Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1086156	04/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center The	919 South 10th Street, Leesville, 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 Clinic, CLIA ID 19D1086156 on April 17, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to verify complete performance specifications for C-Reactive Protein (CRP) testing on the Piccolo analyzer. Findings: 1. Observation by surveyor during the laboratory tour on April 17, 2025 at 12:40 p.m. revealed the laboratory utilized the Metlyte Plus CRP reagent disk on a Piccolo Express for CRP patient testing. 2. Review of the Federad Drug Administration (FDA) categorization database revealed the Metlyte Plus CRP reagent disk for Piccolo Express categorized as moderate complexity testing. 3. Review of the laboratory policy and procedure manual and Piccolo records revealed the laboratory did not verify performance specification for moderate complexity to include accuracy, complete precision, reportable range and reference range. 4. Review of patient test records from calendar year 2024 revealed the laboratory performed ten (10) patient test on the Metlyte Plus CRP. Further review of the 5. In interview on April 17, 2025

	at 1:53 p.m., the Technical Consultant, Testing personnel and clinic manager confirmed the laboratory was not aware the CRP disk was not waived and confirmed the test was not set up as a moderate complexity test to include verification of performance specifications.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of Food and Drug Administration (FDA) website, laboratory test menu, Piccolo records and interview with personnel, the Laboratory Director failed to verify complete performance specifications for C-Reactive Protein (CRP) testing on the Piccolo analyzer. Refer to D6007.
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) (b) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of Food and Drug Administration (FDA) website, laboratory test menu, Piccolo records and interview with personnel, the Technical failed to verify complete performance specifications for C-Reactive Protein (CRP) as moderate complexity testing on the Piccolo analyzer. Refer to D6007.