

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0908423	(X3) Date Survey Completed 03/08/2019
Name of Provider or Supplier Reproductive Specialty Laboratories, Inc.	Street Address, City, State 15500 Sand Canyon Ave Ste 100, Irvine, CA	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on the review of proficiency testing records, laboratory's repeat testing criteria, review of laboratory's procedure manual for proficiency testing, and interview with the technical consultant, the laboratory failed to test proficiency testing samples the same number of times that patient samples are tested. Findings include: a. On September 4, 2018, the laboratory tested [test performed: Estradiol, Follicle Stimulating Hormone (FSH), Leuteinizing Hormone (LH), Progesterone, and Human Chorionic Gonadotropin (hCG) their American Association of Bioanalysis (AAB) 2018 Chemistry Q3 samples. b. On September 8, 2018, the laboratory retested their AAB 2018 Chemistry Q3 samples for Estradiol, FSH, LH, Progesterone, and hCG. c. Patient samples are repeat tested on the orders of the Clinician. d. On September 4th and 8th, 2018, the laboratory tested 16 patients besides the 2018 Q3 AAB proficiency testing samples, were there deviation with these patients or other days of testing that could affect patient care? e. The Technical Consultant (March 8, 2019, 7:45 A.M.) confirmed that the proficiency testing mention above was not tested the same number of times as patient samples were.</p>