

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1102217	(X3) Date Survey Completed 09/17/2025
Name of Provider or Supplier Pediatric Center Of Southwest Louisiana, The	Street Address, City, State 2800 Country Club Road, Lake Charles, LA	
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 Recertification survey was performed at The Pediatric Center of Southwest Louisiana, CLIA ID 19D1102217, on September 17, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policies, CMS-209 form, personnel competencies, and interview with personnel, the laboratory failed to follow their established competency assessment procedures that included assessment of non-waived test performance for all specialties for two (2) of eight (8) testing personnel reviewed for 2024. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Technical Consultant 1 and Technical Consultant 2 also served as testing personnel. 2. In interview on September 17, 2025 at 12:00 pm, Technical Consultant 1 stated herself and Technical Consultant 2 perform complete blood counts (CBC), manual blood cell differentials, urine cultures, urine sediment, KOH, and wet preps if received. 3. Review of the laboratory's "Employee Competency" form revealed "Competencies will take place at designated times after the initial orientation at each location. Upon hire all testing personnel shall undergo an orientation to the laboratory. The initial competency will take place after the 90 days of probationary employment. Another competency will take place after 6 months of employment. A yearly competency will be performed for all testing personnel until the end of their employment. The Laboratory Director or Technical Consultant will conduct the orientation and competency of all personnel that perform moderate and high</p>

complexity testing." 4. Review of the laboratory's competency assessment forms revealed the following six (6) elements are to be assessed: Direct observation of routine patient test performance; monitor test result recording and reporting; review of worksheets, quality control records, proficiency testing results, maintenance records; direct observation of instrument maintenance; assessment of test performance (PT /blind samples); and assessment of problem-solving skills." 5. Review of the 2024 testing personnel competency assessment for Technical Consultant 1 revealed the laboratory did not perform the semi-annual and annual competency assessments for the following tests: manual blood cell differentials, urine cultures, urine sediment, KOH, and wet preps that included direct observation of routine patient test performance; monitor test result recording and reporting; review of worksheets, quality control records, proficiency testing results, maintenance records; direct observation of instrument maintenance; and assessment of problem-solving skills." 6. Review of the 2024 testing personnel competency assessment for Technical Consultant 2 revealed the laboratory did not perform the annual competency assessments for the following tests: manual blood cell differentials, urine cultures, urine sediment, KOH, and wet preps that included direct observation of routine patient test performance; monitor test result recording and reporting; review of worksheets, quality control records, proficiency testing results, maintenance records; direct observation of instrument maintenance; and assessment of problem-solving skills." 7. In further interview on September 16, 2025 at 12:00 pm, Technical Consultant 1 confirmed semi-annual and annual competencies for the identified microscopic tests were not performed in 2024 for herself and Technical Consultant 2.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to follow their established competency assessment procedures that included assessment of non-waived test performance for all specialties for two (2) of eight (8) testing personnel reviewed for 2024. Refer to D5209. 2. The Technical Consultants failed to perform a competency assessment semi-annually during the first year for one (1) of eight (8) testing personnel reviewed. Refer to D6053.

D6046

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

(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--

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, competency assessment records, and interview with personnel, the Technical Consultants failed to perform complete competency assessment procedures for one (1) of eight (8) testing personnel for 2024. Refer to D5209.

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 review of the laboratory's policies, personnel records, and interview with personnel, the Technical Consultants failed to perform a competency assessment semi-annually during the first year for one (1) of eight (8) testing personnel reviewed. Findings: 1. Review of the laboratory's "Employee Competency" form revealed "Competencies will take place at designated times after the initial orientation at each location. Upon hire all testing personnel shall undergo an orientation to the laboratory. The initial competency will take place after the 90 days of probationary employment. Another competency will take place after 6 months of employment. A yearly competency will be performed for all testing personnel until the end of their employment. The Laboratory Director or Technical Consultant will conduct the orientation and competency of all personnel that perform moderate and high complexity testing." 2. Review of the laboratory's competency assessment forms revealed the following six (6) elements are to be assessed: Direct observation of routine patient test performance; monitor test result recording and reporting; review of worksheets, quality control records, proficiency testing results, maintenance records; direct observation of instrument maintenance; assessment of test performance (PT /blind samples); and assessment of problem-solving skills." 3. Review of personnel records revealed a semi-annual competency assessment was not performed for Technical Consultant 1, due August 2024. The laboratory had the following documented competency assessments: Initial: February 8, 2024 Six (6) month: February 28, 2025, due August 2024 4. In interview on September 17, 2025 at 12:00 pm Technical Consultant 1 and Technical Consultant 3 confirmed the semi-annual competency assessment was not performed as required for Testing Personnel 1.