Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2036393	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Christus Good Shepherd Medical Center-Kilgore	1612 S Henderson, Kilgore, 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	In a validation survey conducted from 7/11/2023 to 7/13/2023, the laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the Casper Report 155 Individual Laboratory Profile, proficiency testing records for 2021, 2022 and 2023,policies and procedures and interview of facility personnel, the laboratory failed to participate in one of five proficiency testing events for the specialty of Hematology. The findings include: 1. Review of the Casper Report 155 Individual Laboratory Profile found the laboratory received a score of 0% in the first event of 2023 for Hematology. 2 A review of the American Proficiency Institute (API) proficiency testing records found the laboratory failed to submit the

	results in the time frame specified by the program for the 2023 1st testing event. a. Review of the 2023 API PT Schedule found the PT Results due Date defined as March 29, 2023. b. Review of the 2023 Hematology/Coagulation - 1st Event Attestation Statement found that testing personnel had tested assigned proficiency specimens between 03/07/2023 and 03/21/2023. c. Review of the 2023 Hematology 2nd event Performance Summary found scores of 0% for all analytes due to a failure to participate as defined in the column labeled Notes. 3. Review of the policy QIP2021 Proficiency Testing Procedure found under the heading PROCEDURE: "4.c. Data will be submitted on or before the due date." 4. During interview of testing person one on the CMS Report 209 Laboratory Personnel Report conducted July 11, 2023 at 11:53 AM , she confirmed that the results were not submitted to the PT agency for grading prior to the final submission date of March 29, 2023.
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: Based on a review of laboratory policy, reagent instructions for use, laboratory documents, and confirmed in interview, the laboratory failed to analyze 6 of 19 patients with ammonia testing within 30 minutes of collection on the DxC600 chemistry analyzer in 2022. The findings included: 1. Review of the laboratory policy titled "QIP100 Laboratory Quality Improvement Plan", section "VIII Monitoring Criteria" stated the following: "As a part of the Laboratory Quality Improvement Plan, the laboratory will monitor the following functions for quality:" Bullet 11 "Timely reporting of all test results including "STAT" turnaround time." 2. Review of the reagent instructions for use for Ammonia testing stated the following: "Specimen Storage and Stability: Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes at an RCF of 1500G and analyzed within 30 minutes ..." Surveyor queried on 7/12/2023 at 16:25 hours, for the QA in regards to turn around time (TAT) monitoring for ammonia for 2022 and none was provided. 3. Review of laboratory-provided documents for ammonia testing in 2022 included the following six patients with a TAT from drawn to complete greater than 30 minutes: Patient: Date/Time Drawn - Date/Time Completed - Time to Completion 22-072-006155 - 3/13/2022, 23:04 - 3/13/2022, 23:36 - 00:32 minutes 22-094-003870 - 4/4/2022, 09:10 - 4/4/2022, 09:56 - 00:45 minutes 22-096-008395 - 4/6/2022, 13:44 - 4/6/2022, 14:55 - 1 hour 11 minutes 22-208-007965 - 7/27/2022, 12:33 - 7/27/2022, 13:39 - 1 hour 06 minutes 22-223-002648 - 8/11/2022, 07:54 - 8/11/2022, 08:41 - 00:47 minutes 22-339-005623 - 12/5/2022, 09:54 - 12/5/2022, 11:08 - 1 hour 14 minutes 4. In an interview on 7/13/2023 at 10:37 hours, in the laboratory, the Compliance Coordinator and the Laboratory Administrative Director confirmed that the laboratory failed to ensure that ammonia testing was performed within 30 minutes of collection for patients tested in 2022.
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 a review of laboratory policy, laboratory quality control (QC) instructions for use (IFU), laboratory QC documentation, and confirmed in interviews the laboratory failed to follow its policy for the establishment of means and standard deviation (SD) ranges for three of three analytes in use on the Access 2 chemistry analyzer in 2022. The findings included: 1. Review of the laboratory policy titled "CH 110 Controls", section "Quantitative Controls" had the following instructions: "B. Use of ASSAYED CONTROLS The laboratory mean is established for each new lot of controls. When appropriate the laboratory will establish its own standard deviation (SD). Prior to placing a new lot number of control into use a minimum of 60 samples are tested concurrently with the old lot number. The new control mean and SD (where applicable) is updated and entered in the LIS computer under the new lot number. The only exception is 6C controls which is managed in the DXH software. If controls cannot be tested concurrently, peer mean and SD values are used as target values until a minimum of 60 samples are tested and the laboratory mean and SD (where applicable) are calculated. Package insert ranges can be used as target values if peer data is not available. In conjunction with monthly QC review, laboratory mean and SD are adjusted if needed. Manual cell count manufacturer's control ranges are verified prior to putting a new lot in use. Once verified, the manufacturer's range is acceptable to use by the laboratory." The surveyor queried TC2, on 7/12/2023 at 10: 15 hours, as to which of the above methods they used for the laboratory's assayed controls on the Access 2 chemistry analyzer. It was stated that they establish their own means and use the QC IFU standard deviation (SD) to calculate the acceptable ranges. 2. Review of the assayed QC for Troponin (TNI), B-Type Natriuretic Peptide (BNP), and Human chorionic gonadotropin (hCG), had the following discrepancies between the IFU's SD and SD's used for the acceptability of QC: Cardiac Control 1, Lot 67661, put in use 9/2021 Analyte: TNI Mean: 0.039 IFU Range: 0.023 - 0.055 In Use Range: 0.029 - 0.049 Analyte: BNP Mean: 74.3 IFU Range: 64.6 - 84.0 In Use Range: 64.3 - 84.3 Cardiac Control 2, Lot 67662, put in use 9/2021 Analyte: TNI Mean: 0.793 IFU Range: 0.643 - 0.943 In Use Range: 0.693 - 0.893 Analyte: BNP Mean: 370.0 IFU Range: 328 - 412 In Use Range: 340.0 - 400.0 QC Cardiac 3, Lot 67663, put in use 9 /2021 Analyte: BNP Mean: 1325.0 IFU Range: 1192.34 - 1457.66 In Use Range: 1261.0 - 1389.0 Liquichek Immunoassay Plus Control 1, Lot 85321, put in use 10 /2022 Analyte: hCG Quantitative Mean: 6.00 IFU Range: 5.04 - 6.96 In Use Range: 5.00 - 7.00 Liquichek Immunoassay Plus Control 2, Lot 85322, put in use 10/2022 Analyte: hCG Quantitative Mean: 20.0 IFU Range: 17.74 - 22.26 In Use Range: 18 - 22.0 Liquichek Immunoassay Plus Control 3, lot 85323, put in use 10/2022 Analyte: hCG Quantitative Mean: 400.00 IFU Range: 358.66 - 441.34 In Use Range: 370.00 - 430.00 Surveyor queried about the discrepancies on 7/12/2023 at 12:00 hours, in the laboratory, and TC2 stated that the laboratory will occasionally use the peer SD. Surveyor queried if they recalculated the SD after 60 samples were tested, as described in the policy, and TC stated they were not. 3. In an interview on 7/12/2023 at 13:39, in the laboratory, TC2 confirmed that the laboratory failed to follow its own policy for the establishment of control SDs for new lot QC being put into use on the Beckman Coulter Access 2.

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 gram stain records, laboratory policy, and confirmed in interview, the laboratory failed to include instructions in policy for the processing of pleural body fluids for gram stain testing for one of one patient tested in 2022. The findings included: 1. Review of gram stain records listed the following patient tested in August 2022. Date - Patient MRN - Procedure - Source 8/5/2022 - 025616871 - Gram Stain Only - Pleural Fluid 2. Review of the laboratory policy titled "MI Gram Stain Procedure" did not include instructions for the processing of body fluids other than CSF. Surveyor queried if the laboratory routinely performed gram stains on body fluids other than CSF. Testing personnel (TP) 1 stated the laboratory did not. 3. In an interview on 7/13/2023 at 10:10 hours, in the laboratory, TP1 and technical consultant (TC) 2 confirmed that the processing of body fluids, other than CSF, was not included in the gram stain procedure. Key: CSF: Cerebrospinal fluid
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 review of Beckman ACL Elite coagulation analyzer manufacturer's instructions, reference interval study for PT (prothrombin time) and staff interview, the laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for one of one lot of PT reagent (RecombiPlasTin 2G) used in 2022 and 2023 with the ACL Elite analyzer. The findings included: 1. Review of the manufacturer's instructions found under Limitations: "PT results may be affected by many commonly administered drugs." 2.

	Review of the current MNPT (mean normal prothrombin time) found the laboratory used RecombiPlasTin 2G, Lot N0815334 Expiration 2023-08 with 20 patient specimens drawn by nursing staff in the emergency room. The laboratory did not use a questionnaire to gather information about patients to ensure patient specimens used in the study were from healthy individuals (equal number of male and female) spanning the age range of patients served by the laboratory who are good health and not currently taking medications that might affect results. 3. During interview of technical consultant 2 listed on the CMS Report 209 Laboratory Personnel Report conducted July 13, 2023 at 10:43 AM, she confirmed that the laboratory had no criteria established for patient specimens used in the establishment of the MNPT.
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: Based upon review of the Operator's Manual, Maintenance records and interview of facility personnel, the laboratory failed to perform and document monthly maintenance procedures following the manufacturer's specified frequency for the ACL Elite Coagulation analyzer(SN 111113204) for 9 of 15 months. The findings included: 1. Review of the ACL Elite Operator's Manual found on pages 5.21 and 5.22 under the heading Monthly Preventive Maintenance: "Checking and Cleaning the Air Filter In order to clean the analyzer air filter, it must first be removed from its location on the right side of the instrument. Insert a finger in the holder slot; pull up and slide the filter out(see figure below). Check the filter. If it is dirty or blocked, clean it with compressed air or try washing it in water and blowing it dry. If the filter appears damaged, it should be replaced. Do not place a wet filter back into the analyzer position. Insert the clean or new filter back in its holder." 2. Review of maintenance records for the 15 months between January 2022 and March 2023 found no documentation of monthly maintenance procedures for the following months: March 2022 April 2022 June 2022 July 2022 August 2022 September 2022 October 2022 November 2022 February 2023 3. During interview of testing person one on the CMS report 209 Laboratory Personnel report conducted July 13, 2023 at 9:53 AM, she confirmed that monthly maintenance procedures were not performed and documented on the monthly maintenance logs.
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 upon review of policies and procedures, quality control records and interview of facility personnel the technical consultant failed to document review of quality control records for Hematology as defined by their own written procedure for three of three months reviewed. The findings included: 1. Review of the policy KL CH 111 Quality Control (last approved 09/21/2021) found on page 5 under the heading Printing and Reviewing Control Results: "B. Weekly Review: Each Wednesday a designated technologist is to: Print the QC Exception Report for the 4.1s rule violations for T-7 days. Ensure that Levy-Jennings graphs for any analyte that fails the 4.1s rule is printed for T-30 for all data points. Review the L-J graphs, make appropriate comments on the graphs as to reason for the 4.1s rule violation (i.e., reagent lot number change, maintenance performed, etc.). Enter any recommended adjustments to the mean and SD ranges on the control spreadsheet and document reasons for changes on the graphs. Review the L-J graphs with the supervisor or designee. File the daily exception reports and the weekly exception reports and L-J graphs in the appropriate QC files. Ensure that review is complete by Wednesday of each week. C. Monthly Review: Around the first of each month a designated technologist is assigned to : Print the L-J graphs for all quantitative test procedures and review shifts, trends, and investigate outliers. Prepare the reports for filing by punching holes on the left side of all reports. Present the report to the supervisor or designee for review. All outliers are to be reviewed for corrective action documentation." 2. Review of Hematology quality control records for September 2022, December 2022 and February 2023 found no documentation of weekly and monthly quality control review as defined in their own procedure. 3. During interview of Technical consultant 2 on the CMS Report 209 Laboratory Personnel Report conducted July 12, 2023 at 3:17 PM she confirmed that the laboratory did not perform and document weekly and monthly review as defined in their own policy.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions for use, review of reagent logs, quality control records and interview of facility personnel, the laboratory failed to verify the performance of the Coulter 6C Cell control or establish their own laboratory mean for 11 of 11 lot numbers of Hematology quality controls used between January 2022 and April 2023. The findings included: 1. Review of the Coulter 6C Cell Control

	manufacturer's instructions for use found on page 3 under the heading ASSIGNED VALUES AND EXPECTED RESULTS: "Before your current cell control lot(s) expire, perform the following on your new lot(s): Confirm that recovered values are within the TABLE OF EXPECTED RESULTS. or establish your own laboratory mean." 2. Review of the reagent logs found the laboratory used the following 11 lots of 6C Cell Control between January 2022 and April 2023: lot 4216430K expiration date 03-12-22 in use 1-21-22 lot 4216590K expiration date 05-07-22 in use 3-7-22 lot 4216700K expiration date 06-18-22 in use 5-2-22 lot 4216820K expiration date 7-30-22 in use not documented lot 4216950K expiration date 7-30-22 in use not documented lot 4217080K expiration date 10-22-22 in use 9-7-22 lot 4217200K expiration date 12-10-22 in use 10-19-22 lot 4217330K expiration date 1/21/23 in use not documented lot 4217430K expiration date 02-24-23 in use not documented lot 4217580K expiration date 04/23/23 in use not documented lot 4217720K expiration date 06-10-23 in use 04-22-23 3. During interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted July 12, 2023 at 2:14 PM, she confirmed that the laboratory does not verify the 6C cell control is acceptable for use or establish a new laboratory mean for each new control lot before the expiration of the current lot.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control record, patient test records, and confirmed in interview, the laboratory failed to perform quality control (QC) for one of one patient tested in 2022 for CSF Cell count. The findings included: 1. Review of the laboratory policy titled "Manual Cell Count CSF", section "Quality Control" had the following instructions: "Procedure for running controls 1. Due to low volume of patient testing, both levels of control must be performed in duplicate every 8 hours of patient testing ..." 2. Review of patient testing records had the following one patient who had a CSF cell count performed in 2022: Test Date - Patient MRN 5 /18/2022 - 025952650 3. Review of 2022 QC records for CSF cell count did not include QC documentation for 5/18/2022. 4. In an interview on 7/13/2023 at 09:55 hours, in the laboratory, testing personnel (TP) 1 and technical consultant (TC) 2 confirmed that QC had not been performed on days where patient testing occurred for CSF cell counts in 2022.
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 a review of laboratory policy, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective action for 24 of 54 QC failures reviewed in January and May of 2022 for cholesterol and ammonia chemistry testing. The findings included: 1. Review of the laboratory policy titled "CH111 Quality Control", section III "Guidelines for Investigating OUT OF CONTROL Values when two levels of controls are being tested" stated the following: "A. 1.2s rule violation [Bullet point four] If the control falls within +/- 2SD, enter the result in the designated "REPEAT" area in the computer and document corrective action steps in the comment section. B. 1.3s rule violation [Bullet point 4.2] Enter corrective action in the "COMMENT" area in the computer (i.e., "Re-poured and re-tested the control.")" And then section IV "Printing and Reviewing Control Results": "A. Daily Review: A designated technologist is to: Print a QC summary report for all controls performed on the DXC, Access, Elite, and Clinitek Status to ensure that all QC runs are accounted for and have been posted to LIS. Print the Data Review Report daily Review the report for appropriate corrective action and comments. Ensure that any failure to document corrective action is corrected by the technologist performing the test on their next scheduled working day. Document review by dating and initialing the reports. File the reports in the appropriate QC folder." 3. Review of QC documentation for the chemistry analytes of cholesterol and ammonia for January and 2022 had the following 24 QC failures with no documentation of corrective actions: January 2022: Liquichek Ammonia Level 1, lot 54351 Expected 2SD Range : 43.00 - 55.00 1/05/2022 - 58.00 1/05/2022 - 63.00 1/20/2022 - 56.00 1/26/2022 - 58.00 1/26 /2022 - 59.0 1/28/2022 - 58.00 Liquichek, Cholesterol Level 1, lot 92901 Expected 2SD range: 115.5 - 121.5 1/04/2022 - 115.0 1/07/2022 - 115.0 1/12/2022 - 114.0 1/13 /2022 - 115.0 1/25/2022 - 115.0 1/25/2022 - 115.0 1/28/2022 - 115.0 Liquichek, Cholesterol Level 2, lot 92902 Expected 2SD range: 226.0 - 278.0 1/07/2022 - 258.0 1 /11/2022 - 263.0 1/11/2022 - 261.0 1/25/2022 - 262.0 1/26/2022 - 264.0 1/27/2022 - 265.0 May 2022 Liquichek, Cholesterol Level 1, lot 92901 Expected 2SD range: 115.5 - 121.5 5/2/2022 - 115.0 5/15/2022 - 113.0 5/21/2022 - 115.0 5/23/2022 - 113.0 Liquichek, Cholesterol Level 2, lot 92902 Expected 2SD range: 226.0 - 278.0 5/14 /2022 - 258.0 3. Review of laboratory-provided test volumes had the following patient test volumes for Cholesterol and Ammonia for 2022: Cholesterol: 1,066 Ammonia: 36 4. In an interview on 7/12/2023 at 14:45 hours, in the laboratory, technical consultant (TC) 2 confirmed that corrective action had not been documented for the above QC failures and that daily reviews had not been performed as specified by the laboratory policy.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory quality control (QC) records, and confirmed in an interview, the laboratory failed to follow its policy for the review and correction of QC issues for two of two chemistry analyzers, the Beckman Coulter DxC 600 and Beckman Coulter Access 2, for 2022. The findings included: 1. Review

	of the laboratory policy titled "CH111 Quality Control", section IV "Printing and Reviewing Control Results" had the following instructions: "IV. Printing and Reviewing Control Results: A. Daily Review: A designated technologist is to: Print a QC summary report for all controls performed on the DXC, Access, Elite, and Clinitek Status to ensure that all QC runs are accounted for and have been posted to LIS. Print the Data Review Report daily Review the report for appropriate corrective action and comments. Ensure that any failure to document corrective action is corrected by the technologist performing the test on their next scheduled working day. Document review by dating and initialing the reports. File the reports in the appropriate QC folder. B. Weekly Review: Each Wednesday a designated technologist is to: Print the QC Exception Report for the 4.1s rule violations for T-7 days. Ensure that Levy-Jennings graphs for any analyte that fails the 4.1s rule is printed for T-30 for all data points. Review the L-J graphs, make appropriate comments on the graphs as to reason for the 4.1s rule violation (i.e., reagent lot number change, maintenance performed, etc.). Enter any recommended adjustments to the mean and SD ranges on the control spreadsheet and document reasons for changes on the graphs. Review the L-J graphs with the supervisor or designee. File the daily exception reports and the weekly exception reports and L-J graphs in the appropriate QC files. Ensure that review is complete by Wednesday of each week." 2. Review of laboratory 2022 quality control records for the DxC600 and Access 2 chemistry analyzers did not include a daily and weekly QC review to identify failures and corrective action documentation. Surveyor queried testing personnel (TP) 1 and technical consultant (TC)2 for such documentation, and none was provided. 3. In an interview on 7/12/2023 at 15:45 hours, in the laboratory, TP1 and TC2 confirmed that the laboratory had not been following its policy for the daily and weekly review of QC for the Beckman Coulter DxC 600 and Beckman Coulter Access 2 chemistry analyzers in 2022.
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 a review of the laboratory's proficiency testing records, quality control records, facility procedures, patient record review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure that all testing personnel and technical consultants met the minimum education requirements for performing moderately complexity procedures. (See D 6035 and D 6065)
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

	This STANDARD is not met as evidenced by: Review of the CASPER report 155, proficiency testing records and interview of facility personnel found the laboratory director failed to ensure the proficiency testing results were submitted to the proficiency testing agency within the specified timeframe for one of five Hematology proficiency testing events between the 2021 3rd testing event and the 2023 first testing event (three events per year). (See D 2123)
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 upon review of manufacturer's instructions for use, review of reagent logs, quality control records and interview of facility personnel, the laboratory director failed to establish and maintain the quality control program for Hematology. (See D 5441 and D 5469)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that one of three technical consultants met the qualification requirements of 493.1411 since they were delegated technical consultant duties in 2021. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State

	in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that an evaluation of credentials to confirm the equivalency of a foreign education to an education obtained in the United States (U.S.) was performed for one of one technical consultant (TC) who had a degree from a foreign institution since they were delegated duties in 2021. The findings included: 1. Review of the CMS 209 personnel form included the following personnel with delegated technical consultant duties by the laboratory director in 2021: TC 1 2. Review of personnel documentation for TC1 did not include a U.S. equivalency for a degree awarded from a foreign institution. The surveyor queried if such documentation had been obtained on 7/11/2023 at 11:20 hours, and none were provided. 3. In an interview on 7/11/2023 at 13:45 hours, in the office, the Laboratory Administrative Director confirmed that a U.S. Foreign equivalency had not been conducted for TC1 to confirm the equivalency of their education to an education obtained in the U.S.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records and interview of facility personnel the technical consultant failed to document review of quality

	control records for Hematology as defined by their own written procedure for three of three months reviewed. (See D5441)
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of refrigerator quarterly alarm check records, blood bank temperature recording charts, observations and interview of facility personnel the technical consultant failed to ensure that testing personnel had been properly trained to perform temperature alarm checks for the refrigerator used to store blood products in three of five quarters between January 2022 and March 2023. The findings included: 1. Review of quarterly alarm checks performed in 2022 and 2023 found the laboratory performed quarterly alarm checks in January, April, July and October each year. 2. Review of the refrigerator temperature recording wheels found no change in temperature detected when temperature alarm checks were performed in July 2022, October 2022 and January 2023. 3. Observations made during the alarm check procedure demonstrated by testing person one on July 11, 2023 at 2:54 PM found that testing personnel used only the probe that would initiate the audible alarm in the procedure. 4. During interview of testing person one on the CMS Report 209 Laboratory Personnel report conducted July 11, 2023, she confirmed that she was trained to do the alarm check using only the audible alarm probe.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure two of eight testing personnel met the qualification requirement of 493.1423 reviewed on 7/11/2023. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have

	successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that an evaluation of credentials to confirm the equivalency of a foreign education to an education obtained in the United States (U.S.) was performed for two of eight testing personnel (TP) reviewed on 7/11/2023. The findings included: 1. Review of the CMS 209 personnel form included the following personnel performing moderate complexity testing with a degree from a foreign institution: TP4 TP5 2. Review of personnel documentation for TP4 and TP5 did not include a U.S equivalency for a degree awarded from a foreign institution. The surveyor queried if such documentation had been obtained on 7/11/2023 at 11:20 hours, and none were provided. 3. In an interview on 7/11/2023 at 13:45 hours, in the office, the Laboratory Administrative Director confirmed that a U.S. Foreign equivalency had not been conducted for TP4 and TP5 to confirm the equivalency of their education to an education obtained in the U.S.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 a review of the laboratory's proficiency testing records, quality control records, facility procedures, patient record review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure that all testing personnel met the minimum education requirements for performing high complexity procedures. (See D 6171)
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by:

	Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that testing personnel met the qualification requirements specified at 493.1489 for two of eight personnel performing high complexity testing, reviewed on 7/11/2023. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals

	qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a review of the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that an evaluation of credentials to confirm the equivalency of a foreign education to an education obtained in the United States (U.S.) was performed for two of eight testing personnel (TP) performing high complexity testing in immunohematology, hematology, and bacteriology, reviewed on 7/11/2023. The findings included: 1. Review of the CMS 209 personnel form included the following personnel performing high complexity testing in immunohematology and hematology, testing with a degree from a foreign institution: TP4 TP5 2. Review of personnel documentation for TP4 and TP5 did not include a U.S equivalency for a degree awarded from a foreign institution. The surveyor queried if such documentation had been obtained on 7/11/2023 at 11:20 hours, and none were provided. 3. In an interview on 7/11/2023 at 13:45 hours, in the office, the Laboratory Administrative Director confirmed that a U.S. Foreign equivalency had not been conducted for TP4 and TP5 to confirm the equivalency of their education to an education obtained in the U.S.