

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0903826	<b>(X3) Date Survey Completed</b>  05/05/2021
<b>Name of Provider or Supplier</b>  Pediatric Healthcare Associates	<b>Street Address, City, State</b>  15 Corporate Dr, Trumbull, CT	
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>D0000</b>	The Pediatric Healthcare Associates Laboratory was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendment of 1988 (CLIA). This was an initial survey performed on May 5, 2021 and the laboratory was found to be in compliance with the laboratory requirements for CLIA.
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> 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 record review and staff interview, the laboratory failed to report SARS-CoV-2 negative test results for 22 of 22 days reviewed from January 17, 2021 through April 19, 2021 and 1 positive test result from February 28, 2021. Findings include: 1. Record review on 5/5/2021 of the laboratory 'Rapid Throat/Flu Test/ COVID Test/ Urine Culture Log' from January 17, 2021 through April 19, 2021. 2. Record review on 5/5/2021 of the SARS-CoV-2 test result reporting documentation for the above referenced timeframe revealed that SARS-CoV-2 negative test results were not reported as required for 8 days in January 2021, 10 days in February 2021, 3 days in March 2021 and 1 day in April 2021. In addition, 1 SARS-CoV-2 positive test result from February 28, 2021 was not reported. 3. 95 negative test results were not reported as required during the period of review. 4. Staff interview on 5/5/2021 at 1:20 PM</p>

with the Clinical Nurse Supervisor confirmed the above findings. 5. The laboratory performed 98 SARS-CoV-2 tests during the period of review.