

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0886517	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Givff, Llc D/B/A Givf Fertility	Street Address, City, State 3015 Williams Dr, 3rd Floor, 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 d/b/a GIVF Fertility on May 13, 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 deficiency cited is as follows:
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow the established policy to perform liquid external QC materials each day of semen analysis (SA)/sperm count patient testing for five (5) days out of twenty-two (22) months reviewed while reporting 5 patient results. Review timeframe July 2024 through April 2026. The findings include: 1. A review of the laboratory's policies and procedures revealed a "Laboratory Quality Management Plan", with the following statements, "Quality Control, 13.1...The QC policy and procedure described in this section will in general be the basis for quality control in the laboratory. However, for tests that require specific and different QC procedures, these will be outlined in the written test SOP OR POLICY or a sectional QC policy. 13.1.1 One low value control and one high value control will be used for each quantitative test...13.2.2 QC must be performed prior to patient testing, as directed by the test SOP OR POLICY or by sectional QC SOP OR POLICY or IQCP." 2. A review of CLINICAL PROTOCOL AND SOP-227 Qwik Check Beads: Quality Control for Sperm Counts" revealed the following statements, "...5. Aliquot the two samples (high and low)...Count all 100 squares. Repeat and record results and average on QC-Bead Counting AND FOR-114." 3. A review of the QC-Bead Counting AND FOR-114 and patient test logs logs</p>

from July 2024 until April 2026 (22 months) revealed the laboratory failed to perform two levels of QC on the following dates and patients tested: 10/16/2024-1 11/12/2024-1 12/17/2024-1 02/13/2025-1 11/18/2025-1 A total of 5 patients. The surveyor requested to review documentation of sperm count QC for the above listed dates. The laboratory provided no further QC documentation for review. 4. In an exit interview with the Technical Supervisor on May 13, 2026, at 12:00 PM, the above listed findings were confirmed.