

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0953377	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Fertility Center And Applied Genetics Of Florida	Street Address, City, State 5100 Station Way, Sarasota, FL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209- Laboratory Personnel Report, review of American Association of Bioanalysts (AAB) proficiency testing, and interview with the Testing Personnel #B, the laboratory failed to have all testing people rotate through the testing of proficiency testing for 2 of 2 years (2017-2018) reviewed. Findings Included: 1. Review of the CMS 209 (signed and dated by the Laboratory Director (11/27/2018) had 2 testing people listed (#A and #B). 2. Review of AAB proficiency testing found that Testing Person #B was the only person who performed the proficiency testing in 2017-2018. 3. Interview 11/29/2018 at approximately 12:00 PM, Testing Personnel #B confirmed that Testing Person #B was the only person performing proficiency testing even though Testing Person #A performed patient testing.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of records, procedure manual, and interview with Testing Personnel #B, it was determined that the laboratory did not maintain laboratory records for at</p>

least two years. Findings included: Review of the procedure manual revealed that the procedures, Semen Analysis and Sperm Antibody Test had specific temperature requirements for storage for specimens, reagents, and quality controls, environmental (room temperature), and incubator. Laboratory did not provide temperature records from 2017-2018 due to unable to locate because the records were in boxes that had not been unpacked since the laboratory's move in October 2018. Interview on 11/28 /2018 at 11:50 AM, Testing Personnel #B confirmed the laboratory was unable to provide the requested records.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review, and interview with Testing Personnel #B, the facility failed to maintain documentation for the calibration of pipettes used in the laboratory. The findings included: Review of instrument calibrations records revealed that the laboratory did not have documentation for calibration for the pipettes. Interview on 11 /28/2018 at 11:30 AM, Testing Personnel #B confirmed that records were not kept showing a calibration had been performed.