Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0939802	08/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ivf Florida Reproductive Associates	400 N Hiatus Rd Ste 205, Pembroke Pines, 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 August 13, 2025 to August 18, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to establish appropriate storage criteria at the appropriate temperature requirements to assure performance of the proteolytic enzyme reagent as per manufacturer instructions for 15 out of 16 days in February 2024, 18 out of 23 days in October 2024, and 10 out of 21 days in June 2025. Findings included: 1- During a tour of the laboratory on 08/13 /2025 at approximately 10:13AM, observed a box of the Viscosity Treatment System (VTS) in the freezer containing about 13 vials of frozen 5ML lipolyzed proteolytic enzyme, labeled "Store product at -20 degrees Celsius upon receipt". 2- Review of the Quality Assurance/Quality Control (QC) Form Andrology Laboratory # F.LAB.AND. 102.A Pembroke Daily/Weekly/Monthly Equipment QC random months of February 2024, October 2024, and June 2025 revealed a freezer monitoring temperature range of -10 to -30 degree Celsius. 3 - Review of the Quality Assurance/Quality Control log

	forms for random months of February 2024, October 2024, and June 2025 revealed the recorded freezer temperature was not at -20C for the dates listed: 02/02/2024 recorded -12 degrees C, 02/05/2024 recorded -13 degrees C, 02/06/2024 recorded -11 degrees C, 02/07/2024 recorded -11 degrees C, 02/09/2024 recorded -19 degrees C, 02 /12/2024 recorded -19 degrees C, 02/13/2024 recorded -19 degrees C, 02/14/2024 recorded -16 degrees C, 02/16/2024 recorded -15 degrees C, 02/19/2024 recorded -16 degrees C, 02/20/2024 recorded -16 degrees C, 02/21/2024 recorded -18 degrees C, 02 /23/2024 recorded -17 degrees C, 02/26/2024 recorded -16 degrees C, 02/27/2024 recorded -19 degrees C, 02/28/2024 recorded -18 degrees C, 10/01/2024 recorded -17 degrees C, 10/02/2024 recorded -17 degrees C, 10/03/2024 recorded -16 degrees C, 10 /04/2024 recorded -17 degrees C, 10/07/2024 recorded -15 degrees C, 10/10/2024 recorded -13 degrees C, 10/11/2024 recorded -17 degrees C, 10/14/2024 recorded -16 degrees C, 10/15/2024 recorded -16 degrees C, 10/16/2024 recorded -13 degrees C, 10 /17/2024 recorded -13 degrees C, 10/21/2024 recorded -16 degrees C, 10/24/2024 recorded -14 degrees C, 10/25/2024 recorded -18 degrees C, 10/28/2024 recorded -14 degrees C, 10/29/2024 recorded -16 degrees C, 10/30/2024 recorded -17 degrees C, 10 /31/2024 recorded -16 degrees C, 06/03/2025 recorded -18 degrees C, 06/05/2025 recorded -15 degrees C, 06/10/2025 recorded -19 degrees C, 06/12/2025 recorded -17 degrees C, 06/13/2025 recorded -19 degrees C, 06/16/2025 recorded -19 degrees C, 06 /24/2025 recorded -17 degrees C, 06/26/2025 recorded -16 degrees C, 06/27/2025 recorded -15 degrees C, 06/30/2025 recorded -18 degrees C, 4- Interview on 08/13 /2024 at 12:48 PM the General Supervisor confirmed that the freezer storage temperature did not meet the VTS manufacturer's specifications.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have the Technical Supervisor (TS) or a designee document direct observation of patient testing during competency evaluation for the one testing personnel (TP) for year 2024. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 08/12 /2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant for Hematology specialty. The laboratory had one Technical Supervisor (TS) who was also the General Supervisor (GS), and one Testing Personnel TP#1. 2-Review of personnel records revealed that annual competency for TP#1 for the Hematology specialty, patient testing was observed by GS but was not documented on 10/11/2024. Competency was signed by a manager with no delegation letter to do competency. 3- During an interview on 08/18/2025 at 1:04 PM, the GS/TS confirmed that the laboratory did not have documentation signed by the GS for direct observation of patient testing during annual competency for TP#1 on 10/11/2024.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have the Technical Supervisor (TS) or a designee document the direct observation of performance of instrument maintenance check during competency evaluation for one testing personnel (TP) for the year 2024. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 08/12/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant for Hematology specialty. The laboratory had one Technical Supervisor (TS) who was also the General Supervisor (GS), and one Testing Personnel TP#1. 2-Review of personnel records revealed that annual competency for TP#1, direct observation of performance of maintenance check for Hematology specialty was observed by GS but was not documented on 10/11/2024. Competency was signed by a manager with no delegation letter to do yearly competency. 3- During an interview on 08/18/2025 at 1:04 PM, the GS/TS confirmed that the laboratory did not have documentation signed by the GS for direct observation of maintenance check during annual competency for TP#1 on 10/11/2024.