Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0688729	11/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Pediatrics Of Wilmington	715 Medical Center Drive, Wilmington, 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 instructions for use (IFU), review of laboratory procedure manual and interview with testing personnel (TP) #2 11/18/21, the laboratory failed to follow manufacturers' instructions for the Quidel Sofia SARS Antigen testing performed to ensure authorized Fact Sheets for patients and providers were included with test result reports and failed to ensure a procedure was established for reporting positive and negative test results to the local or state health department. 1. The laboratory failed to ensure authorized fact sheets for patients and providers were included with test result reports. Findings: Review of IFU for Quidel Sofia SARS Antigen revealed on page 15 "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets." Interview with TP #2 at approximately 9:00 a.m. confirmed the laboratory does not provide the authorized Fact Sheets to the patients and providers for the Quidel Sofia SARS Antigen testing. She stated the instructions in the test kit received did not include what authorized laboratories were required to provide and fact sheets were not included with the test kit. 2. The laboratory failed to establish a procedure for reporting positive and negative test results to the local or state health department. Findings: Review of IFU for Quidel Sofia SARS Antigen revealed on page 15 "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." Review of laboratory procedure manual revealed the procedure manual failed to include the laboratories process for reporting positive and negative test results to the local or state health department. Interview with TP #2 at approximately 9:00 a.m. confirmed the laboratory does not have a written procedure for reporting

	positive and negative test results to the local or state health department. She stated the laboratory is reporting only positive results to the local health department and they did not have a written procedure for that process.
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 SARS-CoV-2 test records, SARS-CoV-2 reporting documentation and interview with testing personnel (TP #2) 11/18/21, the laboratory failed to report negative SARS-CoV-2 test results for 1 of 1 day in August of 2020, 1 of 1 day in January 2021 and 1 of 1 day in August of 2021. Findings: Review of SARS-CoV-2 test records and reporting documentation for 8/3/20, 1/21/21 and 8/5/21 revealed the laboratory tested approximately 13 patients. Review of SARS-CoV-2 test records and reporting documentation for 8/3/20, 1/21/21 and 8/5/21 revealed approximately 11 negative test results were not reported. Interview with TP #2 at approximately 9:00 a. m. confirmed the laboratory failed to report negative SARS-CoV-2 test results. She stated they were told by the local health department to send only positive test results.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with TP #2 11/18/21, the laboratory failed to ensure quality control (QC) reagents and test supplies that exceeded their expiration dates were not available for use by TP. Findings: At approximately 9:30 a. m. surveyor observed three tubes of QC reagents, Boule Con-Diff Tri-Level Lot #22106-01, 02 and 03, available for use in the laboratory refrigerator that had exceeded their expiration date. At approximately 9:30 a.m. surveyor observed one test kit for Osmo Mono Test, Lot #2013500, available for use on the laboratory counter top that had exceed the expiration date of 10/31/21. Interview with TP #2 at approximately 9:30 a.m. confirmed the QC reagents and the test kit were expired. She stated she thought she had already thrown the QC reagents away and she was not aware that the Mono test kit was expired. TP #2 disposed of the QC reagents and the test kit at time of interview.