

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0261389	(X3) Date Survey Completed 07/19/2024
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 1485 Jessie Jewell Parkway, Ste 200, Gainesville, 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 July 19, 2024. 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:
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on patient laboratory reports review(2022 to 2024) , interviews with lab staff and laboratory's Technical Consultant(TC), the laboratory failed to provide the units of measure (Reference ranges) in the moderate specialty of Bacteriology from 2022 to 2024. Findings: 1. Review of patient final reports in 2022 to 2022 revealed final patient reports did not have the units of measure (Reference Ranges) for Throat Cultures, Urine Cultures and RSV testing from 2022 to 2024. 2. Interviews with laboratory staff, lab director, and (TC) on 07/19/2024, at approximately 12:45 PM, in the conference room confirmed the units of measure (reference ranges) for the specialty of Bacteriology, were not on the final reports that were randomly selected for review from 2022 to 2024.</p>