

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0462025	<b>(X3) Date Survey Completed</b>  09/16/2025
<b>Name of Provider or Supplier</b>  Pediatric Center Of Southwest Louisiana, The	<b>Street Address, City, State</b>  600 Cypress Street, Sulphur, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed at The Pediatric Center of Southwest Louisiana, CLIA ID 19D0462025, on September 16, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 all non-waived test performance for one (1) of seven (7) testing personnel reviewed for 2024. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Technical Consultant 1 also served as testing personnel. 2. In interview on September 16, 2025 at 1:00 pm, Technical Consultant 1 stated she performs 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 complexity testing." 4. Review of the laboratory's competency assessment forms</p>

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. 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. Technical Consultant 1 stated she performed the proficiency testing for the identified tests.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation by surveyor and interview with personnel, the laboratory failed to label stain solutions stored in two (2) secondary containers with the identity of the contents, lot numbers, and expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2025 at 10:52 am revealed two (2) unlabeled urine specimen containers with a purple and a clear solution in each container. The two (2) containers were not labeled with the identity of the contents, lot number, and expiration dates. 2. In interview on September 19, 2025 at 11:08 am, Technical Consultant 1 stated Wright stain and dI water were stored in the identified urine specimen containers. Technical Consultant 1 confirmed the identified containers were not labeled with the identity of the contents, lot numbers, and expiration dates.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2025 at 10:52 am revealed the following expired items: a) Boule MPA micropipettes plastic 20 uL K2EDTA, lot 22274521, Expiration date: 2025-06-28, Quantity: three (3) containers

b) Bris MicroHaematocrit tubes, lot 2505438, Expiration date: 2025-05, Quantity: one (1) container 2. In interview on September 16, 2025 at 11:07 am, Technical Consultant 2 stated the items identified were not used by the laboratory. Technical Consultant 2 confirmed the identified supplies were expired.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's policies, quality assessment forms, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Monthly QA Checklist" policy revealed "The Medical technologist will review the daily checklist, package inserts, expiration dates, proficiency testing, corrective action, and competencies to verify that all is up to date and the correct procedures have been followed." 2. Observation by surveyor, review of quality assessment forms, and interview with personnel revealed the laboratory's monitors did not identify the following issues within the analytic system: a) The laboratory failed to label marking dyes stored in secondary containers with the identity of the contents, lot numbers, and expiration dates. Refer to D5415. b) The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to label marking dyes stored in two (2) secondary containers with the identity of the contents, lot numbers, and expiration dates. Refer to D5415. 2. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

	<p>Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the quality assessment program was maintained to assure the quality of laboratory testing results. Refer to D5793.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>(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;</p> <p>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. Refer to D5209.</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to label marking dyes stored in two (2) secondary containers with the identity of the contents, lot numbers, and expiration dates. Refer to D5415. 2. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> 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 policies, competency assessment records, and interview with personnel, the Technical Consultants failed to perform complete competency assessment procedures for one (1) of seven (7) testing personnel for 2024. Refer to D5209.</p>