Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0993289	09/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Acadiana Oncology	602 North Lewis Street, Suite 600, New Iberia, 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 September 28, 2022 at Acadiana Oncology, CLIA ID # 19D0993289. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency test records, and interview with personnel, the laboratory failed to maintain and ensure the Laboratory Director reviewed the proficiency testing (PT) performance evaluation results for one (1) of five (5) events reviewed. Findings: 1. Review of the laboratory's "Quality Assurance Program" policy under the "Proficiency Testing" section revealed "PT results are reviewed and retained for a period of at least two years. PT failures are investigated and remedial action is taken." 2. Review of the American Proficiency Institute (API) proficiency testing records for 2021 and 2022 revealed the laboratory did not maintain the evaluation form and documentation of the Laboratory Director's review/signature for the 2022 Hematology/Coagulation 2nd Event. 3. In interview on September 28, 2022 at 2:42 pm, Testing Personnel 1 confirmed the laboratory did not have the evaluation form for the 2022 Hematology/Coagulation 2nd PT Event .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish complete proficiency testing (PT) policies. Findings: 1. Review of the laboratory's "Quality Assurance Program" policy under the "Proficiency Testing" section revealed "PT results are reviewed and retained for a period of at least two years. PT failures are investigated and remedial action is taken." 2. Further review of the laboratory's "Proficiency Testing" policy revealed the laboratory did not include detailed written instructions related to the remedial actions to take for PT failures. 3. In interview on September 28, 2022 at 2:42 pm, Testing Personnel 1 confirmed the laboratory's policy related to proficiency testing did not include detailed written instructions for actions and investigative steps to take for PT failures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer instructions, and interview with personnel, the laboratory failed to label hematology controls with updated expiration dates after opening. Findings: 1. Observation by surveyor during the laboratory tour on September 28, 2022 at 1:04 pm revealed the laboratory stored open Sysmex EightCheck -3 WP X-tra hematology controls (Lot Number: 219307) in a refrigerator without labeling with the "open" and updated "expiration" dates. 2. Review of the Sysmex EightCheck -3WP Xtra manufacturer's instructions under the "Storage and shelf life after first opening" section revealed "Opened and recapped vials and vials whose caps have ben pierced will retain stability for 14 days if stored at 2-8 C after being re-capped." 3. In interview on September 28, 2022 at 1:04 pm, Testing Personnel 1 stated the laboratory maintains a log that includes the expiration date for hematology controls. Testing Personnel 1 confirmed the laboratory does not label the in-use hematology control vials with "open" and "expiration" dates.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
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 proficiency testing evaluation forms were maintained and signed by the Laboratory Director. Refer to D5211.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.