Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0955523	08/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health Urology	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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on proficiency testing records review and interview with staff, the laboratory failed to ensure personnel routinely performing patient testing also performed Prostate Specific Antigen (PSA) proficiency testing. The laboratory performed approximately 3 PSA tests per day. Findings include: 1. Proficiency testing records review failed to include documentation 2 of 3 testing staff members routinely performing patient testing also performed proficiency testing for 4 of 4 American Proficiency Institute (API) reviewed from the 2nd event of 2017 through the first event of 2019. 2. In an interview conducted on 08/16/2019 at approximately 11:15 A.M., the laboratory manager confirmed the two other testing personnel had not participated in proficiency testing form the second event of 2017 through the 1st event of 2019.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on the laboratory's Individualized Quality Control Plan (IQCP) review, lack of documentation, and confirmation by staff, the laboratory failed to follow the IQCP to

	review Prostate Specific Antigen (PSA) quality control performance, in conjunction with proficiency tests results to ensure reducing the frequency of quality control performance to each new lot number or shipment was sufficient. The laboratory performed approximately 3 PSA tests per day. Findings include: 1. The laboratory IQCP lacked documentation the director had reviewed QC performance frequency adequacy since the plan was approved on 06/02/2017. 2. In an interview conducted on 08/16/2019 at approximately 11:15 A.M. staff confirmed the laboratory failed to re-evaluate the IQCP to ensure once per lot number of PSA test kits was sufficient to ensure the Qualigen PSA test system was capable of producing accurate and reliable results.