

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0457919	<b>(X3) Date Survey Completed</b>  07/27/2022
<b>Name of Provider or Supplier</b>  Jefferson Pediatric Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed on July 27, 2022 at Jefferson Pediatric Clinic, CLIA ID # 19D0457919. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform an assessment for one (1) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy under the "Troubleshooting Failed and 'Not Graded' PT Results" section revealed "If any PT test sample result is graded as 'Unacceptable' or 'Fail,' take action to identify and correct the problem, even if the overall event received a passing grade. Document all troubleshooting actions on the PT Event Report." 2. Review of the laboratory's 2020 (2nd and 3rd Events), 2021, and 2022 (1st Event) PT results from the College of American Pathologists (CAP) revealed the following "Unacceptable" PT result: a) 2021 FH9-C Hematology Auto Differential: Sample FH 9-12, "Unacceptable" 3. Review of the laboratory's PT records revealed the laboratory did not have documentation of an assessment performed for the identified "Unacceptable" sample. 4. In interview on July 27, 2022 at 2:00 pm the Laboratory Director confirmed the laboratory did not take any further action for the "unacceptable" PT result.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially</p>

available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with personnel, the laboratory failed to perform annual preventative maintenance for 2020 and 2021 as required.

Findings: 1. Review of the laboratory's calibration certificates revealed the laboratory failed to have documentation of annual preventative maintenance for 2020 and 2021 for the following equipment: a) Microscope b) Centrifuge c) Refrigerator

Thermometer d) Freezer Thermometer e) Back-up Thermometer 2. In interview on July 27, 2022 at 2:52 pm, the Testing Personnel stated the laboratory did not have documentation of annual preventative maintenance for the identified equipment for 2021.

3. In interview on July 27, 2022 at 4:52 pm, the Laboratory Director confirmed the laboratory did not have documentation of annual preventative maintenance for the identified equipment for 2020.

3. In interview on July 27, 2022 at 4:52 pm, the Laboratory Director confirmed the laboratory did not have documentation of annual preventative maintenance for the identified equipment for 2020.

**D5785**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for eleven (11) of seventy eight (78) days in 2021. Findings: 1. Review of the laboratory's "The Testing Environment" policy revealed "Adjust temperature and humidity readings that are out of range, then, recheck to verify that readings have returned to the acceptable range. Document findings on the corrective action log." 2. Review of the laboratory's 2021 temperature logs for the refrigerator revealed the following documented temperatures that exceeded the acceptable range (2-8 degrees Celsius) without corrective actions: April 7, 2021: Max temperature documented 8.45 degrees Celsius April 21, 2021: Max temperature documented 8.10 degrees Celsius April 22, 2021: Max temperature documented 8.22 degrees Celsius April 23, 2021: Max temperature documented 9.27 degrees Celsius July 14, 2021: Max temperature documented 8.71 degrees Celsius August 13, 2021: Max temperature documented 8.04 degrees Celsius August 17, 2021: Max temperature documented 8.44 degrees Celsius August 18, 2021: Max temperature documented 8.44 degrees Celsius August 19, 2021: Max temperature documented 8.44 degrees Celsius November 1, 2021: Max temperature documented 8.60 degrees Celsius November 12, 2021: Max temperature documented 8.04 degrees Celsius 3. In interview on July 27, 2022 at 4:52 pm, the Testing Personnel and Laboratory Director confirmed the laboratory did not perform corrective actions for unacceptable refrigerator temperature readings on the identified dates. II. Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for freezer temperatures that exceeded

the acceptable range for two (2) of eighteen days in September 2021. 1. Review of the laboratory's "The Testing Environment" policy revealed "Adjust temperature and humidity readings that are out of range, then, recheck to verify that readings have returned to the acceptable range. Document findings on the corrective action log." 2. Review of the laboratory's September 2021 freezer temperature logs revealed the following documented temperatures that exceeded the acceptable range (-15 to -50 degrees Celsius) without corrective actions: September 10, 2021: Minimum temperature documented 27.70 degrees Celsius and Maximum temperature documented 25.67 degrees Celsius September 15, 2021: Minimum temperature documented 28.16 degrees Celsius and Maximum temperature documented 25.60 degrees Celsius 3. In interview on July 27, 2022 at 4:52 pm, the Testing Personnel and Laboratory Director confirmed the laboratory did not perform corrective actions for unacceptable freezer temperature readings on the identified dates.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed and documented corrective actions for unacceptable proficiency testing results. Refer to D5221.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:  
Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5433.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and

documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of policies, temperature logs, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785 I and D5785 II.