

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2137456	(X3) Date Survey Completed 11/19/2025
Name of Provider or Supplier Fertility Specialists Medical Group	Street Address, City, State 6125 Paseo Del Norte, Ste 120, Carlsbad, 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
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the AAB-MLE proficiency testing (PT) records, Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, PT documentation, and interviews with the laboratory's technical supervisor (TS); the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the Progesterone and Serum HCG analytes for Fertility Testing for the second PT event of 2025 (Q2-2025). The findings include: 1. AAB-MLA reported for Endocrinology Overall Fertility Testing 66%, which included Progesterone = 60% and Serum HCG =40%. 2. The TS, affirmed by an interview on November 19, 2025, at approximately 9:45 a.m. that the laboratory obtained the unsatisfactory PT scores for Progesterone and Serum HCG for Q2-2025 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 1,211 patient test samples for Progesterone and Serum HCG Fertility Testing analytes annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic,</p>

and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the proficiency testing results documentation, randomly selected patient test records, and interviews with the laboratory technical supervisor on November 19, 2025; the laboratory director is herein cited due to failure to ensure that aspects of the analytic phases of the laboratory testing were monitored.

The findings include: D2089.