

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0941970	(X3) Date Survey Completed 10/07/2025
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 40 Pinnacle Parkway, Ste 206, Elgin, SC	
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	An announced onsite CLIA recertification survey was conducted on October 7, 2025, at the laboratory of Pediatric Associates of Kershaw County by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following is a list of standard level deficiencies cited as a result of the October 7, 2025 recertification survey.
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> <p>This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to follow its own policy for competency assessments in the first year of employment for initial and at 6-months. Findings included: 1. Review of the laboratory's policy and procedure manual reveals the requirement for competency assessments to occur after new employee training is complete (Initial), and at 6-months, and annually thereafter. 2. Review personnel competencies reveals only annual competencies documented. 3. In an interview with TP 11 in the laboratory at 11:35am on October 7, 2025, the findings were confirmed.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and</p>

complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:
Based on records review and staff interview, the laboratory director failed to ensure initial competency assessments were completed on 12 out of 12 employee files reviewed. Findings included: 1. Review of the laboratory's policy and procedure manual reveals the requirement for competency assessments to occur after new employee training is complete (Initial), and at 6-months, and annually thereafter. 2. Review personnel competencies reveals only annual competencies documented. 3. In an interview with TP 11 in the laboratory at 11:35am on October 7, 2025, the findings were confirmed.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on records review and staff interview, the technical consultant failed to ensure 6-month competency assessments were performed for 12 out of 12 testing personnel. Findings included: 1. Review of the laboratory's policy and procedure manual reveals the requirement for competency assessments to occur after new employee training is complete (Initial),and at 6-months, and annually thereafter. 2. Review personnel competencies reveals only annual competencies documented. 3. In an interview with TP 11 in the laboratory at 11:35am on October 7, 2025, the findings were confirmed.