Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0247075	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Morganton Internal Medicine	607 East Parker Road, Morganton, 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
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: Based on review of laboratory records and manufacturer's IFU(instructions for use) and interview with testing personnel 3/10/22, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 rapid antigen testing performed to ensure authorized Fact Sheets for patients and providers were included with the SARS-CoV 2 test result reports. Findings: Review of laboratory records revealed the laboratory began testing the BD Veritor system for Rapid Detection of SARS-CoV-2 and Flu A&B in August 2021. 1. The laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS Cov-2 test result reports. Review of the IFU for the BD Veritor System for Rapid Detection of SARS-CoV-2 and Flu A&B revealed on page 15, "Conditions of Authorization for the Laboratory... Authorized laboratories using your product must include with test result reports, all authorized fact sheets..." During interview at approximately 12:30 p.m, testing personnel #1 confirmed the laboratory does not provide the fact sheets with test result reports.
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 laboratory records, review of laboratory's policies and procedures, and interview with testing personnel 3/10/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: Review of laboratory records revealed the laboratory began testing for SARS-CoV-2 in December 2020 using the CareStart Covid-19 antigen test and in August 2021 using the BD Veritor System. Review of the laboratory's procedure manual revealed the laboratory had manufacturer's IFU on file for the current test used, the BD Veritor System for Rapid Detection of SARS-CoV-2 and Flu A&B. 1. The procedure manual did not include a step-by-step procedure for reporting SARS-CoV-2 test results to the public health authorities. During interview at approximately 12:30 p.m., testing personnel #1 confirmed all negative and positive test results were being reported daily by fax to the local health department, and documentation of the faxed results since December 2020 was reviewed by the surveyor. Testing personnel #1 confirmed the laboratory does not have a step-by-step procedure for reporting the results for SARS-CoV-2.