

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0674566	(X3) Date Survey Completed 08/19/2022
Name of Provider or Supplier Quest Diagnostics Llc	Street Address, City, State 535 Faunce Corner Road, North Dartmouth, 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 SMG Hawthorn Medical Associates - Urology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 proficiency testing record review and interview with the Technical Consultant (TC) on 8/19/2022, the laboratory failed to ensure that four (4) out of five (5) testing personnel (TP) routinely tested proficiency testing samples as evidenced by the following: The surveyor reviewed proficiency testing record attestation statements for calendar years 2020 and 2021(four testing events). The review revealed that only one (1) testing person (TP #1) of the personnel performing moderate complexity testing was also performing proficiency testing samples based on the documented signature on the attestation forms. The TC confirmed in an interview on 8/19/2022 at 3:05 PM that only one (1) out of the five (5) testing personnel was routinely performing proficiency testing samples. The laboratory performs 20,641 Urinalysis tests, 11,178 Urine Microscopic tests, and 226 Sperm Presence/Absence tests annually. .</p>
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</p>

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.

This STANDARD is not met as evidenced by:

. Based on procedure review and interview the Technical Consultant (TC) on 8/19/2022, the laboratory failed to perform twice annual evaluation between two analyzers performing the same test as evidenced by the following: The laboratory performs urinalysis tests using two Clinitek Advantus analyzers. The surveyor reviewed the comparison studies on the two Clinitek Advantus analyzers. For calendar years 2020 and 2021 the laboratory performed comparison studies twice annually. The comparison studies were performed on 2/25/2020, 9/03/2020, 3/04/2021 and 10/28/2021. There have no comparison studies performed in calendar year 2022 to date. It has been more than six months since the last comparison study has been performed. The TC confirmed in an interview on 8/18/2022 at 3:40 PM confirmed that the comparison studies have not been performed in calendar year 2022 to date. The laboratory performs 20,641 Urinalysis tests annually.