Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0993289	01/27/2021
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 January 27, 2021 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.
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 proficiency testing records and interview with personnel, the laboratory failed to perform an assessment for Hematology proficiency test (PT) results that scored less than 100 hundred (100%). Findings: 1. Review of the laboratory's American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results: 2019 3rd Event: Sample HSY-12 for Lymphocytes, API grade: "unacceptable"-80% 2020 3rd Event: Sample HSY-12 for MCH, API grade: "unacceptable"-80 % 2. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the "unacceptable" API PT results. 3. In interview on January 27, 2021 at 2:28 pm, Testing Personnel 1 stated the laboratory did not perform assessments for the identified PT results.
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 a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies and procedures that included: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on January 27, 2021 at 2:02 pm, Testing Personnel 1 confirmed the laboratory did not have a policy for performance specification studies for new tests/analyzers.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. 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 ensure the policy manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include detailed written instructions for actions to take for an inoperable test system. 2. In interview on January 27, 2021 at 1:56 pm, Testing Personnel 1 confirmed the laboratory's policies did not include what happens to samples if the instrument (test system) becomes inoperable.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of installation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the PocH-100 i analyzer. Findings: 1. Direct observation by surveyor during laboratory tour on January 27, 2021 at 1:10 pm revealed the laboratory utilizes the Sysmex PocH-100 i analyzer for Complete Blood Counts (CBC) testing. 2. In interview on January 27, 2021 at 2:02 pm, Testing Personnel 1 stated the laboratory received a new PocH-100 i analyzer to replace their old one in July 2019. Testing Personnel 1 further stated Sysmex's technician performed studies for the laboratory. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy and procedure for performance specification studies. 4. Review of the laboratory's installation manual for the Sysmex PocH-100 i (Serial # G6149) revealed the installation date was August 1, 2019. Further review of the installation manual revealed the following items were not included: a) Accuracy studies to include raw data and acceptability criteria b) Precision studies to include run-to run, day to day, within-run, operator variance studies and acceptability criteria c) Reference Range d) Reportable Range to include acceptability criteria e) Laboratory Director approval/signature 5. Review of the laboratory's test menu revealed the laboratory performs 15,426 CBC tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of calibration records, test menu, and interview with personnel, the laboratory failed to perform calibration verification procedures at least every six (6) months for the PocH-100 i analyzer. Findings: 1. Direct observation by surveyor during laboratory tour on January 27, 2021 at 1:10 pm revealed the laboratory utilizes the Sysmex PocH-100 i analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's calibration records revealed

	calibration was performed during installation on August 1, 2019. Further review of calibration records revealed the laboratory did not have documentation of calibration verification performance in 2020. 3. In interview on January 27, 2021 at 3:39 pm, Testing Personnel 1 stated calibration verification should be done every six (6) months. Testing Personnel 1 further stated calibration verification was not performed in 2020. 4. Review of the laboratory's test menu revealed the laboratory performs 15, 426 CBC tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of the laboratory's policy manual, quality assurance records, and interview with personnel, the laboratory failed to perform quality assurance (QA) monthly in 2019 and 2020 per laboratory policy to identify issues within the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance" policy revealed "Quality Assurance includes the following components: Personnel Training and Qualifications, Proficiency Testing, Procedure Manual, Specimen Collection and Handling Specification, Patient Test Management /Record Keeping, Quality Control Program, Instrument Maintenance Program, and Laboratory Safety. As necessary, revise your Quality Assurance Program based on the results of the monthly evaluations and communicate any revisions to the laboratory staff." 2. Review of the laboratory's monthly QA records revealed the laboratory last performed QA on November 30, 2016. The laboratory did not perform QA monthly in 2019 and 2020. 3. Direct observation by surveyor and record review revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to ensure the policy manual contained complete policies and procedures. Refer to D5403. c) The laboratory failed to have complete performance verification studies for the PocH-100 i analyzer. Refer to D5421. d) The laboratory failed to perform calibration verification procedures at least every six (6) months for the PocH-100 i analyzer. Refer to D5439. 4. In interview on January 27, 2021 at 3:00 pm, Testing Personnel 1 confirmed QA had not been performed since 2016.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include a second patient identifier on final reports. Findings: 1. Review of random selection of patient final reports revealed the laboratory did not include a second unique patient identifier. The patient reports included the patient's name and date of birth. 2. In interview on January 27, 2021 at 3:41 pm, Testing Personnel 1 confirmed the laboratory did not include a second patient identifier on patient final reports. 3. Review of the laboratory's test menu revealed the laboratory performs 15,426 CBC tests annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy manual, quality assurance records, and interview with personnel, the laboratory failed to perform quality assurance (QA) monthly in 2019 and 2020 per laboratory policy to identify issues within the postanalytic system. Findings: 1. Review of the laboratory's "Quality Assurance" policy revealed "Quality Assurance includes the following components: Personnel Training and Qualifications, Proficiency Testing, Procedure Manual, Specimen Collection and Handling Specification, Patient Test Management/Record Keeping, Quality Control Program, Instrument Maintenance Program, and Laboratory Safety. As necessary, revise your Quality Assurance Program based on the results of the monthly evaluations and communicate any revisions to the laboratory staff." 2. Review of the laboratory's monthly QA records revealed the laboratory last performed QA on November 30, 2016. The laboratory did not perform QA monthly in 2019 and 2020. 3. Direct observation by surveyor and record review revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to include a second patient identifier on final reports. Refer to D5805. 4. In interview on January 27, 2021 at 3:00 pm, Testing Personnel 1 confirmed QA had not been performed since 2016.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by:

	Based on direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
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 direct 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 D5439.
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 corrective actions 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 observation, 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 perform quality assurance (QA) monthly in 2019 and 2020 per laboratory policy to identify issues within the analytic system. Refer to D5791. 2. The laboratory failed to

	perform quality assurance (QA) monthly in 2019 and 2020 per laboratory policy to identify issues within the postanalytic system. Refer to D5891.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for Complete Blood Counts (CBC) included pertinent information. Refer to D5805.
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 personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy manual contained complete policies and procedures. Refer to D5403.