Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461133	12/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Acadia-St Landry Hospital Pathology	810 South Broadway Street, Church Point, 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 December 9, 2024 through December 12, 2024 at Acadia St. Landry Hospital Pathology, CLIA ID # 19D0461133. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation, review of laboratory policies and lot rollover records, as well as interview with personnel, the laboratory failed to follow their policy for verification of new Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) reagent lots for one (one) of one (1) lot rollovers reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized a Sysmex CA-600 analyzer for PT and APTT testing. 2. Review of the laboratory's policy "Coagulation Reagents - New Rollover" section "Policy" revealed "The following steps are required for a successful new lot rollover: ...A normal range study for PT and APTT testing." 3. Further review of the laboratory's policy under the section "Specimen" revealed "Specimens obtained from healthy individuals from the population served by the laboratory. Each patient is asked specific questions related to their overall health and medication usage. Their answers are recorded on a Normal Patient Range Study Health Questionnaire (see attached)." 4. Review of the example questionnaire for the "Coagulation Normal Range Study" revealed "All highlighted areas should be completed by the pt." The following highlighted areas were included on the form: - "Sex, age, date - Are you

	feeling healthy and well today? - Are you on Birth Control or any Estrogen containing products? - Are you pregnant or have any known immunologic diseases? - Are you on any "blood thinner" medication such as Coumadin? - Are you on Heparin? - Have you recently taken any Direct Thrombin Inhibitors (Aspirin, Etc.)? - Have you recently taken any antibiotics? - Did you review the list of medications given to you prior to having your blood drawn for this Normal Range Study?" 5. Further review of the form revealed the following instructions: "If they are taking any of the drugs on the second sheet, they do not qualify to be drawn." 6. Review of the laboratory's October 2023 lot rollover revealed the laboratory utilized the following four (4) donors that did not meet the normal donor requirements established by the laboratory, but were utilized in the normal range study: a) Donor M3: - Answered "no" to the question "Did you review the list of medications given to you prior to having your blood drawn for this Normal Range Study?" b) Donor M4: - Answered "yes" to the question "Have you recently taken any Direct Thrombin Inhibitors (Aspirin, Etc.)" - Answered "yes" to the question "Did you review the list of medications given to you prior to having your blood drawn for this Normal Range Study?" and "High Blood Pressure Medications" and "Salicylate" was circled on the medication list. c) Donor M6: - Answered "no" to the question "Did you review the list of medications given to you prior to having your blood drawn for this Normal Range Study?" d) Donor F11 - Answered "no" to the question "Did you review the list of medications given to you prior to having your blood drawn for this Normal Range Study?" 7. In interview on December 11, 2024 at 11:27 a.m., the Laboratory Manager confirmed the laboratory utilized donors that did not meet the normal donor requirements as defined in the laboratory's policy.
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 observation, review of laboratory policies, and interview with personnel, the laboratory failed to establish a complete policy and procedure manual for chemistry. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Dimension EXL for chemistry testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include performance of calibration verification. 3. In interview on

	December 10, 2024 at 3:43 p.m., the Laboratory Manager confirmed the laboratory's policy and procedure manual did not include performance of calibration verification.
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: I. Based on observation, review of the manufacturer's storage requirements and laboratory temperature records, as well as interview with personnel, the laboratory failed to monitor the room temperature for one (1) of two (2) rooms where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the following supplies stored in draw room: a) BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements 4 to 25 degrees Celsius b) BD Vacutainer K2E 7.2 mg - Manufacturer's storage requirements 4 to 25 degrees Celsius c) BD Vacutainer Buffered Sodium Citrate (9NC) Blood Collection Tubes - Manufacturer's storage requirements 4 to 25 degrees Celsius d) BD Vacutainer Gel and Lithium Heparin (LH) - Manufacturer's storage requirements 4 to 25 degrees Celsius 2. Review of laboratory temperature records revealed no documentation of room temperature monitoring for the draw room. 3. In interview on December 11, 2024 at 11:46 a.m., the Laboratory Manager confirmed the laboratory did not monitor the room temperature of the draw room from January 2023 through December 11, 2024. II. Based on observation, review of manufacturer's instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the following supplies stored in the Blood Bank refrigerator: a) Ortho Confidence System - Manufacturer's storage requirements: 2 - 8 degrees Celsius b) Ortho Reagent Red Blood Cells Selectogen - Manufacturer's storage requirements 2 - 8 degrees Celsius d) Ortho Reagent Red Blood Cells (Pooled Cells) Affirmagen - Manufacturer's storage requirements 2 - 8 degrees Celsius 2. Review of the laboratory's Blood Bank refrigerator temperature records from July 2024 through December 11, 2024 revealed the laboratory defined the acceptable temperature limits as 1 - 6 degrees Celsius which exceeded the manufacturer's lower temperature limits. 3. In interview December 11, 2024 at 10:58 a.m., the Laboratory Manager confirmed the laboratory's acceptable refrigerator temperature limits exceeded the manufacturer's limits as identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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: **Repeat deficiency from previous survey February 14, 2023 through February 17, 2023** Based on observation, review of laboratory policies, and interview with personnel, the laboratory failed to ensure blood collection supplies did not exceed their expiration dates in one (1) of two (2) rooms where laboratory supplies are stored. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the following expired items located on a phlebotomy cart in the main laboratory: BD Vacutainer SST Blood Collection Tubes - Lot: 3326494, Expiration date: 11/30/2024, Quantity: Fifty-one (51) tubes 2. Review of the laboratory's policy "Expired Items Audit" revealed "Each area of the laboratory will be audited weekly by all laboratory personnel for items near or beyond expiration date. If there are any beyond the expiration date they must be discarded immediately and noted on the expired items log. Any items near expiration date (within one month), must be brought to the attention of the lab manager. Write these items on the "HOT LIST" form and give this form to the Lab Manager." 3. In interview on December 9, 2024 at 12:25 p.m., the Laboratory Manager confirmed the items identified above were expired.
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: **Repeat deficiency from previous survey February 14, 2023 through February 17, 2023** I. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Sysmex XS-1000i for Complete Blood Count (CBC) testing. 2. Review of the laboratory's 2024 maintenance logs for the Sysmex XS-1000i revealed the following required weekly task: - "Power Down IPU" 3. Further review of the maintenance logs from January 2024 through October 2024 revealed the laboratory failed to perform weekly maintenance for the week of September 1, 2022 - September 7, 2024. 4. In interview on December 11, 2024 at 12:29 p.m., the Laboratory Manager confirmed the weekly maintenance was not performed as identified above. II. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure monthly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for two (2) of ten (10) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Sysmex XS-1000i for Complete Blood Count (CBC) testing. 2. Review of the laboratory's maintenance logs for the Sysmex XS-1000i revealed the following required monthly task: - "Perform Monthly Rinse (1,200 cycles)" 3. Further review of the maintenance logs from January 2024 through October 2024 revealed the laboratory failed to perform monthly maintenance in June 2024 and August 2024. 4. In interview on December 11, 2024 at 12:00 p.m., the Laboratory Manager confirmed the monthly maintenance was

	not performed as identified above. III. Based on observation, review of laboratory maintenance logs, and interview with personnel, the laboratory failed to ensure daily maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of three hundred four (304) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Sysmex CA-600 for coagulation testing. 2. Review of the laboratory's maintenance log for the Sysmex CA-600 revealed the following required daily tasks: - "Turn Power OFF, wait 15 seconds, then turn on - Check/Replace Distilled Water - Load fresh OVB Buffer as needed - Check/Empty Waste Container - Check/Discard Pneumatic Trap Chamber Fluid - Check and Replenish Reaction Tubes - Empty/Clean Reaction Tube Trash Box - Load CA Clean II in Position II - Load Fresh CA Clean I in Position I - Run "Rinse Probe" - Check/Prepare Reagents - Wipe Sample Probe with Alcohol Swab - Check Temperatures - Remove Dew from Reagent Rack" 3. Further review of the laboratory's maintenance records from January 2024 through October 2024 revealed the laboratory failed to perform the following daily maintenance tasks on February 21, 2024: - "Load fresh OVB Buffer as needed - Check/Empty Waste Container - Check/Discard Pneumatic Trap Chamber Fluid - Check and Replenish Reaction Tubes - Empty/Clean Reaction Tube Trash Box - Load CA Clean II in Position II - Load Fresh CA Clean I in Position I - Run "Rinse Probe" - Check/Prepare Reagents - Wipe Sample Probe with Alcohol Swab - Check Temperatures - Remove Dew from Reagent Rack" 4. In interview on December 11, 2024 at 11:18 a.m., the Laboratory Manager confirmed the daily maintenance was not performed as identified above. IV. Based on observation, review of laboratory maintenance logs, and interview with personnel, the laboratory failed to ensure weekly maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Sysmex CA-600 for coagulation testing. 2. Review of the laboratory's maintenance log for the Sysmex CA-600 revealed the following required weekly task: - "Clean instrument interior/exterior" 3. Further review of the maintenance logs from January 2024 through October 2024 revealed the laboratory failed to perform weekly maintenance for the week of September 1, 2022 - September 7, 2024. 4. In interview on December 11, 2024 at 12 p.m., the Laboratory Manager confirmed the weekly maintenance was not performed as identified above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records and interview with personnel, the laboratory failed to perform and document monthly maintenance on centrifuges as required by the laboratory for one (1) of ten (10) months reviewed. Findings: 1. Review of the laboratory's centrifuge maintenance records from January 2024 through October 2024 revealed the following required monthly tasks were not

	performed in April 2024: a) Urinalysis Centrifuge - "Clean the inside of the centrifuge" b) Blood Bank Centrifuge - "Clean all interior surfaces of the centrifuge - Clean the exterior surfaces" c) Chemistry Centrifuge - "Keep the Tube Holders Clean" d) Coagulation Centrifuge - "Keep the Tube Holders Clean" 2. In interview on December 11, 2024 at 11:27 a.m., the Laboratory Manager confirmed the monthly centrifuge maintenance was not performed as identified above.
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 observation, review of the manufacturer's package insert and the laboratory's calibration verification records, as well as interview with personnel, the laboratory failed to perform calibration verification procedures for Potassium (K), Chloride (Cl) and Sodium (Na) at least every six (6) months on the Siemens Dimension EXL for three (3) of four (4) calibration verifications reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2024 at 11:22 a.m. revealed the laboratory utilized the Siemens Dimension EXL for chemistry testing. 2. Review of the manufacturer's package insert "Siemens QuikLYTE Integrated Multisensor" revealed "The Dimension IMT system will routinely perform a one point calibration with each sample measurement. In addition, the system performs a two point automatic calibration in duplicate every 2 hours if no analysis is in progress. Auto-calibration also occurs shortly after turn-on, with the changing of standards A, B, or a sensor and when reset." 3. Review of 2023 and 2024 calibration verification records revealed the laboratory performed a calibration verification for Potassium (K), Chloride (Cl) and Sodium (Na) in February 2023, but did not have documentation of calibration verification these analytes at least every six months for the following months: August 2023, February 2024, and September 2024. 4. In interview on December 10, 2024 at 3:43 p.m., the Laboratory Manager stated the laboratory performs calibration verification for analytes with only two (2) calibration points but missed performing calibration verifications as identified above.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory temperature records and patient test records as well as interview with personnel, the laboratory failed to perform corrective actions when the blood bank heat block temperature was not maintained between 36 - 38 degrees Celsius per laboratory policy for one (1) of three hundred four (304) days reviewed in 2024. Findings: 1. Review of the laboratory's temperature records revealed the laboratory defined the acceptable temperature range of the blood bank heat block as 36 - 38 degrees Celsius. 2. Further review of the heat block temperature logs from January 2024 through October 2024 revealed the following one (1) day documented as outside the laboratory's acceptable range, but no corrective actions were performed: a) March 6, 2024: Documented temperature of 24 degrees Celsius 3. Review of patient test records revealed one (1) patient (Patient 10116614) was tested iin the blood bank on March 6, 2024 at 11 p.m. 4. In interview on December 11, 2024 at 11: 10 a.m., the Laboratory Manager confirmed the laboratory did not perform corrective actions for the unacceptable heat block temperature identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and patient test logs as well as interview with personnel, the laboratory failed to take corrective actions when QC values for acetone testing were unacceptable for one (1) of seven (7) days reviewed. Findings: 1. Review of the laboratory's January 2024 acetest QC records and patient test logs revealed the following one day of unacceptable QC and the laboratory did not perform corrective actions: a) January 6, 2024 resulted at 4:51 p.m.: External Negative Control resulted as Positive (acceptable QC value was Negative); Patient 10114463 2. In interview on December 10, 2024 at 3:18 p.m., the Lab Manager confirmed the quality control level identified above was not acceptable and the laboratory did not perform corrective actions.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to follow their policy for verification of new Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) reagent lots for one (one) of one (1) lot rollovers reviewed. Refer to 5401. 2. The laboratory failed to monitor the room temperature for one (1) of two (2) rooms where laboratory supplies were stored. Refer to5413 I. 3. The laboratory failed to define acceptable temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Refer to D5413 II. 4. The laboratory failed to ensure blood collection supplies did not exceed their expiration dates in one (1) of two (2) rooms where laboratory supplies are stored. Refer to D5417. 5. The laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 I. 6. The laboratory failed to ensure monthly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for two (2) of ten (10) months reviewed. Refer to D5429 II. 7. The laboratory failed to ensure daily maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of three hundred four (304) days reviewed. Refer to D5429 III. 8. The laboratory failed to ensure weekly maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 IV. 9. The laboratory failed to perform and document monthly maintenance on centrifuges as required by the laboratory for one (1) of ten (10) months reviewed. Refer to D5433. 10. The laboratory failed to perform calibration verification procedures for Potassium (K), Chloride (Cl) and Sodium (Na) at least every six (6) months on the Siemens Dimension EXL for three (3) of four (4) calibration verifications reviewed. Refer to D5439. 11. The laboratory failed to perform corrective actions when the blood bank heat block temperature was not maintained between 36 - 38 degrees Celsius per laboratory policy for one (1) of three hundred four (304) days reviewed in 2024. Refer to D5781. 12. The laboratory failed to take corrective actions when QC values for acetone testing were unacceptable for one (1) of seven (7) days reviewed. Refer to D5783.
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 surveyors, review of manufacturer's instructions, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow their policy for verification of new Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) reagent lots for one (one) of one (1) lot rollovers reviewed. Refer to D5401. 2. The laboratory failed to monitor the room temperature for one (1) of two (2) rooms where laboratory supplies were stored. Refer to D5413 I. 3. The laboratory failed to ensure blood collection supplies did not exceed their expiration dates in one (1) of two (2) rooms where laboratory supplies are stored. Refer to D5417. 4. The laboratory failed to perform calibration verification procedures for Potassium (K), Chloride (Cl) and Sodium (Na) at least every six (6) months on the Siemens Dimension EXL for three (3) of four (4) calibration verifications reviewed. Refer to D5439.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. 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 that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(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, review of laboratory policies and records, as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 I. 2. The laboratory failed to ensure monthly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for two (2) of ten (10) months reviewed. Refer to D5429 II. 3. The laboratory failed to ensure daily maintenance was

	performed on the Sysmex CA-600 as required by the manufacturer for one (1) of three hundred four (304) days reviewed. Refer to D5429 III. 4. The laboratory failed to ensure weekly maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 IV. 5. The laboratory failed to perform and document monthly maintenance on centrifuges as required by the laboratory for one (1) of ten (10) months reviewed. Refer to D5433.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5783.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
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 by surveyors, 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 follow their policy for verification of new Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) reagent lots for one (one) of one (1) lot rollovers reviewed. Refer to D5401. 2. The

	laboratory failed to establish a complete policy and procedure manual for chemistry. Refer to D5403. 3. The laboratory failed to monitor the room temperature for one (1) of two (2) rooms where laboratory supplies were stored. Refer to D5413 I. 4. The laboratory failed to ensure blood collection supplies did not exceed their expiration dates in one (1) of two (2) rooms where laboratory supplies are stored. Refer to D5417. 5. The laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 I. 6. The laboratory failed to ensure monthly maintenance for the Sysmex XS-1000i instrument was performed as required by the manufacturer for two (2) of ten (10) months reviewed. Refer to D5429 II. 7. The laboratory failed to ensure daily maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of three hundred four (304) days reviewed. Refer to D5429 III. 8. The laboratory failed to ensure weekly maintenance was performed on the Sysmex CA-600 as required by the manufacturer for one (1) of forty-three (43) weeks reviewed. Refer to D5429 IV. 9. The laboratory failed to perform and document monthly maintenance on centrifuges as required by the laboratory for one (1) of ten (10) months reviewed. Refer to D5433. 10. The laboratory failed to perform calibration verification procedures for Potassium (K), Chloride (Cl) and Sodium (Na) at least every six (6) months on the Siemens Dimension EXL for three (3) of four (4) calibration verifications reviewed. Refer to D5439.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 II.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Refer to D5413 II.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on observation record review and interview with personnel, the Technical Supervisors failed to ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Refer to D5781.