

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0671793	(X3) Date Survey Completed 03/01/2019
Name of Provider or Supplier Georgia Public Health Laboratory	Street Address, City, State 1749 Clairmont Road, Decatur, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on suveyor record review and interview of Virology records, the laboratory failed to perform comparison of test instrumentation and evaluation two times a year for the same clinical test procedures performed on multiple instruments. Findings Include: 1. The labortory HIV Viral Load records did not incude any documentation of comparison studies during 2017 and 2018 for the Abbott m2000. The surveyor found the laboratory was performing the same test on two different Abbott m2000's. CLIA requires laboratories performing the same test on mulitple instruments to compare results two times a year. 2. The laboratory Quality Assessment Plan did not include any language detailing when and how laboratories should complete comparison studies and evaluations. 3. The laboratory General Supervisor confirmed during the interview on February 28, 2019 at 11:00 am, the laboratory did not perform comparison studies in 2017 and 2018.</p>