

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2124603	(X3) Date Survey Completed 08/14/2018
Name of Provider or Supplier Hamilton Physician Group Murry Campus	Street Address, City, State 800 G I Maddox Parkway, Chatsworth, 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	Based on a CLIA Certification Survey performed on August 14, 2018 this facility was found to be non-compliant with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing personnel (TP), the lab failed to monitor room temperature (RT) and relative humidity (RH) per the manufacturer's manual. Findings include: 1. Review of the temperature charts provided revealed the Beckman Coulter ACT Diff 2 required RT and RH be maintained at specific ranges. 2. Interview with TP #1 (CMS 209 form) on 08/14/18 in the lab at approximately 3:21 PM, confirmed the RT/RH was not monitored.</p>
D5429	<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>

This STANDARD is not met as evidenced by:
Based on observation and interview with testing personnel (TP), the lab failed to calibrate the LabCorp Horizon Mini E centrifuge per the procedure manual. Findings include: 1. Observation during the lab tour revealed the LabCorp Horizon Mini E centrifuge was last calibrated on October 19, 2015. 2. Interviews with TP #1 (CMS 209 form) on 08/14/18 in the lab at approximately 3:21 PM, confirmed the centrifuge had not been calibrated since 10/19/15.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on review of personnel documents and interviews with the office manager and testing personnel, the laboratory failed to employ a qualified person to fulfill the position of Technical Consultant (TC). Findings include: 1. Review of personnel documents revealed the lab director (LD) did not qualify for the position of TC. 2. Interview with the corporate manager and TP#1 (CMS 209) on 8/14/18 at 1:15 PM in the corner office confirmed the LD did not have the experience to fulfill the duties of TC.