

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0111810	<b>(X3) Date Survey Completed</b>  04/06/2021
<b>Name of Provider or Supplier</b>  Pediatricare Associates	<b>Street Address, City, State</b>  90 Prospect Ave, Hackensack, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3000</b>	<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> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the COVID 19 Cepheid Xpert Xpress, patient test results and interview with the Testing Personnel (TP), the laboratory failed to report Negative COVID 19 test results to the State of New Jersey (NJ) from 2/9/21 to the date of the survey. The findings include: The laboratory did not report as follows: 1. The Laboratory did not report negative COVID 19 results to the State of NJ. 2. The Laboratory performed approximately 2 COVID 19 tests per day up to the date of the survey. 3. The TP #1 listed on CMS form 209 confirmed at 11:30 am on 4/6/2021 that the laboratory did not report COVID test results to the state.</p>
<b>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or</p>

produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

a) Based on review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of BBL Group A select agar for, sterility from 7/23/18 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 4/6/21/20 at 10:50 am the laboratory did not perform the above QC. b) Based on review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new shipment of BBL Group A select agar for, the ability to support growth and select or inhibit organisms from 1/3/20 to 3/16/20. The TP #1 listed on CMS form 209 confirmed on 4/6/21 at 10:50 am the laboratory did not perform the above QC.