Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221993	10/01/2025
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 off-site CLIA proficiency testing (PT) desk review was conducted for GIVFF, LLC on October 1, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an interview with the Technical Supervisor on October 1, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 CFR. 493.803 Condition: Successful Participation D6000 - 42 CFR. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's proficiency testing (PT) records and interview, the laboratory failed to successfully participate in the Thyroid Stimulating Hormone (TSH) analyte for two consecutive PT testing events. The laboratory had unsatisfactory TSH scores for the first and second events of calendar year 2025. Refer to D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, College of American Pathologists (CAP) PT records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Thyroid Stimulating Hormone (TSH) for two consecutive Endocrinology events in calendar year 2025 resulting in an initial unsuccessful PT performance as reviewed on the date of the inquiry on October 1, 2025. The findings include: 1. Review of the CASPER 0155 report revealed the following results: Chemistry 2025 - 1st Event - unsatisfactory score of 0% for analyte 0585 TSH; Chemistry 2025 - 2nd Event - unsatisfactory score of 0% for analyte 0585 TSH. 2. Desk review of the CAP 2025 PT records outlined above revealed unsatisfactory TSH scores of less than 80% for the following 2 consecutive Endocrinology events: 2025 CAP Event A: TSH scored 0% 2025 CAP Event B: TSH scored 0% resulting in an initial unsuccessful PT performance noted by CAP. 3. In an interview with the Technical Supervisor on October 1, 2025 at 11:00 AM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's 2025 proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management and ensure the overall quality of the laboratory services provided. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's 2025 proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. Refer to D2107.