

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0663089	(X3) Date Survey Completed 05/30/2025
Name of Provider or Supplier Clinical Pediatrics Associates	Street Address, City, State 8355 Walnut Hill Ln # 205, Dallas, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. 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 CMS-209 form, review of the laboratory's policy, review of the laboratory's personnel records, and confirmed in interview, the technical consultant failed to ensure two of three testing persons had complete competency assessment to perform moderate complexity testing in 2023 and 2024. Findings include: 1. Review of the laboratory's submitted CMS-209 form determined there were three testing persons performing moderate complexity testing. 2. Review of the laboratory's policy titled "Lab personnel competency policy" stated: "The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem solving skills. Competency assessment, which includes the six procedures, must be performed for testing personnel ..." 3. Review of</p>

the laboratory's personnel competency records determined the technical consultant failed to evaluate the six required elements of competency for two of three testing persons in 2023 and 2024: Testing-person 2: a. Date of competency: 05/01/2023 Frequency: Annual Competency elements assessed: 5 b. Date of competency: 05/24/2024 Frequency: Annual Competency elements assessed: 5 Testing-person 3: a. Date of competency: 05/04/2024 Frequency: 6 month review Competency elements assessed: 3 b. Date of competency: 11/24/2024 Frequency: Annual Competency elements assessed: 3 4. The technical consultant confirmed the findings during an interview on 05/30/2025 at 1120 hours in the laboratory. Key: CMS - Centers for Medicare and Medicaid Services