

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0952503	(X3) Date Survey Completed 11/01/2022
Name of Provider or Supplier Genetics & Ivf Institute/Molecular Inf Dis Lab	Street Address, City, State 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 Genetics & IVF Institute Molecular Infectious Disease Lab on November 1, 2022 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 is as follows:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), tour of the lab, review of the policy and procedures, lack of</p>

documentation, and interviews, the laboratory failed to have a written policy for reporting patient SARS-CoV-2 (COVID-19) molecular test results to the State agency from January 2021 until the date of the survey on November 1, 2022. Findings include: 1. Review of the CMS 116 application revealed the laboratory performs COVID-19 RT-PCR testing. 2. A tour of the facility and interview with the laboratory director on November 1, 2022 at approximately 9:00 AM revealed the facility utilized the BioRad CFX C1000 thermocycler and Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test to perform COVID-19 patient testing. 3. Review of the Biosearch Technologies' manufacturer's IFU's revealed the following statement, "Conditions of Authorization for the Laboratory... D. Authorized laboratories using the SARS-CoV-2 Real Time and End-Point RT-PCR Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 4. Review of the the laboratories policies and procedures revealed a lack of documentation of a process for reporting test results to the state agency. The surveyor requested to review a process for reporting test results to the state agency. The laboratory provided no documentation to review. In an interview with the laboratory director on November 1, 2022 at approximately 12:00 PM, the laboratory director stated they did not have a written protocol for reporting to the state agency. 5. In an exit interview with the laboratory director on November 1 2022 at approximately 12:30 PM, the above findings were confirmed.