Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0931584	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
White Oak Urgent Care Asheboro	197-B Nc Highway 42 North, Asheboro, 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 manufacturer's instructions, review of the FDA (Food and Drug Administration) website, and interview with the laboratory supervisor 9/15/22, the laboratory failed to include Fact Sheets with patient Quidel Sofia SARS Antigen FIA test reports. Manufacturer's instructions for the Quidel Sofia SARS Antigen FIA test state on page 15 "... Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. ..." Review of the FDA website revealed a "FACT SHEET FOR PATIENTS" and a "FACT SHEET FOR HEALTHCARE PROVIDERS". During interview at approximately 8:45 a.m., the laboratory supervisor confirmed that the Fact Sheets were not given to patients with their laboratory's results. She stated they did not know it was required.
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 laboratory supervisor 9/15/22, the laboratory's procedure manual was not complete and current for the SARS-CoV-2 testing performed using the Quidel Sofia SARS Antigen FIA test. Review of the laboratory's procedure manual revealed it did not include a written step-by-step procedure for reporting patient SARS-CoV-2 test results to state or local public health authorities. During interview at approximately 8: 45 a.m., the laboratory supervisor stated they fax positive SARS-CoV-2 test results to the local health department, but she confirmed the laboratory did not have a written procedure describing the reporting process.