Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0978424	01/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Virus Isolation And Serology Lab	Bldg 310, Floor 1, Ware Drive, Frederick, MD	

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	The Centers for Medicare and Medicaid Services (CMS) Philadelphia Office CLIA Surveyors conducted an announced routine CLIA recertification survey at VIRUS ISOLATION AND SEROLOGY LAB on January 15, 2021.
D1002	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 review of SARS-CoV-2 documentation, Standard Operating Procedure (SOP), form CMS-116 application for certification, and interview with Technical Supervisor, the laboratory failed to report SARS-CoV-2 test results to the Secretary. 1. In review of form CMS-116 application for certification, the lab listed SARS-CoV-2 Serology, RightSign Rapid Test (FDA EUA). The lab resulted 256 tests since August 11, 2020. 2. In review of Standard Operating Procedure, "SARS-COV-2 Antibody Detection Using the RightSign COVID-19 IgG/IgM Rapid Test Cassette," the reporting section stated: "Report for all patient samples tested are reviewed by the VISL Technical Supervisor and entered into Crimson for access by NIH clinicians." There was no indication of reporting test results to the Secretary. 3. In an interview on January 15, 2021 at 11:45 AM, Technical Supervisor stated that the lab has not reported SARS-CoV-2 test results to the Secretary and she was unaware of a requirement to do so.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of test report, and interview with Technical Supervisor, the laboratory failed to put normal values in the test report. 1. In review of excel sheet that contains patient test report and electronically send to the NIH Clinical Center, the normal value was missing. 2. In an interview on January 15, 2021 at 11:50 AM, Technical Supervisor confirmed that the lab has not put the normal value in the test report.