

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D0679021	<b>(X3) Date Survey Completed</b> 11/06/2024
<b>Name of Provider or Supplier</b> Ivf Florida Reproductive Associates	<b>Street Address, City, State</b> 3251 N State Rd 7 Suite 200, Margate, FL	
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>D0000</b>	A recertification survey was conducted on October 30th, 2024 to November 6th, 2024. IVF FLORIDA REPRODUCTIVE ASSOCIATES clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have corrective action for the biyearly verification of proficiency testing with split-sample analysis in one (S2-2023) of two event (S1 -S2) in 2023 and first event (S1-2024). Findings included: 1- Review of the split-sample proficiency testing (PT) results for the second event in 2023 did not match first set tested 11/28/2023. The laboratory did not record a corrective action for repeat test on 12/15/2023. 2- Review of the split sample PT results for the first event in 2024 did not match samples tested on 05/29/2024. The laboratory did not record a corrective action. 3- Interview on 10/30/2024 at 12:48 PM the General Supervisor confirmed that the corrective action was not documented.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to perform quality control for the days of split-sample analysis in the second event in 2023 and first event in 2024. Findings included: 1- Review of the Andrology Daily Quality Control Checks records for Seminal Fructose tested on 05/04/2023, 11/28/2023, 12/15/2023, 05/29/2024 revealed that the laboratory did not record quality control. 2- Review the Proficiency Testing SOP-LAB-GEN-106 Version Date: October 01,2024. Section VIII C. Procedure [split sample with another laboratory] revealed in step 2(d.) Aliquot 5 milliliters of either a positive or negative control into each set of tubes and document what they are on a sheet of paper. The laboratory did not document as instructed in their laboratory procedure. 3- Interview on 10/30/2024 at 12:48 PM the General Supervisor confirmed that the quality control was not documented.