

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0239916	(X3) Date Survey Completed 01/07/2022
Name of Provider or Supplier Goldsboro Pediatrics, Pa	Street Address, City, State 2706 Medical Office Place, Goldsboro, 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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use (IFU) and interview with laboratory manager 1/7/22, the laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. Findings: Review of IFU for Quidel Sofia-SARS Antigen Fluorescent Immunoassay (FIA) revealed on page 14 "Conditions of Authorization for the Laboratory...Authorized laboratories using your product will include with test result reports, all Authorized Fact Sheets." Interview with laboratory manager at approximately 11:20 a.m. confirmed the laboratory failed to provide authorized Fact Sheets with test result reports. She stated they were unaware Fact Sheets had to be provided.</p>