Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D1053042	**(X3) Date Survey Completed** 12/01/2021
Name of Provider or Supplier Generations Family Practice Dba	**Street Address, City, State** 1309 Lees Chapel Road, Greensboro, NC	
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**
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 review of 2020 and 2021 SARS-CoV-2 test records and interview with the TC (technical consultant) 12/1/21, the laboratory failed to report negative SARS-CoV-2 test results to state or local public health authorities as required. Findings: Review of 2020 and 2021 SARS-CoV-2 test records revealed the laboratory started performing COVID testing on 12/17/20. Review of 2020 and 2021 SARS-CoV-2 records revealed the laboratory failed to report approximately 383 negative SARS-CoV-2 test results to state or local public health authorities on 136 days of testing from 12/17/20 through 10/27/21 as described below: 1. December 17-31, 2020 - 65 negative results not reported on 13 days of testing; 2. January 2021 - 104 negative results not reported on 28 days of testing; 3. February 2021 - 35 negative results not reported on 19 days of testing; 4. March 2021 - 29 negative results not reported on 20 days of testing; 5. April 2021 - 27 negative results not reported on 18 days of testing; 6. May 2021 - 7 negative results not reported on 7 days of testing; 7. June 2021 - 14 negative results not reported on 7 days of testing; 8. July 2021 - 3 negative results not reported on 3 days of testing; 9. August 2021 - 0 negative results; 10. September 2021 - 1 negative result not reported on 1 day of testing; 11. October 1-27, 2021 - 98 negative results not reported on 20

	days of testing. During interview at approximately 10:35 a.m., the TC stated that the laboratory faxes positive COVID results to the health department but does not report negative COVID test results. The TC stated they were unaware that they were required to report negative COVID results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the TC (technical consultant) 12/1/21, the laboratory's procedure manual was not complete and current for the SARS-CoV-2 testing performed. Review of the laboratory's procedure manual revealed it did not include a written step-by-step procedure for reporting positive and negative patient SARS-CoV-2 test results to state or local public health authorities. During interview at approximately 10:35 a.m., the TC confirmed the laboratory did not have a procedure for reporting positive and negative patient SARS-CoV-2 test results to appropriate public health authorities.