

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2087760	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Kinder Pediatrics, Pc	Street Address, City, State 1201 River Avenue, Lakewood, NJ	
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 surveyor observation of the Quidle QuickVue SARS Antigen Test system and interview with the Testing Personnel (TP), the laboratory failed to follow the Information for Use (IFU) when performing COVID tests from November 2021 to the date of the survey. The findings include: The laboratory did not follow the IFU as below: 1. The IFU states "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." 2. The Laboratory did not report positive SARS-CoV-2 results to the State of New Jersey. 3. The TP confirmed at 1:30 pm on 3/22/23 that the laboratory did not follow the IFU.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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.</p>

This CONDITION is not met as evidenced by:

Based on surveyor review of the Quidle QuickVue SARS Antigen Test system, and interview with the Testing Personnel (TP) the laboratory failed to report all SARS-CoV-2 test results from November 2021 to the date of the survey. The findings include: 1. The laboratory did not report positive COVID-19 Antigen test results to the State of New Jersey. 2. The LD confirmed on 3/22/23 at 1:30 pm the laboratory failed to report the aforementioned test results.