

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0724464	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier North Atlanta Pediatric Associates Pc	Street Address, City, State 1100 Lake Hearn Drive, #100, Atlanta, 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 May 16, 2023. 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:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to ensure a policy for the eyewash station and perform maintenance. Findings include: 1. SOP review revealed the laboratory failed to establish an eyewash procedure for safety of the testing personnel. 2. The laboratory failed to perform eyewash maintenance for 2021, 2022 (January- December), and thus far 2023. 3. During an interview with Testing Personnel #1 (CMS-209) on May 16, 2023 in the Laboratory Director's office, confirmed there was not an eyewash procedure present, during the time survey.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow the required 6-step criteria competency for 11 out of 11 Testing Personnel (TP). Findings include: 1. Competency document review revealed the laboratory was performing competency, but failed to follow the required 6-step criteria policy and procedure for all Testing Personnel (TP) listed on the CMS-209 form. 2. During an interview with Testing Personnel #1 (CMS-209) on May 16, 2023 at 12:50 PM, in the Laboratory Director's office, confirmed that competency was performed for all Testing Personnel (TP), but the laboratory failed to follow the required 6-step criteria for competency.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's testing personnel competency assessment checklist and staff interview, the Technical Consultant failed to ensure the competency assessment policy and procedure for testing performed, in the speciality of hematology and chemistry, met the 6 required criteria, and failed to perform the assessment on 11 out of 11 testing personnel.. The Findings include: 1. Competency document review revealed the Technical Consultant (TC) failed to perform the 6 required criteria for hematology and chemistry for 11 out of 11 Testing Personnel. 2. During an interview with Testing Personnel #1 (CMS-209) on May 16, 2023 at 12:50 PM in the Laboratory Director's office, confirmed the Technical Consultant failed to perform the 6 required criteria for competency.