Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0995563	01/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Allyson Agathis Md	395 Main Street, Bedminster, NJ	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Sofia 2 SARS-CoV-2 Antibody Test system Instructions For Use (IFU), interview with the Laboratory Director (LD) the laboratory failed to follow the Information For Use (IFU) when performing Covid tests from November 20212 to the date of the survey. The findings include: 1. The IFU stated " Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. " but the laboratory did not report test results to relevant public health authorities. 2. The LD confirmed on 1/10/23 at 10:14am that the laboratory did not follow the IFU. b) Based on surveyor review of the Accula SARS-CoV-2 Test system, interview with the LD on 1/10/23 the laboratory failed to follow the IFU when performing Covid tests from November 2021 to the date of the survey. The findings include: 1. The IFU stated " Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. " but the laboratory did not report test results to relevant public health authorities. 2. The LD confirmed on 1/10/23 at 10:14am that the laboratory did not follow the IFU.
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 surveyor review of the Sofia 2 SARS-CoV-2 Antibody Test system, Accula SARS-CoV-2 Test system and interview with the Laboratory Director (LD) the laboratory failed to report all SARS-CoV-2 test results from November 2021 to the date of the survey. The findings include: 1. The laboratory did not report positive COVID-19 Antigen test results to the State of New Jersey. 2. The laboratory did not report all Polymerase Chain Reaction (PCR) SARS-CoV-2 test results to the State of New Jersey. 3. The LD confirmed on 1/10/23 at 10:30 am the laboratory failed to report the aforementioned test results.