Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1104293	08/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Lukes Health Lakeside Hospital	17400 St Luke'S Way, The Woodlands, TX	

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	An announced on site validation survey was performed on 7/29/2024 to 7/30/2024. The laboratory was found NOT in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition(s) not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; Exit was extended to 8/12/2024 when requested documentation were provided.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility transfusion policy, AABB (Association for the Advancement of Blood and Biotherapies) Standards for Blood Banks and Blood Transfusions, and random review of transfused patients from January to June 2024, and confirmed in interview, the facility failed to follow their policy to identify, investigate, and report possible blood product transfusion reactions to the laboratory for one of ten patients (Patient ID 01271576) reviewed. Findings included: 1. Review of the facility policy Transfusion of Blood Products - Patient Care (effective October 2020) under Transfusion reactions, it stated "with each set of vital signs, assess patient and document the presence / absence of a possible transfusion reaction; new onset or unexpected development of any of the following may represent transfusion reaction: i. Temperature elevation during transfusion 1. Greater than 1 degree Celsius (C), or. 2. Greater than 2 degrees Fahrenheit (F). ii. Decrease in blood pressure of greater than or equal to 30 mmHg iii. Hypoxemia, or acute respiratory distress (Shortness of Breath, wheezing or cough) iv. Chest pain or tightness v. Back/flank pain vi. Chills/rigors vii.

	Pain, burning or bleeding at infusion site viii. Urticaria/hives ix. Hematuria/dark urine Signs or symptoms of a transfusion reaction may occur 24 hours or more after transfusion is complete. All suspected transfusion reactions must be immediately reported to the blood bank." 2. Review of the above policy under Related documents listed the AABB Standards for Blood Banks and Transfusion Services. In review of the AABB Standards for Blood Banks and Transfusion Services (13th edition) under chapter 27 "noninfectious Complications of Blood Transfusions" it stated "few data are available on the incidence rate of transfusion-induced circulatory overload in the general population, but young children and the elderly are considered most at risk, and incidence rates of up to 1% have been observed in a study of elderly orthopedic patients ...hypervolemia must be considered if dyspnea, cyanosis, orthopnea, severe headache, hypertension or congestive heart failure occur during or soon after transfusion." 3. Random review of transfusion records from January 2024 to June 2024 revealed one of ten patients (Patient ID 01271576 - 80 year old female) with a rapid increase of blood pressure of 74 HHmg and a decrease of blood pressure of 38 mmHg when she received blood products (1 platelet, 2 red blood cells (RBC)) on 3/19 /2024. Platelet start at 1428 hours and ended 1555 hours Pre transfusion blood pressure: 126/71 End of transfusion blood pressure: 162/77 1st unit RBC start at 1620 hours and ended at 1949 hours Pre transfusion blood pressure: 162/89 End of transfusion blood pressure: 200/99 2nd unit RBC start at 2054 hours and ended at 0015 (3/20/2024) Pre transfusion blood pressure: 172/73 End of transfusion blood pressure: 162/72 4. An interview with the nurse on 7/29/24 at 1430 hours in the conference room confirmed the above findings. She also confirmed that a possible transfusion reaction was not called, only IV medications to lower her blood pressure was provided.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory's Prothrombin Time (PT) Innovin reagent's new lot roll over records, laboratory's policies/procedures and staff interview, the laboratory failed to retain donor questionnaires ensuring donors' inclusivity in studies for establishing new lot's normal mean for 2 of 2 new Innovin lots implemented in 2023 and 2024. Findings included: 1. Review of laboratory's new lot of Inovin reagent's roll over records revealed 2 new lots were implemented in 2023 and 2024 as follows: Innovin lot number: 564617A Expiration date: 03/17/2025 Roll over completed: 07/25/2023 Innovin lot number: 564640A Expiration date: 12/01/2025 Roll over completed: 05/20 /2024 2. Further review of the above records revealed the following acceptability statement for donor inclusivity in the final evaluation of the normal mean of Innovin establishment studies: "Donnor selection for the Pt (prothrombin time) normal reference range study was screened by the following questions: All answered 'no'. - Pregnant - Blood thinner medication taken - Antibiotic medication taken - Gender recorded." 3. The laboratory was asked to provide documentation of donors' responses to the screening questions for establishing donor's inclusivity in the two above studies and no such documentation was available for review prior to survey exit. 4. Review of the laboratory's policy "New Lot Number Roll Over Verification" (effective April 2023) revealed: "Donors selected for the new PT normal reference range study

	provide one sodium citrate blue top tube and are screened for medication history (Cumadin, heparin products, thrombin inhibitors and antibiotics), pregnancy and known immunologic disease." There were no protocols in place addressing documentation of donors' responses or donors' attestation to the questionnaire to ensure donors' eligibility for inclusivity in the study. 5. In an interview on 07/30/2024 at 1000 hours in the conference room, the laboratory's technical consultant number 3 (as indicated on submitted Form CMS 209) confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, surveyor observation, and confirmed in staff interview, the laboratory failed to monitor and evaluate overall quality of the pre-analytic systems and identify problems. The findings include: 1. The laboratory failed to ensure its policies included criteria to notify provider of specimen rejection. Refer to D5311-A 2. The laboratory failed to reject specimens per the manufacturer's instructions for coagulation testing on the Siemens Sysmex analyzer. Refer to D5311-B 3. The laboratory failed to ensure its policies included criteria for rejection based on sample stability for all iSTAT CG8+ testing. Refer to D5311-C 4. The laboratory's quality assessment plan failed to detect issues in the preanalytical systems of the laboratory (refer to D5391).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on surveyor's observations, review of analyzer test records, manufacturer instructions for use, laboratory's policies/procedure, patient test records, and staff interview, the laboratory failed to follow its own policies for rejection of samples of insufficient volume for 8 of 44 samples reviewed from 2023 and 2024. Findings included: 1. Surveyor's observations on 07/29/2024 at 0945 hours in the laboratory revealed the following samples collected in Blue Top Vacutainer Citrate tubes were stored in the refrigerator that did not have required (marked on the tube) specimen volume for coagulation testing: Sample: 24L-205L0056 Patient number: 06778438 Collected/tested: 07/23/2024 Sample: 24L-205L0029 Patient number: 05521210 Collected/tested: 07/23/2024 2. Review of the laboratory's Siemens Sysmex CS-2500

coagulation analyzer records for the above samples revealed these samples had flags of "VOL" (Volume). 3. Review of the coagulation Siemens analyzer's "Sysmex CS-2500 System Quick Reference Guide" (Version 01-70) revealed the definition of the "VOL" flag was "Sample tube fill out of range". 4. Review of coagulation Siemens analyzer's "Sysmex CA-Series Systems Technical Bulletin; Answers for Life" (February 2014) revealed: "Variables that can affect the results obtained include: ...the concentration of anticoagulant ..., the blood to anticoagulant ratio ..." 5. Review of patient test records for the above samples revealed these samples were tested and result were reported to provider. 6. Review of laboratory's policies "Innovance D-Dimer", "Prothrombin Time (PT)" and "Activated Partial Thromboplastin Time (aPTT)" (all effective April 2023), revealed: "Unacceptable specimens that should be rejected: ... 3. Samples collected with incorrect blood to anticoagulant ratio. ... 6. Samples that are not properly collected or have less than 90% expected fill of the collection tubes." 7. A random review of laboratory's Siemens Sysmex CS-2500 coagulation analyzer's test records and corresponding patient test records from February and August 2023 revealed the following patient samples had analyzer "VOL" flags with reported results: Sample: Tested: 23L-041L0007 02/10/2023 23L-041L0014 02/10/2023 23L-041L0017 02/10/2023 23L-041L0054 02/10/2023 23L-041L0058 02/10/2023 23l-222L0056 08/10/2024 8. In an interview on 07/29/2024 at 1440 hours in the laboratory, the testing person number 2 (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on surveyor's observations, review of laboratory's specimen logs, policies/procedures and staff interview, the laboratory failed to notify provider of specimen rejection for 1 of 1 hemolyzed Prothrombin Time (PT) specimen observed. Findings included: 1. Surveyor's observations on 07/29 /2024 at 0945 hours in the laboratory revealed the following Blue Top Vacutainer Citrate tube with hemolyzed sample stored in the refrigerator: Sample: 24L-205L0008 Collected: 07/23/2024 2. Review of laboratory's specimen logs revealed the laboratory documented rejection of this specimen in its Epic Laboratory information System by marking it for redraw. There was no documentation of notification of specimen rejection to provider. 3. In an interview on 07/29/2024 at 1425 hours in the laboratory, testing person number 2 (as indicated on submitted From CMS 209) stated that laboratory's policy was to notify the provider (patient's unit) via the telephone of the rejection of a sample, and to document communication in the Epic system. 4. The laboratory was asked to provide a list of other rejected samples and documentation of provider notification, and no such list was available for review prior to survey exit. 5. Review of laboratory's policy "Quality Program" (effective April 2023) revealed there were no protocols in place for ensuring sample's rejection was documented and/or communicated to provider. Review of laboratory's policy "Prothrombin Time (PT)" (effective April 2023) revealed there were no protocols in place for documentation of rejected samples or documentation of notification to provider. 6. In an interview on 07 /30/2024 at 1430 hours in the conference room, the laboratory's technical consultant number 3 (as indicated on submitted Form CMS 209) confirmed the findings. 38387 C. Based on review of manufacturer's instructions, laboratory policy, and confirmed in interview, the laboratory failed to establish the specimen acceptability and rejection for one of two tests on the iSTAT chemistry analyzer (CG8+ blood gas). Findings included: 1. Review of the Instructions for use for the i-STAT CG8+ Cartridge (REF 03P88-25) under Specimen Collection and Preparation for Analysis, it stated "Blood Collection options and Test timing (time from collection to cartridge fill) Analyte pH, PCO2, PO2: evacuated tubes with balanced anticoagulant - 10 minutes; capillary tubes - 3 minutes" 2. Review of the laboratory policy i-STAT1 Analyzer System - Abbott Diagnostics (CG8+) Blood Gases and Ionized Calcium (effective May 2023) revealed no documentation of the specimen acceptability and rejection for pH, PCO2, and PO2 testing. 3. Random review of patient records from 2023 to 2024 confirmed

	the laboratory performed the following 10 blood gas testing (pH, PCO2, PO2) using the iSTAT CG8+ cartridges. Patient ID 23M-037P0774 Patient ID 23M-102P1342 Patient ID 23M-108P0720 Patient ID 24M-08P1722 Patient ID 24M-066P1639 Patient ID 24M-079P0481 Patient ID 24M-089P1426 Patient ID 24M-134P1406 Patient ID 24M-183P1430 Patient ID 24M-199P1154 4. An interview with the technical consultant #3 on 7/30/2024 at 1100 hours in the conference room confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, patient final reports, analyzer printouts, and confirmed in interview, the laboratory failed to identify and correct problems in specimen collection times for five of five blood gas reports reviewed. Findings included: 1. Review of the Instructions for use for the i-STAT CG8+ Cartridge (REF 03P88-25) under Specimen Collection and Preparation for Analysis, it stated "Blood Collection options and Test timing (time from collection to cartridge fill) Analyte pH, PCO2, PO2: evacuated tubes with balanced anticoagulant - 10 minutes; capillary tubes - 3 minutes" 2. Random review of patient records from 2023 to 2024 confirmed the laboratory performed the following five blood gas testing (pH, PCO2, PO2) using the iSTAT CG8+ cartridges. However, the specimen collection time and the analyzer printout for analysis for all the tests were the same time. No process was in place to ensure the collection time were within the required time interval of 10 minutes per manufacturer's instructions. Patient ID 23M-108P0720: analyzer and collection date and time 04/18/2023 1053 Patient ID 24M-066P1639: analyzer and collection date and time 03/06/2024 1809 Patient ID 24M-079P0481: analyzer and collection date and time 03/19/2024 0840 Patient ID 24M-089P1426: analyzer and collection date and time 03/29/2024 1834 Patient ID 24M-134P1406: analyzer and collection date and time 5/13/2024 1713 3. An email received on 08/06 /2024 from the technical consultant #3, she stated that the LIS automatically populates the collection time as the time the iSTAT cartridge is loaded/analyzed. There is not a process for the laboratory personnel to go back to enter the correct collection time.
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 surveyor's observations, review of manufacturer instructions, laboratory's records, policies/procedures, pharmacy records and staff interview, the laboratory failed to document new lot of APTT (activated partial thromboplastin time) reagent's heparin therapeutic range studies for 1 of 2 heparin manufacturers used by the

	facility's pharmacy in 2023 and 2024. Findings included: 1. Surveyor's observations on 07/30/2024 at 0950 hours in the pharmacy revealed 2 kinds of heparin for administration to patients: PREMIER ProRx Heparin Sodium Injection, 5,000 USP per mL (milliliter) Meitheal Heparin Sodium Injection, 1,000 USP per mL 2. Review of Siemens manufacturer instructions for "Establishing APTT Values Corresponding to the Unfractionated Heparin Therapeutic Range" (Technical Bulletin, February 2014) revealed: "The APTT is the most popular laboratory test for monitoring the effectiveness of unfractionated heparin therapy. There are many in-vivo variables that can affect the test results, such as ... type of heparin used in therapy ..." And, "The reagent chosen to perform the APTT has considerable influence on the therapeutic range." 3. Review of laboratory's records revealed the new lot of APTT reagent's heparin therapeutic range studies were performed on 06/16/2023 and 05/12/2024. There was no documentation of the kind of heparin used in the studies. 4. In an interview on 07/30/2024 at 1000 hours in the conference room, the testing person number 2 (as indicated on submitted Form CMS 209) stated that the new lot of APTT reagent's heparin therapeutic range studies were performed using only the 5,000 USP per mL PREMIER ProRx Heparin Sodium. She confirmed there were no heparin therapeutic range studies for the 1,000 USP per mL Meitheal Heparin Sodium. 5. Review of laboratory's policy "New Lot Number Roll Over Verification" (effective April 2023) revealed "With each reagent lot number, the APTT therapeutic range should be verified...". There were no protocols in place addressing studies for establishing APTT values corresponding to the unfractionated heparin therapeutic range for different concentrations and/or different manufacturers of heparin with each new lot of APTT reagent. 6. On 07/30/2024 at 1310 hours in the conference room, facility's pharmacy representative provided an email stating that heparin was distributed for administration to 455 patients in 2023. 7. In an interview on 07/30 /2024 at 1510 hours in the conference room, the laboratory's technical consultant number 3 (as indicated on submitted Form CMS 209) confirmed the findings.
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 review of laboratory records from 2023 to 2024 and confirmed in interview, the laboratory failed to evaluate precision for one of one test (Troponin I) on the Alere Triage meter. Findings included: 1. Review of laboratory records confirmed the laboratory started patient testing on the Troponin I on the Alere Triage meter in November 2023. 2. Review of the laboratory policy Method Performance Evaluation (effective 2023), under Procedures it stated "initial precision testing must be completed for each new method. Precision testing can be performed using reference material of a known value, or patient samples. Day to day precision and within-run precision is assessed by reviewing instrument quality control including manufacturer and patient controls. A. choose at least 1 to 3 samples. B Run each sample 10 times. Enter appropriate data into EP evaluator or another recommended statistical program.

	D. Data must have a CV within manufacturer's stated limits or less than 10. E. Retain all documentation." 3. Review of available laboratory records on site on 7/30/2024 and data submitted via email dated 08/12/2024 revealed no documentation of the precision study as required. 4. In an interview on 7/30/2023 at 1020 hours, in the conference room, the technical consultant #3 confirmed the above findings.
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 review of manufacturer's instructions for use, laboratory's policies /procedures, calibration records and staff interview, the laboratory failed to document 6-month calibration as per its own policy for 1 of 2 instances 6-month calibrations were required in 2023. Findings included: 1. Review of manufacturer's "Automated Hematology Analyzer XN Series (XN-1000) Instructions for Use" (revised November 2015) revealed: "Perform calibration verification as needed ..." 2. Review of laboratory's policy "Sysmex XN 1000 CBC" (effective April 2023) revealed: "CALIBRATION ...b. The laboratory must verify calibration every 6 months or on "as-needed" basis to ensure accuracy of system." 3. Review of laboratory's calibration records for 2023 revealed 6-month calibration was documented on 06/06/2023. There was no documentation of 6-month calibration verification in December 2023. The next documented 6-month calibration was on 07/24/2024. 4. In an interview on 07/29 /2024 at 1600 hours in the conference room, the testing person number 2 (as indicated on submitted Form CMS 209) confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory's quality control (QC) records, policies/procedures and staff interview, the laboratory failed to document evaluation of quality control over time for three of three coagulation and two of three point of care chemistry tests in 2023 and 2024. A. Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and D-Dimer B. iSTAT Blood gas (pH, PCO2, PO2) C. Triage Troponin Findings included: A. Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and D-Dimer 1. Review of laboratory's QC records for 2023 and 2024 revealed the laboratory did not document evaluation of QC over time for the PT and APTT tests since 07/25/2023. There was no documentation of evaluation of D-Dimer QC over time at any time in 2023 or 2024. 2. Review of laboratory's policies /procedures revealed there were no protocols in place for evaluation of PT, APTT and D-Dimer QC over time. 3. In an interview on 07/29/2024 at 1500 hours in the conference room, the laboratory's testing person number 2 (as indicated on submitted Form CMS 209) confirmed the findings. 38387 B. iSTAT Blood gas (pH, PCO2, PO2) 1. Review of the laboratory iSTAT quality control records from 2023 revealed the laboratory performed quality control for the CG8+ cartridge for blood gases for the following months. 01/06/2023 TriControl Level 1 (lot 301151, exp 7/31/2023) pH - 7.050 (acceptable range 7.005-7.105) pCO2 - 64.2 mmHg (acceptable range 55.4-70.4 mmHg) pO2 - 84 mmHg (acceptable range 70-100mmHg) TriControl Level 3 (lot 321151, exp 7/31/2023) pH - 7.655 (acceptable range 7.617-7.717) pCO2 - 21.9 mmHg (acceptable range 15.1-27.7 mmHg) pO2 - 139 mmHg (acceptable range 123-167 mmHg) 02/06/2023 TriControl Level 1 (lot 301151, exp 7/31/2023) pH - 7.061 (acceptable range 7.005-7.105) pCO2 - 62.3 mmHg (acceptable range 55.4-70.4 mmHg) pO2 - 82 mmHg (acceptable range 70-100mmHg) TriControl Level 3 (lot 321151, exp 7/31/2023) pH - 7.658 (acceptable range 7.617-7.717) pCO2 - 21.4 mmHg (acceptable range 15.1-27.7 mmHg) pO2 - 141 mmHg(acceptable range 123-167 mmHg) 06/05/2023 TriControl Level 1 (lot 301157, exp 1/31/2024) pH - 7.068 (acceptable range 7.019-7.119) pCO2 - 59.9 mmHg (acceptable range 52.2-67.2 mmHg) pO2 - 83 mmHg(acceptable range 69-99 mmHg) TriControl Level 3 (lot 321157, exp 1/31/2024) pH - 7.640 (acceptable range 7.596-7.696) pCO2 - 23.1 mmHg (acceptable range 16.7-29.3 mmHg) pO2 - 136 mmHg (acceptable range 124-168 mmHg) 08/02/2023 TriControl Level 1 (lot 301157, exp 1/31/2024) pH - 7.061 (acceptable range 7.013-7.113) pCO2 - 60.9 mmHg (acceptable range 51.8-66.8 mmHg) pO2 - 86 mmHg (acceptable range 70-100mmHg) TriControl Level 3 (lot 321157, exp 1/31/2024) pH - 7.649 (acceptable range 7.599-7.699) pCO2 - 23.3 mmHg (acceptable range 16.2-28.8 mmHg) pO2 - 147 mmHg(acceptable range 126-170 mmHg) 2. Review of laboratory records available revealed no documentation of the laboratory monitoring over time the accuracy and precision of the above quality controls. 3. Random review of patient test records from 2023 confirmed the laboratory performed blood gas testing for the following three patients. Blood gas Patient ID 23M-108P0720 Patient ID 23M-102P1342 Patient ID 23M-037P0774 4. In an interview on 7/30/2024 at 1320 hours, in the conference room, technical consultant #3 confirmed the above findings. C. Triage Troponin 1. Random review of the quality control records from 2024 for the Troponin testing on the triage Meter confirmed the

	laboratory performed quality control the following days. 05/27/2024 Troponin - 0.43 ng/mL Control lot # C3997AN level 1 (acceptable range 0.29 - 0.89 ng/mL) Troponin - 13.3 ng/mL Control lot # C4002AN level 2 (acceptable range 10.9-20.3 ng/mL) 05 /08/2024 Troponin - 0.49 ng/mL Control lot # C3971AN level 1 (acceptable range 0.24-0.74 ng/mL) Troponin - 16.3 ng/mL Control lot # C3976AN level 2 (acceptable range 11.8-22.0 ng/mL) 04/07/2024 Troponin - 0.43 ng/mL Control lot # C3971AN level 1 (acceptable range 0.37 - 0.61 ng/mL) Troponin - 15.2 ng/mL Control log # C3976AN level 2 (acceptable range 14.3-1936 ng/mL) 2. Review of laboratory records available revealed no documentation of the laboratory monitoring over time the accuracy and precision of the above quality controls. 3. Random review of patient test records from 2024 confirmed the laboratory performed troponin testing for the following three patients on the Alere Triage meter. Patient ID 2081150627 Patient ID 2081154472 Patient ID 39215949 4. In an interview on 7/30/2024 at 1320 hours, in the conference room, technical consultant #3 confirmed the above findings.
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 records, quality control records from 2023 to 2024 and confirmed in interview, the laboratory failed to document a complete Individualized Quality Control Plan (IQCP) to reduce frequency of quality control testing to once monthly for one of one testing (Troponin) on the Triage chemistry analyzer and one of two testing on the iSTAT chemistry testing (Blood gases). A. Troponin B. Blood gases Findings included: A. Troponin 1. Review of laboratory records revealed the laboratory started Troponin testing on the Triage meter in November 2023. 2. Random review of the quality control records from 2024 for the Troponin testing on the triage Meter confirmed the laboratory performed monthly quality control and/or when laboratory received new lot of quality control or cartridges. 05/27/2024 Control lot # C3997AN (level 1) and Control C4002AN (level 2) 05/08/2024 Control lot # C3971AN (level 1) and Control C3976AN (level 2) 04/07 /2024 Control lot # C3971AN (level 1) and Control C3976AN (level 2) 3. Review of the laboratory records available revealed no documentation of three of three components of an IQCP (Risk Assessment, Quality Control Procedure, and Quality Assessment) to reduce frequency of quality control testing to once monthly for Troponin on the Triage chemistry analyzer. 4. Random review of patient test records from 2024 confirmed the laboratory performed troponin testing for the following three patients on the alere Triage meter. Patient ID 2081150627 Patient ID 2081154472 Patient ID 39215949 5. In an interview on 7/30/24 at 1320 hours, in the conference room, the technical consultant #3 confirmed the above findings. B. Blood gas 1. Review of the laboratory policy I-STAT1 Analyzer System - Abbott Diagnostics - (CG8+) Blood gases and Ionized Calcium (effective May 2023), it stated "i-STAT Tri Controls for blood gases, electrolytes, chemistries, and HCT are aqueous assayed

	control fluids are used for verifying the integrity of all new lots/shipment and every 30 days until supply is depleted." 2.Random review of the laboratory quality control records from 2023 confirmed the laboratory performed monthly quality control testing for blood gases on the iSTAT. Blood Gases 01/06/2023 TriControl Level 1 (lot 301151, exp 7/31/2023) TriControl Level 3 (lot 321151, exp 7/31/2023) 02/06/2023 TriControl Level 1 (lot 301151, exp 7/31/2023) TriControl Level 3 (lot 321151, exp 7 /31/2023) 06/05/2023 TriControl Level 1 (lot 301157, exp 1/31/2024) TriControl Level 3 (lot 321157, exp 1/31/2024) 08/02/2023 TriControl Level 1 (lot 301157, exp 1 /31/2024) TriControl Level 3 (lot 321157, exp 1/31/2024) 2. Review of the IQCP for the iSTAT blood gas testing revealed no documentation of one of three components of the IQCP (Quality Control Plan). No documentation of the number, type, frequency of testing and criteria for acceptable result(s) of the quality control were available for review. 3. Random review of patient test records from 2023 confirmed the laboratory performed blood gas testing for the following three patients. Blood gas Patient ID 23M-108P0720 Patient ID 23M-102P1342 Patient ID 23M-037P0774 4. In an interview on 7/30/24 at 1320 hours, in the conference room, the technical consultant #3 confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on random review of patient final reports, analyzer printouts, and confirmed in interview, the laboratory failed to ensure that the final test report reflected the correct received date and time for one of ten test reports reviewed. Findings included: 1. Random review of patient final reports and corresponding analyzer printouts revealed discrepancies in the received and verified time on the final report Patient ID 23M-037P0774 Final report Collected: 2/4/2023 2040; Received 2/6/2023 1153; Verified 2 /6/2023 1153 Analyzer printout shows handwritten notes of "sent to ED 2/4/23 at 8:43 PM" 2. In an interview on 7/30/2024 at 1030 hours, in the conference room, the technical consultant #3 confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management of the laboratory. The

	findings included: 1. The laboratory director failed to ensure policies and procedures for test systems were established and followed to provide quality laboratory services in preanalytical systems (refer to D6007). 2. The laboratory director failed to ensure verification procedures was followed prior to patient testing (refer to D6013). 3. The laboratory director failed to ensure a quality control program was developed and followed (refer to D6020).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, surveyor observation, and confirmed in staff interview, the laboratory director failed to ensure the laboratory developed systems to monitor and evaluate overall quality of the pre-analytic systems and identify problems. Refer to D5311-A, B, C; Refer to D5391
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 review of laboratory records from 2023 to 2024 and confirmed in interview, the laboratory director failed to ensure the laboratory verification procedures were adequate to determine precision of Troponin I testing on the Alere Triage meter. Refer to D5421
D6020	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 program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of quality controls records, laboratory policies, and confirmed in interview, the laboratory director failed to ensure a quality control program was established and maintained to assure quality of laboratory testing. Refer to D5441-I, II; D5445
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 review of transfusion records from 2022 to 2024 and confirmed in interview, the laboratory director failed to establish and maintain a quality assessment program to monitor and identify failures in transfusion services for 2022 and 2023. Findings included: 1. Review of records available revealed blood transfusions were monitored in 2021. The facility monitored the completeness of the education and informed consent to the patient for blood transfusion and the timeliness of vital signs and suspected transfusion reactions. 2. No records of the blood transfusion monitoring were available for review for 2022 and 2023. No policy was available for review by the end of survey on 7/30/2024. 3. An interview with the nursing supervisor on 7/29 /2024 at 1540 hours in the conference room confirmed the above findings. She stated that there used to be a blood transfusion coordinator, but she left in 2021, which was the last time that the quality assurance had been done.