

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0676145	(X3) Date Survey Completed 02/26/2020
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 February 26, 2020. 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:
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 on equipment maintenance document review and staff interview, the laboratory failed to perform and document equipment maintenance as required by CLIA (Clinical Laboratory Improvement Amendments). Findings include: 1. Equipment maintenance document review revealed required maintenance had not been performed for the following Quest Horizon centrifuges since 7/27/2018 (one centrifuge per health center) : Newton, Buford, Lawrenceville, and Rockdale. 2. An interview with the nursing director in the conference room on 2/26/2020 at approximately 2:30 p.m. confirmed the lack of required equipment maintenance since 7/27/2019 for the aforementioned health centers at the time of survey. .</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following</p>

	<p>for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory quality control (QC) logs and staff interview, the laboratory failed to perform required QC for qualitative laboratory testing. Findings include: 1. QC document review revealed the laboratory failed to provide documentation of positive and negative QC for Potassium Hydroxide (KOH) and Wet Prep (Parasitology) testing for 2018, 2019, and 2020 thus far. 2. An interview with the nursing director in the conference room on 2/26/2020 at approximately 3:45 p.m. confirmed the lack of QC for the aforementioned tests for 2018, 2019, and 2020 thus far.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency test document review and staff interview, the laboratory director (LD) failed to provide overall management and direction on the laboratories as required. Findings: For details refer to D6018.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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. (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;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to review PT reports to evaluate laboratory performance and to identify any problems that require corrective action as required. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the LD did not review Potassium Hydroxide (KOH) and Wet Mount (Parasitology)PT reports for the following health centers for 2018 (Event 3) and 2019 (Events One and Three) -- Newton, Buford, Lawrenceville, Norcross, and Rockdale. 2. An interview with the nursing director on 2/26/2020 in the conference room at approximately 1:00 p.m. confirmed the lack of LD review for the aforementioned PT events in 2018 and 2019. This is a REPEAT deficiency.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to ensure an approved SOP was available to all personnel responsible for any aspect of the testing process. Findings include: 1. SOP review revealed the LD had not approved and signed the current laboratory SOP at the time of survey.. 2. An interview with the nursing director in the conference room on 2/26/2020 at approximately 3:30 p.m. confirmed the lack of SOP approval by the current LD.