

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0861722	(X3) Date Survey Completed 10/15/2019
Name of Provider or Supplier Norton Community Medical Associates	Street Address, City, State 3101 Poplar Level Rd, Suite 101, Louisville, KY	
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 staff interview and record review, on October 15, 2019, the laboratory failed to perform method comparison between the two (2) Roche Cobas analyzers from November 2, 2017 through October 14, 2019. The findings include: 1. Record review revealed the laboratory failed to review any documented method comparisons between method one (1) and method (2) of the Roche Cobas analyzers from November 2, 2017 through October 14, 2019. 2. Interview with the laboratory staff, on October 15, 2019 at 10:02 AM, revealed the laboratory did not have a system in place to ensure the two (2) analyzers had method comparisons performed on a six (6) month interval between November 2, 2017 through October 14, 2019.</p>