

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0911244	(X3) Date Survey Completed 09/24/2019
Name of Provider or Supplier Reproductive Care Center	Street Address, City, State 10150 South Petunia Way, Sandy, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) record review and interview with staff, the director and the testing person failed to attest PT samples were integrated into the patient workload and handled like patient samples for 4 of 4 semen analysis PT testing events reviewed from the 2nd event of 2017 to the 1st event of 2019. Findings include: 1. Semen analysis test records for 4 of 4 testing events reviewed failed to include a signed attestation statement by the analyst and the director stating PT samples had been handled in the same manner as patient samples. 2. Staff confirmed in interview on 06/24/2019 at approximately 12:00 PM, they were not aware that a signature by the analyst and director was required.</p>
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review and interview with staff, the laboratory failed to retain, for at least 2 years, the test requisition for 1 of 4 complete semen analysis tests reviewed. Findings include: 1. Patient test records failed to include the original order</p>

for semen analysis testing on patient 33204 tested on 10/10/2017. 2. Staff confirmed during interview on 09/24/2019 at approximately 12:30 PM, testing for patient 33204 was ordered by an outside provider and they were unable to locate the original test requisition.