Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0993289	08/29/2024
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 August 29, 2024 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and as interview with personnel, the laboratory failed to ensure the Testing Personnel and Laboratory Director signed the attestation statement for three (3) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the Laboratory Director and/or Testing Personnel did not sign the following attestation statements: a) 2023 Hematology/Coagulation - 2nd event: Not signed by the Laboratory Director and Testing Personnel b) 2023 Hematology/Coagulation - 3rd event: Not signed by the Laboratory Director c) 2024 Hematology/Coagulation - 2nd event: Not signed by the Laboratory Director 2. In interview on August 29, 2024 at 2 p.m., Testing Personnel 1 confirmed the attestation sheets were not signed as identified above.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	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 unacceptable proficiency testing (PT) results for one (1) of six (6) 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 laboratory's "API Quarterly Event Testing Checklist" revealed "When results are less than 100% - Corrective Action Checklist (form provided by API, found in API Binder) must be completed and reviewed with Laboratory Director." 3. Review of the laboratory's American Proficiency Institute (API) 2023 Hematology/Coagulation - 3rd Event proficiency testing evaluation report revealed the laboratory had the following unacceptable result; however, the laboratory did not document an assessment for the result: a) HSY-12: MCHC 4. In interview on August 29, 2024 at 2 p.m., Testing Personnel 1 confirmed the laboratory did not evaluate the unacceptable results identified above.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include instructions for review and documentation of PT evaluation results that are ungraded. 2. Review of the laboratory's American Proficiency Institute (API) 2023 Hematology/Coagulation - 3rd Event evaluation report revealed the following "not graded" result; however, the laboratory did not document an assessment for the result: a) HSY-13: MPV 3. In interview on March 20, 2024 at 11:50 a.m., the Testing Personnel 1 confirmed the laboratory's proficiency testing policy did not include review of ungraded proficiency testing results. II. Based on review of the laboratory's policies and proficiency testing records as well as interview with personnel, the laboratory failed to follow their policy for quality assessment of proficiency testing for three (3) of four (4) events reviewed. Findings: 1. Review of the laboratory's "Quality Assurance Program" policy under section "Proficiency Testing" revealed "API Quarterly Testing Checklist will be completed upon each event done." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the following events did not have a checklist completed: a) 2023 Hematology/Coagulation - 2nd event b) 2024 Hematology/Coagulation - 1st event c) 2024 Hematology/Coagulation - 2nd event 3. In interview on August 29, 2024 at 3 p.m., Testing Personnel 1 confirmed that the checklist was not completed as required by the laboratory for the events identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for laboratory supplies stored in one (1) of one (1) rooms where supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on August 29, 2024 at 1 p.m. revealed the following blood collection supplies stored in the laboratory: a) BD Vacutainer K2EDTA Blood Collection Tubes - Manufacturer's storage requirements 4 - 25 degrees Celsius b) BD SST Blood Collection Tubes- Manufacturer's storage requirements 4 - 25 degrees Celsius 2. Review of the laboratory's room temperature logs revealed the laboratory defined the acceptable temperature limits as 16 - 35 degrees Celsius which exceeded the manufacturer's upper temperature limit. 3. In interview on August 29, 2024 at 1:15 p.m., Testing Personnel 1 confirmed the acceptable temperature limits defined by the laboratory exceeded the manufacturer's temperature limits.
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 the laboratory personnel performed test methods as required. Refer to D5413.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D2009.
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 followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to maintain a complete policy for proficiency testing. Refer to D5291 I. 2. The laboratory failed to follow their policy for quality assessment of proficiency testing for three (3) of four (4) events reviewed. Refer to D5291 II.