

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0457919	(X3) Date Survey Completed 03/20/2026
Name of Provider or Supplier Jefferson Pediatric Clinic	Street Address, City, State 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 Recertification survey was performed at Jefferson Pediatric Clinic, CLIA ID 19D0457919, on March 20, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies, manufacturer's flagging guide, patient test records, and interview with personnel, the laboratory failed to follow their policy for instrument flags for Complete Blood Count (CBC) testing for one (1) of five (5) randomly selected patients reviewed. Findings: 1. Observation during the laboratory tour on March 20, 2026 at 1:09 pm revealed the laboratory utilizes the Sysmex XN-330 analyzer for CBC testing. 2. Review of random selection of patient test reports revealed the following patient had results reported with instrument flags without further documented action: March 19, 2026: Patient 20715: HGB 17.5 * g/dL, MCH 30.4 * pg , MCHC 38.2 * g/dL, #35: MCHC-Poss turbid or high Glu/Na. WBC IP Message: Neutropenia, RBC IP Message: Turbidity/HGB Interf?" 3. Review of the "Sysmex XN-L Series Flagging Interpretation Guide" revealed for "Suspect, Turbidity/HGB Interference?" flags revealed " The Turbidity /HGB Interference ? IP Message occurs when the MCHC is >37.5 g/dL and indicates that turbidity may be present in the diluted and lysed sample. This turbidity could interfere with the HGB detection light path and falsely increase the HGB value. Other interfering substances or conditions may impact the hematocrit and also cause an</p>

increased MCHC. Asterisks(*) appear next to the HGB, MCH, and MCHC parameters. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." 4. Review of the laboratory's "Troubleshooting Flagged Results" policy revealed "The Sample Results screen shows sample identification number, sample mode, sample results, and gives messages. Follow the manufacturer's instructions for handling codes, flags and messages displayed with patient results, including flagged automated differential reports. If SYSMEX Coulter's specific troubleshooting advice does not solve the problem, retest the patient sample. Mix the specimen then re-test; if flags do not clear, refer results to provider or Laboratory Director for a decision as to further actions. See attached Document for Flagged Results. Take corrective action as described in the operators manual. The laboratory is following all instructions in the operators manual. Do not report patient results on values that are flagged and require another method to validate. Indicate to the provider and write that the VALUE IS NOT REPORTABLE." 5. In interview on March 20, 2026 at 2:47 pm, the Testing Personnel stated she did not repeat the identified patient sample. The Testing Personnel confirmed the laboratory did not follow their established policy for patient results that have instrument flags.

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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5401.