Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0015920	(X3) Date Survey Completed 02/08/2021
Name of Provider or Supplier Virginia Beach Dept Of Public Health	**Street Address, City, State** 4452 Corporation Lane, 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 at Virginia Beach Department of Public Health on February 8, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance telephone interview with remote record review conducted on 02/03/21 and virtual exit interviews/tour on 02/08/21. Specific deficiency cited is the following Condition under 42 CFR part 493 CLIA Regulations: D3000- 42 CFR. 493.1100 Condition: 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 interviews, review of procedures, and patient log sheet records, the laboratory failed to report SARS-CoV-2 test results as required on thirty-three (33) days during the timeframe of November 18, 2020 to the date of the survey entrance interview, February 3, 2021. Findings include: 1. During an entrance interview on 02 /03/21, at approximately 2:00 PM, the inspector was informed that the laboratory utilized BinaxNOW COVID-19 Ag Cards for rapid SARS-CoV-2 patient testing. The inspector requested to review the test procedure and evidence of results reporting to state agency. The lab supervisor stated at approximately 2:20 PM: "We have not

	reported results to the state. We do run our tests in conjunction with collecting specimens for PCR testing to outside lab". 2. A remote/virtual review of the laboratory's patient Binax COVID-19 Test Log documentation and reporting protocols from 11/18/20 to 2/04/21 revealed one hundred ninety one (191) rapid SARS-CoV-2 patient tests were analyzed: Eight (8) positive SARS-CoV-2 results were assayed /resulted but were not reported as required; One hundred eighty three (183) negative SARS-CoV-2 results were assayed/resulted but were not reported as required. 3. During a virtual tour and exit interview on 02/08/21 at approximately 2:30 PM, the the lab supervisor and primary testing personnel shared that they had reached out to their health department epidemiologist to assist them in contacting the state agency to set up reporting. The inspector reviewed an email provided (dated 02/03/21 at 4:40 PM). The email revealed that the Portal Support Team Division of Informatics and Information Systems explained to the epidemiologist: "It is our understanding that instructions were sent via email with a link to the VDH LHD COVID-19 Point of Contact Registration REDCap survey to submit the main point of contact and back up for each local health department. Please fill out the survey with the information requested so that we can initiate the first step of granting access to the main point of contact. Please send us an email when the RedCap survey is completed to add you to the portal as soon as possible." The lab supervisor stated on 02/08/21 at approximately 3:00 PM: "I do not recall ever getting the instruction email and link to set up the reporting as the support tech described, but as of Friday, 2/5/21 we are set up and did submit Friday's results". The inspector noted that a user enrollment for the health department's COVID-19 Manual Reporting registration form had been completed on 02/04/21. 4. The lab supervisor and primary testing personnel confirmed the above findings on 02/08/21 at approximately 3:30 PM.