Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0457919	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson Pediatric Clinic	1111 Medical Center Blvd Suite N813, Marrero, 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 Certification survey was performed at Jefferson Pediatric Clinic, CLIA ID 19D0457919, on April 24, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, calibration

	records, and interview with personnel, the laboratory failed to perform calibration procedures on the Sysmex XN-330 utilized for Complete Blood Count (CBC) testing at least once every six (6) months in 2022. Findings: 1. Observation by surveyor during the laboratory tour on April 24, 2024 at 1:27 pm revealed the laboratory utilizes the Sysmex XN-330 for CBC testing. 2. Review of the laboratory's CBC policies under the "Calibration Procedures" section revealed "Calibrate at least once every six months. Keep calibration printouts (Reproducibility Summary Report, Carryover Summary Report, and Calibration Summary Report) for at least 2 years." 3. Review of the laboratory's calibration records revealed the laboratory did not have documentation of performance, due in October 2022. The "Certificate of Calibration" report for April 8, 2022 stated the certificate's expiration date was October 7, 2022. 4. In interview on April 24, 2024 at 4:03 pm, the Testing Personnel stated the calibration report listed one performance in 2022, April. The Testing Personnel confirmed the laboratory did have documentation of performance of calibration procedures in October 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, records, and interview with personnel, the laboratory failed to perform quality assessment procedures monthly per laboratory policy in 2023 and January 2024 through March 2024. Findings: 1. Review of the laboratory's "Quality Assessment" policy revealed "The Monthly QA Checklist is our means of ongoing assessment which helps evaluate how well our polices and procedures are working, and minimizes the possibility of recurrent problems. Quality assessment activities are comprehensive and are documented monthly by the technical consultant and reviewed by the Medical Director. Once a month, complete the Monthly QA Checklist, including the chart review portion. If an item is marked 'no,' then action (and documentation of action taken) is needed. Action to take involves determining why a quality measure was not taken." 2. Review of the laboratory's records revealed the laboratory did not have documentation of performance of the "Monthly QA Checklist" for 2023 and January 2024 through March 2024. 3. In interview on April 24, 2024 at 4:30 pm, the Laboratory Director stated he does not use the Monthly QA Checklist.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (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, review of records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5439.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.