the same TP performed the aforementioned PT.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and staff interview, the lab failed to establish and</p>

	<p>follow a written procedure to assess personnel competency. Findings include: 1. Review of the procedure manual revealed the lack of a competency assessment procedure. 2. Interview with testing personnel #2 (CMS 209 form) on 5/16/18 at 10:30 AM in the nurses' office, confirmed the lack of the aforementioned procedure.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing personnel (TP), the lab failed to calibrate the AO one-fifty (150) microscope per the manufacturer. Findings include: 1. Observation during the lab tour revealed the AO 150 microscope did not have documentation of calibration. 2. Interview with TP #2 (CMS 209 form) on 05/16/18 in the procedure room at approximately 1035 AM, confirmed the microscope had not been calibrated.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES 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, procedure review, and staff interview, the lab failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Review of QC documents revealed the lab was not monitoring, printing, or reviewing QC over time (Levey-Jennings charts or peer comparisons). No long term QC documents available for patient testing period of August 2016-2018 thus far. 2. Review of the procedure manual revealed the controls were to be reviewed weekly for shifts and trends. 3. An interview with testing personnel #2 (CMS 209 form) on 5/16/18 at 11:30 AM in the nurses office, confirmed the QC was not monitored over time.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:

Based on the lack of testing personnel (TP) documents and staff interview , the technical consultant (lab director) failed to perform annual competency on testing personnel. Findings include: 1. No documents were available to review for personnel competencies during the time period of 2016-2018. 2. Interview with testing personnel #2 (CMS 209 form) on 5/16/18 at 10:30 AM in the nurses' office, confirmed the lack of the aforementioned personnel competencies.