

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0955523	(X3) Date Survey Completed 06/13/2022
Name of Provider or Supplier Revere Health Urology	Street Address, City, State 1055 N 500 W Ste 211, Provo, UT	
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
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 review of proficiency testing documentation and interview with the office manager, the laboratory failed to ensure personnel who routinely perform patient testing also performed the Prostate Specific Antigen (PSA) proficiency testing for the Qualigen Total PSA FastPack. The laboratory performs approximately 1465 PSA tests annually. Findings include: 1. A review of proficiency testing records on 6/13/22 at 3:00 pm revealed that the laboratory failed to include documentation that 2 of 3 testing personnel that routinely perform patient testing also performed proficiency testing for 4 of 4 American Proficiency Institute (API) events including the 2nd event of 2021, 3rd event of 2021, 1st event of 2022, and the 2nd event of 2022. 2. In an interview on 6/13/22 at approximately 3:30 pm, the office manager confirmed that 2 of 3 testing personnel had not participated in 4 of 4 American Proficiency Institute (API) events including the 2nd event of 2021, 3rd event of 2021, 1st event of 2022, and the 2nd event of 2022. This is a REPEAT Deficiency.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:

Based on a review of procedure manuals and an interview with the office manager, the laboratory failed to have a written procedure available for the Qualigen Total PSA FastPack test. The laboratory performs approximately 1465 PSA tests annually.

Findings include: 1. A review of the procedure manuals on 6/13/22 at 4:45 pm revealed that, at the time of survey, the laboratory failed to have a written procedure available for the Qualigen Total PSA FastPack test. 2. In an interview on 6/13/22 at 4:50 pm with the office manager, it was confirmed that, at the time of survey, the laboratory failed to have a written procedure available for the Qualigen Total PSA FastPack test.