Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1086156	01/10/2024
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 on January 10, 2024 at Th Pediatric Center, CLIA ID #19D1086156. The following condition level deficiencies were identified: 493.801: Successful Participation 493.1403: Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-153D, CMS-155D and American Proficiency Institute (API) and interview with laboratory personnel, the

	laboratory failed to achieve a score of at least 80% for White Blood Cell Differential (WBC Diff) in two out of three events for 2023, resulting in an initial unsuccessful performance. Refer to D2130
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS-155D report and American Proficiency Institute (API) proficiency testing results, the laboratory failed to submit results to API prior to the event cutoff for Event 1 in Hematology resulting in a score of 0. Findings: 1. Review of the API results and CMS-155 for individual laboratory PT data revealed Event 1 of 2023 score of 0* for all Hematology analytes. 2. In interviewat 11:45am, testing personnel stated that the laboratory did not have a testing personnel during this time and did not submit results to API. Testing personnel confirmed the laboratory did not participate in Event 1 of 2023.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the CMS-153D and CMS-155D reports, the laboratory failed to achieve a score of at least 80% for White Blood Cell Differential (WBC Diff) in two out of three events for 2023, resulting in an initial unsuccessful performance. Findings: 1. Review of proficiency testing records from the CMS-153D and CMS 155D reports revealed the laboratory received a score of less than 80% for the following analytes for two (2) of three (3) events resulting in initial unsuccessful performance: a. 2023 Event 1: Score of 0% for Cell ID or WBC Diff (instrument) b. 2023 Event 3: Score of 67% for Cell ID or WBC Diff (instrument)
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for White Blood Cell Differential (WBC Diff) in two out of three events for 2023, resulting in an initial unsuccessful performance. Refer to D2130 2. The laboratory failed to submit results to API prior to the event cutoff for Event 1 in Hematology resulting in a score of 0. Refer to D2127