

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2028521	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Pediatric Associates, Pc	Street Address, City, State 2863 Johnson Ferry Road, Suite 100, Marietta, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 23, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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 test results on all patients to the Department of Public Health(DPH). Findings include: 1. Record review revealed that SARS-CoV-2 results were not reported to the DPH, the account was suspended as of October 2021. 2. The CLIA Coordinator stated that results were being sent to the Department of Public Health , but was ceased for a period of time, due to staff shortage. The email was sent to the State on November 12, 2021 to DPH. 2. During an interview with the CLIA Coordinator on November 23, 2021 at approximately 2:00 PM, confirmed the SARS-CoV-2 results were not reported to the DPH.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to ensure quality controls not be used after their expiration date as required. Findings include: 1. Observation during the laboratory tour on November 23, 2021 at approximately 10:09 AM, revealed the Hematology Sysmex quality controls expired on 11-17-2021. Observation during the tour on November 23, 2021 revealed there were no replacement controls or stability studies available at the time of survey. It was stated by the CLIA Coordinator that Sysmex was behind with their shipments for the quality controls for Hematology. 2. During an interview with the CLIA Coordinator in the laboratory on November 23, 2021 at approximately 10:09 AM, confirmed the quality controls for the Sysmex Hematology analyzer had expired and there were no replacements or stability studies for continued use of the expired reagents.