Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221993	05/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Genetics & Ivf Institute-Endocrinology Laboratory	3015 Williams Drive, Fairfax, VA	

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 GIVFF, LLC on May 12, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, analyzer performance verification records, lack of documentation, and an interview, the laboratory failed to follow their established policy to perform and document calibration, quality control analysis and patient sample comparison/verification for two of two Roche Cobas Endocrinology analyzers after a physical move/installation to a new suite in February 2025 prior to reporting 1715 patient results as of the date of the inspection on May 12, 2026. The findings include: 1. During a tour of the laboratory on May 12, 2026 at 9:00 AM, the surveyor noted the laboratory had physically moved the two Roche Cobas analyzers (serial numbers 1122-08 and 1122-11) from a first floor suite to a third floor suite location. The surveyor inquired of the move date. The technical consultant (TC) stated: "We moved the two instruments from the first floor in February 2025." The surveyor noted the analyzers were in use for Estradiol (E2), Progesterone (P4), Luteinizing Hormone (LH), and Beta Human

	Chorionic Gonadotropin (BHCG) patient testing. 2. A review of the laboratory's policies and procedures revealed a "Quality Management Plan" with the statements, "10.2.7 Equipment which is moved from one location to another permanent location must be handled in the following manner....Upon arrival at the testing site, the instrument must be recalibrated, if required by the manufacturer, two-level QC must be performed together with representative patient samples (similar to lot-lot verification requirements, see 14.1) to verify the instrument functions properly prior to patient testing." 3. Review of the 2 Roche Cobas analyzers' performance verification documentation (serial numbers 1122-08 and 1122-11) revealed no laboratory director approved evaluation/verification of post-move calibration, quality control analysis, and comparison of analytes, E2, P4, LH, and BHCG, prior to patient testing, for the timeframe of the re-installation in the new laboratory location (2/2025) up to the date of the inspection on 05/12/2026. The surveyor requested to review the post-move performance verification records. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, technical consultant and testing personnel at 1:30 PM on May 12, 2026, the findings were confirmed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the laboratory's policies and procedures, analyzer calibration verification records, calibrator package inserts, lack of documentation and interview, the laboratory failed to follow their established policy to perform calibration verification for the two Roche Cobas Endocrinology analyzers every six months during the twenty-three (23) months reviewed from June 2024 through May 12, 2026. The findings include: 1. During a tour of the laboratory on May 12, 2026 at 9:00 AM, the surveyor noted two Roche Cobas Endocrinology Analyzers (serial numbers SN 1122-08 and 1122-11) in use for Estradiol (E2), Progesterone (P4), Luteinizing Hormone (LH), and Beta Human Chorionic Gonadotropin (BHCG) patient testing. 2. Review of the laboratory's policies and procedures revealed a Quality Management Policy with the statement, "15. Calibration Verification, 15.1 Calibration verification (analytical measurement range verification/linearity) will be performed at six-month intervals if calibration does not

	span a sufficient part of the linear range with at least three calibrators." 3. Review of the Roche Cobas calibrator material package inserts revealed the following analytes with two or less routine calibrators: E2, P4, LH and BHCG. 4. Review of the laboratory's Roche Cobas calibration verification records from June 2024 through May 12, 2026 revealed calibration verification were performed for the analyzers (SN 1122-08 and 1122-11) for analytes E2, P4, LH and BHCG in 09/2024, 04/2025 and 04 /2026. The surveyor requested to review E2, P4, LH and BHCG calibration verification documentation performed in the timeframe of 10/2025. The laboratory provided no further documentation for review. 4. In an exit interview with the laboratory director, technical consultant and testing personnel at 1:30 PM on May 12, 2026, the findings were confirmed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) records, laboratory policies and procedures, lack of documentation, and interviews, the laboratory director failed to ensure the performance of annual competency assessments as defined in the laboratory's policy for two of three TP in calendar year 2025. The findings include: 1. Review of the CMS-209 form and an interview with the Technical Consultant (TC) on May 12, 2026, at 9:30 AM revealed three Testing Personnel (TP #1-3) performed moderate complexity patient testing in the specialty of Endocrinology hematology in the calendar year 2025. 2. Review of available TP competency records revealed a lack of documentation of annual competency assessments for TP 2 and 3 in calendar year 2025. 3. Review of the laboratory's "Quality Management" policy revealed the following statements, "7.4 Competency Evaluations of Personnel, 7.4.1 A competency evaluation must be performed for each test a person performs. Evaluations will be performed six months after initial training is completed, and annually thereafter." 4. In an exit interview with the laboratory director, technical consultant and testing personnel at 1:30 PM on May 12, 2026, the findings were confirmed.