

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0071463	(X3) Date Survey Completed 02/17/2022
Name of Provider or Supplier Merrimack Urology Associates	Street Address, City, State 31 Village Square, Chelmsford, MA	
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 CLIA recertification survey was conducted for the Merrimack Urology Associates, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview, the laboratory failed to perform twice a year evaluations between two analyzers performing the same test as evidenced by the following: Two Qualigen chemistry analyzers: The laboratory performed prostate specific antigen (PSA) using two Qualigen chemistry analyzers. A review of calendar years 2020 and 2021 records revealed the following: a) For calendar year 2020 the laboratory performed comparisons of PSA on the two analyzers on 1/6/20 (10 specimen comparison) and 1/8/20 (5 specimen comparison). However there was no analysis of the data obtained to ensure that it met the 10% difference criteria set up by the laboratory. b) A review of 2021 records revealed that no twice a year comparisons were performed on the two Qualigen analyzers for PSA. c) The office manager interviewed on 2/17/22 at 10:40 a.m. confirmed that no data analysis had been performed on the 2020 analyzer comparison data and that no twice a year comparisons on the two analyzers had been performed in calendar year 2021.</p>