

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0963476	<b>(X3) Date Survey Completed</b>  07/16/2019
<b>Name of Provider or Supplier</b>  St Francis Oncology Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was conducted at Oncology Associates of Monroe-CLIA ID # 19D0963476 on July 16, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Testing Personnel signed the attestation statement for two (2) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's Proficiency Testing records revealed Personnel 6 performed proficiency testing for the following events: a) American Proficiency Institute (API) 2018 Chemistry - Miscellaneous - 2nd event b) American Proficiency Institute (API) 2019 Immunology /Immunochemistry - 1st event 2. Further review of the laboratory's Proficiency Testing records for 2018/2019 revealed the laboratory did not have documentation of the following: a) 2018 Chemistry - Miscellaneous - 2nd event: Testing Personnel signature on the attestation statement b) 2019 Immunology/Immunochemistry - 1st event: Testing Personnel signature on the attestation statement 3. In interview on July 16, 2019 at 10:30 am, the Technical Consultant stated she was unaware the attestation statements for the above events was not signed by the testing personnel. The Technical Consultant confirmed the above findings.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with personnel, the laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on July 16, 2019 revealed the following expired items: a) Located in a red plastic container under counter: \* Thermo Scientific VersaTREK REDOX 2 80 mL anaerobic blood culture collection bottles, Lot 348493, Expiration date: 05/2019, Quantity four (4) bottles 2. In interview on July 16, 2019 at 09:25 am, the Technical Consultant confirmed the identified blood collection supplies were expired and in place for patient testing.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to ensure weekly maintenance for the Beckman Coulter AU 680 chemistry analyzer was documented for seven (7) of eighteen (18) months reviewed. Findings: 1. Review of the laboratory's "Beckman Olympus AU680 Procedure Manual" under "Maintenance" revealed "Maintenance guidelines established by the manufacturer will be performed at the frequency suggested. See maintenance schedule in the User's Guide for weekly, monthly, and as needed requirements". 2. Review of the laboratory's "AU 680 Maintenance Schedule" revealed the following weekly tasks: a) "Perform a W2" b) "Perform a Photocal" 3. Review of the laboratory's "ISE Maintenance Schedule" revealed the following weekly tasks: a) "Enhanced Cleaning of Electrode Line" b) "Manually Washing the Mix Bar and Liquid Level Sensors Sample pot and Sample pot Tubing" 4. Further review of the AU 680 Maintenance Schedule and ISE Maintenance Schedule logs for January 2018 through June 2019 revealed the laboratory did not have documentation of weekly maintenance performance for the following: a) Week of January 8, 2018 - AU 680 maintenance and ISE maintenance b) Week of July 9, 2018 - AU 680 maintenance c) Week of August 13, 2018 - ISE maintenance d) Week of October 8, 2018 - AU 680 maintenance and ISE maintenance e) Week of October 22, 2018 - AU 680 maintenance and ISE maintenance f) Week of November 5, 2018 - AU 680 maintenance and ISE maintenance g) Week of January 7, 2019 - AU 680 maintenance and ISE maintenance h) Week of January 28, 2019 - AU 680 maintenance and ISE maintenance i) Week of June 10, 2019 - AU 680 maintenance 5. In interview on July 16, 2019 at 12:03 pm, the Technical Consultant stated she was unaware weekly maintenance was not documented for the identified weeks. The Technical Consultant confirmed the laboratory did not have documentation of weekly maintenance performance for the above.

**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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings:

1. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 2. The laboratory failed to ensure weekly maintenance for the Beckman Coulter AU 680 chemistry analyzer was documented for seven (7) of eighteen (18) months reviewed. Refer to D5429.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory.

Findings: 1. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 2. The laboratory failed to ensure weekly maintenance for the Beckman Coulter AU 680 chemistry analyzer was documented for seven (7) of eighteen (18) months reviewed. Refer to D5429.