Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464876	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lasalle General Hospital	187 9th Street, Jena, 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 conducted September 16, 2024 through September 18, 2024 at LaSalle General Hospital - CLIA ID # 19D0464876. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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 policies and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to perform assessment activities for an unacceptable proficiency testing (PT) result for one (1) of eleven (11) events reviewed. Findings: 1. Review of the laboratory's policy "Proficiency Testing" revealed "When scoring is received, results are reviewed by tech performing PT testing, by the general supervisor and Laboratory Director. Remedial action is taken as necessary." 2. Review of the laboratory's American Proficiency Institute (API) 2024 Chemistry - Core - 2nd Event revealed sample CH-07 AST/SGOT was unacceptable, but the laboratory did not perform any remedial actions. 3. In interview on September 16, 2024 at 5:17 p.m., General Supervisor 2 stated the unacceptable result was missed when the report was evaluated. She confirmed the laboratory did not perform any remedial actions for the unacceptable result 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: Based on review of the laboratory's policies and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to follow their quality assessment policy for proficiency testing (PT) for one (1) of eleven (11) events reviewed. Findings: 1. Review of the laboratory's policy "Proficiency Testing" revealed "When scoring is received, results are reviewed by tech performing PT testing, by the general supervisor and Laboratory Director. Remedial action is taken as necessary." 2. Review of the laboratory's American Proficiency Institute (API) 2024 Chemistry - Core - 2nd Event revealed sample CH-07 AST/SGOT was unacceptable, but the laboratory did not perform any remedial actions. 3. In interview on September 16, 2024 at 5:17 p.m., General Supervisor 2 stated the unacceptable result was missed when the report was evaluated. She confirmed the laboratory did not perform any remedial actions for the unacceptable result identified above.
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 performance specification verification records, as well as interview with personnel, the laboratory failed to follow their policy for performance specification verification of the Siemens Dimension EXL. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the laboratory utilized a Siemens Dimension EXL Serial DR253115 for chemistry testing. 2. Review of the laboratory's policy "Method Performance Specifications" section "Linearity/Reportable Range" revealed "Note: If unable to verify the manufacturer's reportable range for a test, you can only report results to the limits you verified (undiluted)." 3. Review of the laboratory's performance specification verification records revealed the laboratory began patient testing on the analyzer identified above on October 10, 2023 and utilized the manufacturer's analytical measurement range (AMR) and not the AMR verified by the laboratory for analytes to include, but not limited to, the following: a) Ammonia - AMR verified by the laboratory: 0.67 - 656.67 - Manufacturer's AMR: 9.98 - 749.60 b) Triglycerides - AMR verified by the laboratory: 17.0 - 488.0 - Manufacturer's AMR: 15.0 - 500.0 4. In interview on September 17, 2024 at 11:30 a. m., General Supervisor 2 confirmed the laboratory utilized the manufacturer's reportable range and not the reportable range verified by the laboratory.
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 laboratory policies and patient test records as well as interview with personnel, the laboratory failed to have a complete policy for reporting critical results for blood gas testing. Findings: 1. Review of the laboratory's policy "Arterial Blood Sampling Technique" revealed "When values are outside the normal range, the RT department will notify the Head Nurse or Chief Therapist who will in turn notify the Physician of the results and take specific orders on course of action." 2. Further review of laboratory policies revealed a job aid which stated the following: - "If panic values are triggered, edit these with the by typing the numbers to the left of the blanks and use keyboard to type documentation." * "6. Called To: _____" * "7. Date /Time _____" * "8. Tech Initials _____" * "9. Rep/Verified _____" 3. Review of a random selection of final patient test reports revealed the laboratory documented communication of critical results as follows: a) Patient 10058563 resulted 6/17/2024: - "Called to: ER MD" - did not include the name of the person the critical was reported to. - Rep/Verified is not included in the documentation. - Results for pCO2 and pO2 flagged as critical; however, the critical communication documentation did not indicate what results were reported to the physician as critical. b) Patient 10057347 resulted 6/3/2024 - "Called to: ER Nurse"- did not include the name of the person the critical was reported to. - Result for pCO2 flagged as critical; however, the critical communication documentation did not indicate what results were reported to the nurse as critical. c) Patient 10057347 resulted 6/4/2024 - Rep/Verified is not included in the documentation. - Result for pCO2 flagged as critical; however, the critical communication documentation did not indicate what results were reported to the physician as critical. d) Patient 10057347 resulted 6/3/2024 - "Called to: ER Nurse" - did not include the name of the person the critical was reported to. e) Patient 10054693 resulted 5/4/2024 - "Called to: ER DR"- did not include the name of the person the critical was reported to. - "Date/Time 050424" - did not include the time. 4. In interview on September 17, 2024 at 10:18 a.m., the Respiratory Supervisor confirmed the laboratory's policies did not include how to report the name of the person notified and how to document the result(s) reported as critical.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on observation, review of laboratory polices and manufacturer's instructions, as well as interview with personnel, the laboratory failed to follow manufacturer's instructions for centrifugation of coagulation specimens. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the laboratory utilized an Iris StatSpin Express and McKesson Powerspin for centrifugation of sodium citrate tubes for coagulation testing. 2. In interview on September 17, 2024 at 1:25 p.m., General Supervisor 2 stated sodium citrate tubes are centrifuged in the McKesson Powerspin at approximately 3200 RPM (1705 RCF) for ten (10) minutes. 3. Review of the laboratory's policy "Specimen and Reagent Preparation" revealed "Laboratory testing personnel will handle, prepare, and process specimens for testing according to guidelines and recommendations outlined in this policy and procedure manual, in the manufacturer's operation, and test methodologies guides, or in the laboratory reference manuals." 4. Review of the manufacturer's instructions for use "BD Vacutainer Evacuated Blood Collection System" section "Centrifugation" revealed the required centrifugation RCF and time for citrate tubes was 1500 RCF for 15 minutes. 5. In interview on September 18, 2024 at 11:06 a.m., General Supervisor 2 confirmed the laboratory was not following the manufacturer's requirements for centrifugation of sodium citrate tubes in the McKesson Powerspin.
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 manufacturer's instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the respiratory laboratory. Findings: 1. Observation by surveyor during the tour of the respiratory laboratory on September 17, 2024 at 8:56 a.m. revealed the following quality control material: Opti Check Multi Analyte Control - Manufacturer's storage requirements: 15 - 30 degrees Celsius 2. Review of the respiratory laboratory's temperature records from January 2024 through August 2024 revealed the laboratory defined the acceptable room temperature limits as 10 - 30 degrees Celsius which exceeded the manufacturer's lower temperature limit. 3. In interview on September 17, 2024 at 10:45 a.m., the Respiratory Supervisor confirmed the room temperature limits defined by the laboratory exceeded the manufacturer's limits as identified above. II. Based on observation, review of manufacturers' instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in two (2) of two (2) rooms in the main laboratory. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the following supplies stored in the

laboratory: a) Lab Small Room: - Copan Transystem Amies W/O CH Plastic Applicator Rayon Tipped - Manufacturer's storage requirements 5 - 25 degrees Celsius - UTM-R - Manufacturer's storage requirements 2 - 25 degrees Celsius b) Lab Room Temp: - BD Vacutainer C&S Preservative Urine Tube - Manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer Gel and Lithium Heparin - Manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer Buffered Sodium Citrate (9NC) Blood Collection Tubes - Manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer K2E 7.2 mg Blood Collection Tubes - Manufacturer's storage requirements 4 - 25 degrees Celsius 2. Review of the laboratory's temperature records from January 2024 through June 2024 for both the "Lab Room Temp" and the "Lab Small Room" revealed the laboratory defined the acceptable room temperature limits as 20 - 28 degrees Celsius which exceeded the manufacturers' upper limits. 3. In interview on September 16, 2024 at 1:30 p.m., General Supervisor 2 confirmed the room temperature limits defined by the laboratory exceeded the manufacturers' requirements as identified above. III. Based on observation; review of the manufacturer's storage requirements, operating instructions, and package inserts; review of laboratory temperature records; as well as interview with personnel, the laboratory failed to monitor the room temperature and humidity for one (1) of three (3) rooms where laboratory supplies were stored and testing is performed. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the following supplies stored in the Blood Bank: a) ID-Micro Typing System Anti-IgG (Rabbit) - Manufacturer's storage requirements 2 to 25 degrees Celsius b) ID-Micro Typing System A/B/D Monoclonal and Reverse Grouping Card - Manufacturer's storage requirements 2 to 25 degrees Celsius 2. Further observation by surveyor revealed the laboratory utilized an Ortho Workstation for Immunohematology testing. 3. Review of the "Ortho Workstation ID-MTS Gel Cards Reference Guide Section 3 - Installation and Specifications" revealed the following: a) "Environmental Requirements" - "Temperature: 15 - 30 degrees Celsius" - "Relative Humidity: 15 - 85%" 4. Review of the package insert "MTS A/B /D Monoclonal and Reverse" section "Test Procedure" revealed "Bring the samples and reagents to room temperature (18 - 25 degrees Celsius)." 5. Review of laboratory temperature records revealed no documentation of room temperature and humidity for the Blood Bank room. 6. In interview on September 16, 2024 at 1:30 p.m., General Supervisor 2 stated the laboratory did not monitor the room temperature or humidly of the room where Immunohematology supplies are stored and testing is performed. IV. Based on observation, review of manufacturer's instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable room 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 September 16, 2024 at 1:20 p.m. revealed the following supplies stored in the Blood Bank refrigerator: a) Ortho Clinical Diagnostics Reagent Red Blood Cells 0.8% Selectogen - Manufacturer's storage requirements 2 - 8 degrees Celsius b) Ortho Clinical Diagnostics Reagent Red Blood Cells (Pooled Cells) 0.8% Affirmagen - Manufacturer's storage requirements 2 - 8 degrees Celsius c) Ortho Clinical Diagnostics Ortho Confidence System - Manufacturer's storage requirements 2 - 8 degrees Celsius d) Ortho Clinical Diagnostics Reagent Red Blood Cells (Pooled Cells) Ortho Coombs Control - Manufacturer's storage requirements 2 - 8 degrees Celsius e) ID-Micro Typing System MTS Diluent - Manufacturer's storage requirements 2 - 8 degrees Celsius 2. Review of the laboratory's August 2024 Blood Bank refrigerator temperature records revealed the laboratory defined the acceptable temperature limits as 1 - 6 degrees Celsius which exceeded the manufacturer's lower temperature limits. 3. In interview on September 17, 2024 at 5 p.m., General Supervisor 2 confirmed the laboratory's

	acceptable refrigerator temperature exceeded the manufacturer's limits as identified above.
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, review of manufacturer's requirements and laboratory quality control records, as well as interview with personnel, the laboratory failed to document the open expiration date for saline utilized for Immunohematology testing. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the laboratory had the following saline bottle in use for immunohematology testing: EKI Blood Bank Saline - Lot: 2413002, Expiration date: 11/06/2025 2. Review of the manufacturer's instructions for use revealed "To reduce the risk of microbial contamination, consume entire contents within 30 days of opening." 3. Further observation of the saline bottle revealed the laboratory did not document the open expiration date on the bottle. 4. Review of the laboratory's quality control records for July 2024 through September 2024 revealed the laboratory documented the saline's bottle's lot number and the original manufacturer's expiration date, but did not document the open expiration date. 5. In interview on September 16, 2024 at 2:21 p.m., General Supervisor 2 confirmed the laboratory did not document the open expiration date of the Blood Bank saline as identified above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: I. Based on observation, review of the laboratory's policies and manufacturer's manual, as well as interview with laboratory personnel, the laboratory failed to establish function check protocols for the Ortho Workstation. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p. m. revealed the laboratory utilized the Ortho Workstation for ID-MTS Gel Cards for Immunohematology testing. 2. Review of the laboratory's policies revealed the laboratory did not include function checks with frequency for the workstation. 3. Review of the manufacturer's manual "Ortho Workstation for ID-MTS Gel Cards Reference Guide" revealed the following "As Needed" procedures: a) Speed

	Verification b) Centrifuge Timing Verification c) Incubator Temperature Verification 4. In interview on September 17, 2024 at 5:20 p.m., General Supervisor 2 confirmed the laboratory did not have a function check protocol for the Ortho Workstation. II. Based on observation, review of the laboratory's policies and manufacturer's manual, as well as interview with laboratory personnel, the laboratory failed to establish function check protocols for the Iris StatSpin and McKesson centrifuges. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p. m. revealed the laboratory utilized the Iris StatSpin Express 3 and McKesson Powerspin centrifuge. 2. Review of the laboratory's policies revealed the laboratory did not include function checks for the centrifuges identified above to include timer and speed checks as well as frequency of performance. 3. In interview on September 17, 2024 at 5:20 p.m., General Supervisor 2 confirmed the laboratory did not have a policy that included a function check protocol for the Iris StatSpin and McKesson Powerspin centrifuges.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) records and interview with personnel, the laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for blood gas testing. Findings: 1. Review of the laboratory's IQCP for blood gas testing revealed the laboratory did not a Quality Assessment Plan (QAP). 2. In interview on September 17, 2024 at 10:28 a.m., the Respiratory Supervisor confirmed the laboratory's IQCP did not include a QAP as identified above.
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 review of laboratory policies, maintenance and quality assurance records, as well as interview with personnel, the laboratory failed to follow their quality assurance policy to correct problems within the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment Plan" section "Indicators" revealed the following: a) "Analytical Monitors" *Indicator: Maintenance of Equipment *Description: All equipment procedures and function checks are documented

	according to schedule. Unscheduled maintenance is documented and available." *Participants/Occurrence/Threshold: Staff members, Lab manager review/Daily/100% compliance 2. Further review of the laboratory's "Quality Assessment Plan" section "Assessment of Actions Taken" revealed "A study will be performed to determine if the action taken to resolve an issue has been effective. The assessment of the outcome will be performed as promptly as possible after the action has been taken, and will be reported to the Laboratory Director by the Laboratory Manager. Should the outcome results show that the issue has not been resolved, another course of action will be defined, action taken and another assessment made." 3. Review of the laboratory policy "Blood Bank Alarm Check" revealed "The blood bank alarm must be tested quarterly and documented." 4. Review of blood bank alarm check records revealed the following alarm checks were performed late: a) November 2022 b) June 2023 c) April 2024 5. Review of the laboratory's "Quality Assurance Corrective Action Report" for the late alarm checks revealed the following: a) November 2022 alarm check * "Critical Indicator: BB alarm done late" * "Nature and/or Cause of Problem: BBank alarm due 11-30-22 but not done until 12-20-22 due to short staff." * "Corrective Action: No issues; all temps and graph in range during time not done" b) June 2023 alarm check * "Critical Indicator: BB alarm done late" * "Nature and/or Cause of Problem: The Blood bank alarm check was due 6-15-23, but wasn't done until 7-6-23" * "Corrective Action: There have been no outlying temps and no issues w/ BB refrigerator. The next check will be done at usual due date." c) April 2024 alarm check * "Critical Indicator: BB alarm done late" * "Nature and/or Cause of Problem: The blood bank alarm check was due in April, but not done until May 13th." * "Corrective Action: There were no temps out of range and no alarms recorded during period between April and May." 6. Review of the document "Laboratory's Quality Improvement (January-April, 2024)" section "Quarterly/Annual Checks" revealed "All quarterly and annual checks were performed as required and documented appropriately." 7. In interview on September 17, 2024 at 4:13 p.m., General Supervisor 2 confirmed the quality assurance measures taken did not correct the problem of missing the blood bank alarm checks.
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 established quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to follow their policy for performance specification verification of the Siemens Dimension EXL. Refer to D5401. 2. The laboratory failed to have a complete policy for reporting critical results for blood gas testing. Refer to D5403. 3. The laboratory failed to follow manufacturer's instructions for centrifugation of coagulation specimens. Refer to D5411. 4. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the respiratory laboratory. Refer to D5413 I. 5. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in two (2) of two

	(2) rooms in the main laboratory. Refer to D5413 II. 6. The laboratory failed to monitor the room temperature and humidity for one (1) of three (3) rooms where laboratory supplies were stored and testing is performed. Refer to D5413 III. 7. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Refer to D5413 IV. 8. The laboratory failed to document the open expiration date for saline utilized for Immunohematology testing. Refer to D5415. 9. The laboratory failed to establish function check protocols for the Ortho Workstation. Refer to D5435 I. 10. The laboratory failed to establish function check protocols for the Iris StatSpin and McKesson centrifuges. Refer to D5435 II. 11. The laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's performance specification validation records and policies, as well as interview with personnel, the laboratory failed to ensure the final patient test reports included the laboratory's validated reference ranges for chemistry testing. Findings: 1. Observation by surveyor during the laboratory tour on September 16, 2024 at 1:20 p.m. revealed the laboratory utilized a Siemens Dimension EXL Serial DR253115 for chemistry testing. 2. Review of performance specification validation records for the analyzer identified above revealed the laboratory began patient testing on October 10, 2023. 3. Further review of the validation records revealed "Reference Range study accepted from previous instrument validation since both instruments correlated." 4. Review of final patient reports revealed the reference ranges on the final reports did not match the reference ranges included in the validation records to include, but not limited to, the following analytes: a) 8/13/2024 Patient 10064016 *Cholesterol - Test report normal reference range: 50 - 200 mg-dL - Validated range: 0 - 200 mg /dL *Triglycerides - Test report normal reference range: 30 - 150 mg-dL - Validated range: 0 - 150 mg /dL b) 8/30 /2024 Patient 10065788 *Hgb A1C - Test report normal reference range: 4.5 - 6.2 % - Validated range: 3.8 - 5.6 % c) 9/16/2024 Patient 10067291 *BUN - Test report normal reference range: 5 - 20 mg-dL - Validated range: 7 - 18 mg /dL *AST - Test report normal reference range: 4 - 34 U/L - Validated range: 15 - 37 U/L 5. In interview on September 17, 2024 at 12 p.m., General Supervisor 2 confirmed the reference ranges on the patient final reports did not match the ranges from the verification study as identified above.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and patient test records as well as interview with personnel, the laboratory failed to ensure providers were notified of blood gas testing critical values for two (2) of forty-three (43) patients reviewed. Findings: 1. Review of the laboratory's policy "Arterial Blood Sampling Technique" revealed "When values are outside the normal range, the RT department will notify the Head Nurse or Chief Therapist who will in turn notify the Physician of the results and take specific orders on course of action." 2. Further review of laboratory policies revealed a job aid which stated the following: - "If panic values are triggered, edit these with the by typing the numbers to the left of the blanks and use keyboard to type documentation." * "6. Called To: _____" * "7. Date/Time _____" * "8. Tech Initials _____" * "9. Rep/Verified _____" 3. Review of a random selection of patient final reports revealed the following patients with results flagged as critical, but the laboratory did not notify providers: a) Patient 10055887: pH = 7.13, pCO2 = 61.0 mmHg resulted 5/20/2024 b) Patient 10054626: pCO2 = 63.0 mmHg resulted 5/3/20224 4. In interview on September 17, 2024 at 10 a.m., the Respiratory Supervisor confirmed the laboratory did not have documentation that providers were notified of the critical results.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D5813.
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:
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. Findings: 1. The laboratory failed to follow their policy for performance specification verification of the Siemens Dimension EXL. Refer to D5401. 2. The laboratory failed to follow manufacturer's instructions for centrifugation of coagulation specimens. Refer to D5411. 3. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the respiratory laboratory. Refer to D5413 I. 4. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in two (2) of two (2) rooms in the main laboratory. Refer to D5413 II.
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 have a complete IQCP to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445. 2. The laboratory's established quality assessment monitors failed to correct issues identified with the analytic system. 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, record review, and interview with personnel, the Laboratory

	Director failed to ensure the establishment of function protocols as required. Refer to D5435 II.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for hematology testing included pertinent information. Refer to D5807.
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. 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, 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 perform assessment activities for an unacceptable proficiency testing (PT) result for one (1) of eleven (11) events reviewed. Refer to D5221. 2. The laboratory failed to follow their policy for performance specification verification of the Siemens Dimension EXL. Refer to D5401. 3. The laboratory failed to have a complete policy for reporting critical results for blood gas testing. Refer to D5403. 4. The laboratory failed to follow manufacturer's instructions for centrifugation of coagulation specimens. Refer to D5411. 5. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range

	for supplies stored in the respiratory laboratory. Refer to D5413 I. 6. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in two (2) of two (2) rooms in the main laboratory. Refer to D5413 II. 7. The laboratory failed to establish function check protocols for the Iris StatSpin and McKesson centrifuges. Refer to D5435 II. 8. The laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445. 9. The laboratory failed to ensure the final patient test reports included the laboratory's validated reference ranges for chemistry testing. Refer to D5807.
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. Findings: 1. The laboratory failed to monitor the room temperature and humidity for one (1) of three (3) rooms where laboratory supplies were stored and testing is performed. Refer to D5413 III. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Refer to D5413 IV. 3. The laboratory failed to document the open expiration date for saline utilized for Immunohematology testing. Refer to D5415.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 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 established and maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to follow their quality assurance policy to correct problems within the analytic system. Refer to D5791. 2. The laboratory's established quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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, record review, and interview with personnel, the Laboratory

	Director failed to ensure the establishment of function protocols as required. Refer to D5435 I.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the General Supervisors failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to monitor the room temperature and humidity for one (1) of three (3) rooms where laboratory supplies were stored and testing is performed. Refer to D5413 III. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Refer to D5413 IV. 3. The laboratory failed to document the open expiration date for saline utilized for Immunohematology testing. Refer to D5415. 4. The laboratory failed to establish function check protocols for the Ortho Workstation. Refer to D5435 I.