Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661011	10/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Laboratory Services, Inc	12011 Lee Jackson Memorial Hwy Suite 200, 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 unannounced, Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00052827) was conducted at Metropolitan Laboratory Services , Inc on September 13, 2021 to October 4, 2021 by a Medical Facilities Inspector from the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Based on a tour, review of documents and interviews, the inspector found the complainant's allegation of not reporting all positive and negative COVID-19 test results to the Virginian Department of Health was substantiated. Due to lack of evidence the allegations of inaccurate results and delay in result reporting were not substantiated. Specific deficiency cited is as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D3000 - 42 C.F. R. 493-1100 Condition: Reporting of SARS-CoV-2 Test Reports.
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 review of laboratory policies and procedures, patient test results, lack of documentation and interviews, the laboratory failed to report SARS-CoV-2 positive

	and negative test results for thirty-five (35) of 35 testing dates from July 22, 2021 until September 13, 2021 while reporting four-hundred and fifty-two (452) patient results . Findings include: 1. An interview with the Laboratory Manager on September 13, 2021 at approximately 10:30 AM revealed the laboratory performed SARS CoV-2 testing utilizing the "BioGX Xfree COVID-19 Direct RT-PCR" test kit from November 2020 until September 13, 2021. 2. Review of the manufacturer's instructions for use (IFU) for "BioGX Xfree COVID-19 Direct RT-PCR", revealed a statement, "Conditions of Authorization for the Laboratory- ...c) Authorized laboratories that receive the BioGX Xfree COVID-19 Direct RT-PCR assay must notify the relevant health authorities of their intent to run the BioGX Xfree COVID-19 Direct RT-PCR assay prior to initiating testing. d) Authorized laboratories using BioGX Xfree COVID-19 Direct RT-PCR assay must have a process in place for reporting test results to healthcare providers and relevant public health authorities." 3. Review of SARS CoV-2 patient test reports and test logs from July 22, 2021 until September 13, 2021 revealed 452 SARS CoV-2 patient results resulted and reported during the period of review (35 testing dates). The surveyor requested to review documentation of the reporting of the 452 SARS CoV-2 patient results to the Virginia Department of Health. The laboratory provided no documentation to review. 4. A phone interview with the Laboratory Manager on October 15, 2021 at approximately 12:30 PM, confirmed the findings.