

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0676145	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Lawrenceville Health Center	Street Address, City, State 455 Grayson Highway, Suite 300, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 9, 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:
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 proficiency testing (PT) documents and staff interview, the laboratory failed to test the PT samples with the laboratory's regular workload by testing personnel (TP) who routinely perform the testing in the laboratory. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed all three 2017 Clinical Microscopy PT events were performed by Staff #3 (CMS 209). 2. An interview with the director of nursing on May 9, 2018, in a conference room at approximately 3 p.m. confirmed all three 2017 Clinical Microscopy PT testing events were performed by the same TP.</p>
D2009	<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>

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) documents and staff interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the laboratory director (LD) failed to sign the attestation statements for all three Clinical Microscopy PT events in 2017 and the first two Clinical Microscopy PT events in 2018. 2. The PT attestation statements included the following testing facilities within the East Metro Health District: Norcross Health Center, Newton County Health Department, Buford Health Center, Rockdale County Health Department, and Lawrenceville Health Center. 3. An interview with the LD on 5/9/18 in a conference room at approximately 10:15 a.m. confirmed the LD did not sign the attestation statements for the aforementioned PT events for the aforementioned testing facilities.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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 the laboratory director reappoints 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 review of testing personnel (TP) competencies and staff interview, the laboratory director (LD) failed to employ qualified personnel to perform the duties of technical consultant (TC). Findings include: 1. TP competency document review revealed initial training competencies, six month competencies, and annual competencies for 2017 and 2018 thus far were performed by unqualified personnel. 2. An interview with the TC on 5/9/18 in a conference room at approximately 11:00 a.m. confirmed the aforementioned TP competencies were performed by unqualified personnel.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) document review and staff interview, the laboratory

director (LD) failed to review the PT reports to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the LD failed to review PT reports for all three Clinical Microscopy events in 2017 and the first event in 2018. 2. The AAB proficiency test reports are inclusive of the following testing facilities for the East Metro Health District: Norcross Health Center, Newton County Health Department, Buford Health Center, Rockdale County Health Department, and Lawrenceville Health Center. 3. An interview with the LD on 5/9/18 in a conference room at approximately 10:15 a.m. confirmed the LD did not review the PT reports for the aforementioned AAB PT events for the aforementioned testing facilities.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on review of laboratory employee qualification documentation and staff interview, the laboratory failed to employ an individual qualified to perform the duties and responsibilities of technical consultant (TC). Findings include: 1. Review of laboratory employee qualification documentation revealed the laboratory failed to

employ a qualified TC due to lack of documentation of at least one year of laboratory training or experience in the designated specialty for which the TC is responsible. 2. An interview with the TC on 5/9/18 in a conference room at approximately 11:00 a.m. confirmed there was no documentation available at the time of survey of at least one year of laboratory training or experience in the designated specialty for which the TC is responsible.