Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0952503	11/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Genetics & Ivf Institute/Molecular Inf Dis Lab	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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was conducted at Genetics & IVF Institute-Molecular Infectious Disease Laboratory on November 1, 2022 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The surveyor performed a focused COVID-19 Reporting Survey which concluded November 7, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. During the recertification survey, the inspector found that the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulation: D3000- 42 CFR. 493.1100 Condition Facility Administration (Reporting of SARS-CoV-2 test results).
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a laboratory tour, manufacturer's instruction for use (IFU), SARS CoV-2 patient test records, lack of documentation and interviews, the laboratory failed to report SARS-CoV-2 molecular test results as required for seven hundred ninety-seven (797) patients on one-hundred sixty-seven (167) of 167 testing dates reviewed (timeframe September 17, 2021 to November 1, 2022). Findings include: 1. 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 to COVID-19 patient testing. 2. 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." 3. Review of the laboratory's SARS CoV-2 patient test records revealed 797 patient tests were performed and resulted on 167 testing days from September 17, 2021 to November 1, 2022. The inspector requested to review documentation of the reporting of the SARS CoV-2 test results to the Virginia Department of Health. The laboratory provided no documentation for review. In an interview with the Laboratory Director on November 2, 2022 at approximately 12:00 PM, the laboratory director stated the laboratory had a malware attack and the algorithm the laboratory used to extract information to report COVID-19 results to the Virginia Department of Health was affected. 4. 797 SARS CoV-2 Molecular test results were not reported as required during the timeframe of review (167 testing dates). 5. In an email with the laboratory director on November 7, 2022 at 1:27 PM, the above findings were confirmed.