

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1001114	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Gwinnett Clinic Ltd	Street Address, City, State 475 Philip Boulevard, Suite 301, Lawrenceville, 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	An offsite revisit survey was conducted on October 1, 2018, for all previous deficiencies cited on 9/5/2018. All deficiencies have been corrected. The facility is in compliance with with all regulations surveyed.
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> <p>This STANDARD is not met as evidenced by: Based upon observation and staff interview, the laboratory failed to perform and document maintenance of laboratory equipment as required. Findings include: 1. Observation during the laboratory tour in the chemistry area at approximately 5:30 p. m. on 9/5/18 revealed the MLA pipettes (5, 10-50, and 50-200 microliter) had not calibration stickers. 2. An interview with Staff #3 (CMS 209) in the laboratory on 9/5 /18 at approximately 5:30 p.m. confirmed the MLA pipettes were not calibrated in 2017 and 2018 thus far.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If</p>

the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all laboratory responsibilities were properly performed. Findings include: 1. TP document review revealed a six-month competency was not performed for the technical consultant in 2018. 2. An interview with Staff #3 (CMS 209) in a laboratory office on 9/5/18 at approximately 6:00 p.m. confirmed a six-month competency was not performed for the TC in 2018.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each of the individuals involved in all phases of laboratory testing. Findings include: 1. SOP review revealed the LD did not specify in writing the duties and responsibilities of the LD, technical consultant, clinic consultant, and testing personnel. 2. An interview with Staff #3 (CMS 209) in a laboratory office at approximately 6:00 p.m. confirmed there was not a duties and responsibilities policy in the SOP.