Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2213167	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Blue Horizons Group Health Services, Llc	4317 Bonney Rd Suite 6, Virginia Beach, 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 focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Blue Horizons Group Health Services, LLC on December 14, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included interviews and remote record review with the Allied Health Instructor and Lab Director on 12/14/21, 12/15/21 respectively. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is the following: 42 CFR part 493 CLIA Regulation: D1002- 42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.
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 interviews, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), testing records, and lack of documentation, the facility failed to report four (4) negative COVID-19 results to the state public health department on three (3) of the 3 test dates reviewed during the timeframe of October 6, 2021 to November 30, 2021. Findings include: 1. During an interview with the entity's Allied Health Instructor on 12/14/21, at approximately 11:00 AM, the inspector was informed that the agency had utilized Mesa Biotech Accula and Salofa Oy Clarity for rapid SARS-CoV-2 testing from October 2021 and up to the date of the survey. The inspector requested to review the test procedures, policy related to SARS-CoV-2 test reporting, and evidence of reporting results to the state agency. 2. Review of the Accula and Clarity FDA EUA's revealed under Authorized Laboratories Instructions: "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." 3. A review of the available Accula and Clarity test logs from 10/01/21 to 12/15/21 revealed the following recorded COVID-19 test results: 10/06/2021 Accula - two negative results, 11/03/2021 Clarity - one negative result, 11/28/2021 Clarity - one negative result. The inspector requested evidence of the facility reporting the negative results outlined above to the state agency. No documentation was available for review. The lab director stated on 12/15/21 at approximately 9:00 AM: "We have recently started testing. We were not aware that we had to report to the state. We will need to implement reporting to the state going forward." 4. An exit interview with the lab director on 12/15/21 at approximately 9:00 AM confirmed the above findings.