

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0963476	(X3) Date Survey Completed 07/17/2025
Name of Provider or Supplier St Francis Oncology Laboratory	Street Address, City, State 411 Calypso Street, Suite 200, Monroe, 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 July 17, 2025 at St Francis Oncology Laboratory, CLIA ID # 19D0963476. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and maintenance logs, as well as interview with personnel, the laboratory failed to ensure maintenance was performed as required per the manufacturer's instructions on the Abbott Alinity ci chemistry analyzer for seven (7) of eighteen (18) months reviewed from January 2024 through June 2025. Findings: 1. Observation by surveyor during the laboratory tour on July 17, 2025 at 10:46 am revealed the laboratory utilizes the following Abbott Alinity ci analyzers for chemistry testing: a) Abbott Alinity ci series: serial number AC05006 b) Abbott Alinity ci series: serial number Ai24264 2. Review of laboratory policy and maintenance logs revealed the following maintenance requirements for the Abbott Alinity ci chemistry analyzer: a) Monthly: * Clean ICT Drain Tip b) Quarterly: * Sample Syringe Maintenance * Wash Solution Syringe Maintenance * Reagent Syringe Maintenance * Change Lamp c) Triannual * Change 1mL Syringes * Check and Change ICT Check Valves * Check and Clean High Concentration Waste Sensor d) Semi-yearly * Air Filter Cleaning 3. Review of laboratory policy and maintenance logs from January 2024 through June 2025 revealed the laboratory did not document the performance of monthly, quarterly, triannual, and semi-yearly maintenance for the following seven (7) of eighteen (18) months reviewed: a) Monthly: * November 2024 (Serial Number AC05006) b) Quarterly: * January 2024</p>

(Serial Number AC05006) * May 2024 (Serial Number AC05006) * August 2024 (Serial Number AC05006) * January 2025 (Serial Number AC05006) * May 2025 (Serial Number AC05006) c) Triannual: * September 2024 (Serial Number AC05006) * January 2025 (Serial Number AC05006) d) Semi-yearly: * November 2024 (Serial Number Ai24262) 4. In interview on July 17, 2025 at 2:40 pm, the Technical Consultant stated maintenance is included with the service contract for quarterly, triannual and semi-yearly. The Technical Consultant further stated that the laboratory calls to schedule maintenance when due and the service representatives continuously reschedules the appointments. 5. In further interview on July 17, 2025 at 2:40 pm, the Technical Consultant stated that she understood the maintenance has to be performed per the manufacturer's instructions. The Technical Consultant confirmed the identified maintenance was not performed as required by the manufacturer.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

(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 observation by surveyor, review of laboratory records and policy, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of laboratory records, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5429.