

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1023296	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Pediatrics, Carla J Cole, Do, Pa	Street Address, City, State 323 N Shiloh Road, Garland, TX	
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 validation survey of the laboratory was completed on 03/04/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid form 209 (CMS-209), review of the laboratory's policy, review of the laboratory's personnel records, and confirmed in interview, the Technical Consultant (TC-1) failed to have documentation of assessment of competency for five of five testing personnel in 2025. Findings include: 1. Review of form CMS-209 submitted at time of survey, 03/04/2026, determined the following laboratory personnel performing moderate complexity testing: a. Testing Person 1 (TP-1) b. Testing Person 2 (TP-2) c. Testing Person 3 (TP-3) d. Testing Person 4 (TP-4) e. Testing Person 5 (TP-5) 2. Review of the laboratory's policy titled "LABORATORY PERSONNEL POLICIES", approved by the laboratory director on 03/14/2024, stated: "Competency ...Competency is assessed using the following six methods, when applicable: Direct observation of activities associated with patient collection, testing and result interpretation Monitoring the recording and reporting of test results Review of applicable laboratory worksheets, quality control, proficiency testing, and maintenance records Direct observation of instrument maintenance and function checks Assessment of test performance through testing previously analyzed specimens, internal blind samples,</p>

or external proficiency testing samples, and Assessment of problem solving skills." 3. Review of the laboratory's personnel records determined TC-1 failed to have documentation of assessment of competency for five of five laboratory testing personnel in 2025: a. TP-1: Frequency: Annual b. TP-2: Frequency: 6 months Frequency: Annual c. TP-3: Frequency: 6 months Frequency: Annual d. TP-4: Frequency: 6 months Frequency: Annual e. TP-5: Frequency: Annual 4. The Laboratory Director confirmed the findings in an interview on 03/04/2026 at 1108 hours in the office.