

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0859540	<b>(X3) Date Survey Completed</b>  03/20/2019
<b>Name of Provider or Supplier</b>  Reproductive Technology Laboratories	<b>Street Address, City, State</b>  11818 Wilshire Blvd Ste 300, Los Angeles, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2100</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by:</p> <p>1. Based on interviews with the staff on March 20, 2019, and review of College of American Pathologists proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to participate in a testing event in the subspecialty of endocrinology. The findings included: a. Laboratory proficiency testing records showed the laboratory attained a score of 0% for human Chorionic Gonadotropin (hCG) testing during the 2nd proficiency testing event of 2017. b. A testing person affirmed on March 20, 2019 at approximately 10:30 am, the unsatisfactory score of 0% obtained by the laboratory for hCG testing during the 2nd proficiency testing event of 2017. c. Based on the annual test volume reported, the laboratory performed and reported approximately 23,500 tests for the subspecialty of Endocrinology. 2. Based on interviews with the staff on March 20, 2019, and review of College of American Pathologists proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to participate in a testing event in the subspecialty of endocrinology. The findings included: a. Laboratory proficiency testing records</p>

showed the laboratory attained a score of 0% for free T4, T4, and TSH testing during the 3rd proficiency testing event of 2018. b. A testing person affirmed on March 20, 2019 at approximately 10:30 am, the unsatisfactory score of 0% obtained by the laboratory for free T4, T4, and TSH testing during the 3rd proficiency testing event of 2018. c. Based on the annual test volume reported, the laboratory performed and reported approximately 23,500 tests for the subspecialty of Endocrinology.

**D2121**

**HEMATOLOGY**  
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
Based on interviews with the staff on March 20, 2019, review of College of American Pathologists proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to attain a score of at least 80 percent in the specialty of hematology. The findings included: a. The laboratory performs complete blood count (CBC) testing on the Abbott Cell Dyn 1800 analyzer. b. Laboratory proficiency testing records showed the laboratory attained the following scores for the individual analyte. 1) Hematocrit proficiency test results indicated that three out of five College of American Pathologists proficiency samples tested were not within acceptable range. Specimen ID Lab Result Acceptable Range FH-1 38.10 \* 38.44 - 43.36 FH-2 34.30 33.74 - 38.06 FH-3 30.80 \* 30.95 - 34.91 FH-4 46.60 \* 46.80 - 52.79 FH-5 17.80 17.69 - 19.96 \*not within acceptable range c. A testing person affirmed on March 20, 2019 at approximately 11:00 am, the unsatisfactory score of 40% obtained by the laboratory for hematocrit testing during the 3rd proficiency testing event of 2018. d. Based on the annual test volume reported, the laboratory performed and reported approximately 10,690 tests for the specialty of Hematology.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the staff, it was determined that the laboratory director failed to ensure that proficiency testing samples are tested as required under subpart H of this part. The findings included: a. See D2100. b. See D2121.