

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2164222	(X3) Date Survey Completed 09/11/2020
Name of Provider or Supplier Life Ivf Center Los Angeles	Street Address, City, State 289 W Huntington Dr Ste 400, Arcadia, 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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient, quality control and proficiency testing records for the years of 2019 and 2020, and interview with the laboratory testing person # 1 on September 11, 2020 at 11:50 am, the laboratory failed to evaluate its proficiency testing performance for the quantitative results of the analyte hCG, for 4 events out of 4 events, reviewed. The findings include: 1. The laboratory participated CAP proficiency testing program in the year of 2019 and 2020 for its quantitative hCG test which is done on Tosoh AIA-900 instrument. However, it did not evaluate its proficiency testing performance upon receiving no score from CAP due to insufficient peer group data. Therefore, the accuracy of the laboratory's test results to the patients for quantitative hCG test can not be assured. a. The laboratory participated CAP proficiency testing program for the events of S-A 2019, S-B 2019, S-C 2019 and S-A 2020. However, CAP did not grade laboratory's results due to insufficient peer group data. b. The laboratory director reviewed the ungraded report from CAP but did not evaluate its own performance by verifying the accuracy of its results for the quantitative hCG test. 2. The laboratory testing person # 1 on September 11, 2020 at 11:50 am, affirmed that the laboratory did not evaluate its own performance by verifying test accuracy for the quantitative hCG test. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/3/2020, stated that the laboratory performs 296 quantitative hCG tests, annually.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p>

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure and proficiency testing records, and interview with the laboratory testing person # 1 on September 11, 2020 at 11:50 am, it was determined that the laboratory director failed to ensure that all proficiency testing reports received are reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. See D5213.