Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1029616	02/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ivf Florida Reproductive Associates	126 Aragon Ave Ste 126, Coral Gables, 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
D0000	An announced CLIA recertification survey was conducted at IVF FLORIDA REPRODUCTIVE ASSOCIATES on February 17, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the current laboratory director (LD) failed to approve, sign and date 21 out of 29 policies of the procedure manual before use after his approval as LD on 12/16/2024. Findings included: -Review of the Confirmation of Change dated 12/16/2024 revealed the approval of the current LD based on the laboratory request from 11/21/2024. -Review of the procedure manual showed that the current LD failed to sign and date the following policies (as they are listed in the procedure manual): 1- SOP-LAB-GEN-100 Quality Management Plan. 2-SOP-LAB-GEN-102 QUALITY CONTROL OF THE ANDROLOGY LABORATORY 3- SOP-LAB-GEN-103 ELEMENTS OF A QUALITY IMPROVEMENT PROGRAM. 4-SOP-LAB-GEN-104 Personnel Training Procedures and Policies. 5-SOP LAB-GEN 105 Assignment and Delegation of Activities and Responsibilities 6-S0P-LAB-GEN 106 PROFICIENCY TESTING. 7-SOP-LAB-GEN- 109 DETECTION AND CORRECTION OF CLERICAL AND ANALYTICAL ERROS AND UNUSUAL RESULTS. 8-SOP-GEN-11-REPORTING OF CRITICAL AND PANIC VALUES. 9-SOP- LAB GEN 111 Policy regarding sample identification, accession and chain of custody. 10-SOPLAB.GEN. 113 GUIDELINES FOR RETENTION OF LABORATORY RECORDS & SPECIMENS. 11-SOP-LAB-114 LABORATORY SAFETY PROCEDURES. 12-

	SOP.LAB.GEN.115 LATEX EXPOSURE POLICY. 13-SOP.LAB.GEN 116 ERGONOMICS POLICY. 14-SOP-LAB-GEN 117 LABORATORY EMERGENCY SAFETY DISATER PLAN. 15-SOP-LAB-GEN-118 LABORATORY IT/IS POLICY. 16-SOP-LAB-GEN-120 SCOPE OF SERVICES, HOURS OF OPERATION, AND TURN AROUND TIME FOR RESULT REPORTING (TAT). 17-SOP-LAB-GEN-400 EQUIPMENT MAINTENANCE PROCEDURES AND SCHEDULE. 18-SOP.LAB.GEN.402 THERMOMETER CALIBRATION. 19-SOP-LAB-GEN 413 COVID-19 Protocol for the Andrology Laboratory. 20-SOP-LAB-GEN-405 LABORATORY CLEANING PROCEDURES FOR THE ANDROLOGY LABORATORY. 21-SOP-LAB-GEN-406 DAILY LABORATORY MAINTENANC & MONITORING During an interview on 02/17/2025 at 12:45 PM, the Technical Supervisor acknowledged that the current LD failed to review, approve and sign the policies listed above after his approval as LD.