Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220805	04/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Meritus Medical Laboratory, Llc	11110 Medical Campus Rd Suite 230, Hagerstown, MD	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of blood gas proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that each testing person who performed the test signed the attestation worksheet showing that PT samples were tested in the same manner as the patients. Findings: 1. The blood gas PT records from 2023 and 2024 were reviewed. The attestation worksheet for PT event SEM-A 2023 listed two testing personnel. The worksheet only had one of the two signatures required. 2. During the exit interview on 04/08/2025 at 11:45 AM, the TC confirmed that the signature of the second testing person was not on the attestation worksheet.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

	This STANDARD is not met as evidenced by: I. Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure the accuracy of the records maintained. Findings: 1. The blood gas PT records from 2023 through 2024 were reviewed. 2. The records from the SO-C 2024 PT event showed that the name of testing person (TP)#1 was typed on the attestation worksheet with no signature. TP#2 is listed as the operator on the blood gas analyzer instrument printout. The TC stated that the ID# from the previous TP#1 had not been updated prior to TP#2 testing the PT samples. 3. During the survey on 04/07/2025 at 1:00 PM, the TC confirmed that the incorrect ID# of the TP was listed on the attestation worksheet and the blood gas analyzer instrument printout. II. Based on review of the PT records and interview with the TC, the laboratory failed to maintain a copy of all instrument printouts showing the results obtained during each PT event. Findings: 1. The hematology, coagulation, and urinalysis PT records from 2023 through 2024 were reviewed. 2. The following events were missing the instrument printouts showing the original test results: SEM-A 2023; RT4-A 2023; SCM-A 2023, CRS-A 2023, and SCS-A. 3. During the survey on 04/08/2025 at 11:45 AM, the TC confirmed that the original instrument printouts with the results of the PT samples had not been included with the PT records for 2023.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the chemistry department supervisor, the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. The laboratory performs chemistry testing on a Beckman UniCel DxI 800 Access Immunoassay System (DxI). The instrument calculates the due date of the next calibration for each analyte on the instrument. Calibration records are printed and stored in a binder. 2. A review of calibration records for the "DxI #2" from January through April 2025 showed that the analytes digoxin (Dig), ferritin, free triiodothyronine (FT3), and human chorionic gonadotropin (hCG5) must be calibrated every 28 days. 3. Record review showed that the calibration performed on 01/01/2025 for Dig expired on 01/29/2025. The next record available showed that Dig was calibrated on 02/16/2025. There was no record that Dig had been calibrated between the expiration date of the previous calibration (01/29/2025) and 02/16/2025; 4. Record review showed that the calibration performed on 01/29/2025 for ferritin expired on 02 /26/2025. The next record available showed that ferritin was calibrated on 03/23/2025. There was no record that ferritin had been calibrated between the expiration date of the previous calibration (02/26/2025) and 03/23/2025; 5. Record review showed that the calibration performed on 02/16/2025 for FT3 expired on 03/16/2025. The next record available showed that FT3 was calibrated on 04/02/2025. There was no record that FT3 had been calibrated between the expiration date of the previous calibration (03/16/2025) and 04/02/2025; and 6. Record review showed that the calibration performed on 01/31/2025 for HCG5 expired on 02/28/2025. The next record available showed that HGC5 was calibrated on 03/09/2025. There was no record that HCG5 had been calibrated between the expiration date of the previous calibration (02/28 /2025) and 03/09/2025. 7. During an interview on 04/10/2025 at 11:45 AM, the

	chemistry department supervisor stated that they had searched the calibration records onboard the "DxI #2" instrument, however the instrument had not maintained the missing calibration records. They confirmed that the laboratory failed to maintain all analytic systems records for at least 2 years.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on review of proficiency testing (PT) records and interview with the quality assurance supervisor (QAS), PT results evaluations were missing, not reviewed, or not investigated for seven of 97 microbiology and immunology PT events reviewed. Findings: 1. The laboratory was enrolled in PT with Wisconsin State Laboratory of Hygiene (WSLH) and the College of American Pathologists (CAP). 2. The results evaluations were missing for four of 12 WSLH PT events reviewed (2023 Immunology3, 2024 Immunology1, 2024 Bacti_Viral1, and 2024 Bacti-Viral3) and two of 85 CAP PT events reviewed (2024 LN39-A and VR3-A). 3. The results evaluation from the CAP VR3-B event were not signed as reviewed by the laboratory director or designee. 4. The results evaluation for the CAP 2024 COV2Q-B event showed that one of three samples had an incorrect result (67%). There was no documentation of an investigation into the root cause of the incorrect result. 5. During the survey on 04/10/2025 at 1:00 PM, the QAS confirmed that some of the PT evaluations were missing or not signed as reviewed and that there was no documentation of an investigation into the root cause of the incorrect result from the 2024 COV2Q-B PT event. II. Based on record review and interview, the blood bank corrective action report for proficiency testing event 1 (J-A 2023), antibody identification was incomplete. Findings: 1. The corrective action report for the antibody identification proficiency testing failure for antibody identification did not include steps taken to ensure that any needed corrective actions were taken so that the problem does not reoccur. This was confirmed with staff during interview on April 7, 2025 at 1:00 pm.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: I. Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory PT investigation of failures did not include a review of the patients tested around the time of the failure to ensure that no patient test results were affected by the failure. Findings: 1. The hematology, coagulation, and urinalysis PT records from 2023 through 2024 were reviewed. 2. The following events had failures in PT results: a. CGL-A 2023- prothrombin time 60%; b. CGL-B 2023-

	fibrinogen 80%; c. CGL-C 2023- activated partial thromboplastin time 80%; d. CGS1-A 2023- activated partial thromboplastin time 67% and International Normalized Ratio 50%; e. CM-A 2023- urine sediment identification 67%. 3. During the survey on 04/08/2025 at 11:45 AM, the TC confirmed that the investigation of the PT failures did not include a review of the patients tested around the time of the failure to ensure that no patient test results were affected by the failure. 43123 II. Based on review of the proficiency testing (PT) procedure, review of PT records, and interview with the microbiology supervisor, the laboratory failed to self-evaluate ungraded microbiology and immunology PT results. Findings: 1. The laboratory was enrolled in PT with Wisconsin State Laboratory of Hygiene (WSLH) and the College of American Pathologists (CAP). 2. The "Proficiency Testing" procedure (POL ASMT-001) stated "G. Any challenges that are ungraded by the vendor must be assessed by finding the most appropriate consensus result from the survey critique and writing this in on the evaluation form. The extent to which we have agreed with the consensus shall be addressed in the summary, and any significant lack of agreement treated as if it were a failure." 3. The CAP's guidance for code [26] educational challenge stated to "Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 4. The CAP's guidance for code [27] lack of participant or referee consensus stated to "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." 5. The PT results evaluations contained the following codes: a. Samples HSV-7, HSV-9, and HSV-10 from the WSLH 2023 Bacti_Viral2 PT event were graded with the statement "Not scored - see Event Notes." b. Sample D-08 from the CAP 2024 D-B PT event was graded with code [26]. c. Sample P-15 from the CAP 2024 P-C PT event was graded with code [26]. d. Sample P-16 from the CAP 2024 P-C PT event was graded with code [27]. 6. There was no documentation that the laboratory performed a self-evaluation of the above ungraded PT results. 7. During the survey on 04/10/2025 at 11: 00 AM, the microbiology supervisor confirmed that ungraded PT results were not consistently self-evaluated for accuracy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of immunology proficiency testing (PT) records and interview with the quality assurance supervisor (QAS), two immunology targets were not included in the PT modules ordered from the College of American Pathologists (CAP) and were not verified for accuracy at least twice annually. Findings. 1. The laboratory was enrolled in PT with the CAP. 2. The laboratory tested for anti-histone and anti-JO-1. 3. These two targets were not included in the laboratory's CAP PT modules and their accuracy was not verified at least twice annually. 4. During the survey on 04/10/2025 at 1:30 PM, the QAS confirmed that anti-histone and anti-JO-1 were not included in the CAP PT modules ordered by the laboratory.

D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the blood bank laboratory did not have a system in place to monitor corrective actions that were reported as being taken by the clinical staff (in response to problems identified and reported by the laboratory to the clinical staff) and that the corrective action was taken, and included a resolution to the problem(s), any additional actions to ensure no recurrence, if indicated, and how the correction(s) will be monitored to ensure effectiveness. Two of eight reports concerning transfusions were reviewed and found to be incomplete, in that the clinical staff did not take corrective actions. Findings: 1. On December 10, 2024 a report was sent by the blood bank to the clinical staff to document the ending time for a transfusion to a patient. The transfusion record was reviewed during the survey on April 9, 2025 and the ending time for the transfusion was still not documented. This was confirmed with laboratory staff on April 9, 2025 during the review at 12:00 pm. 2. On February 27, 2025 a report was sent by the blood bank to the clinical staff to follow up on a transfusion that was six hours long (procedures state that a transfusion should be completed by four hours). The task was assigned to investigate the length of time reported for the transfusion. The transfusion record was reviewed during the survey on April 9, 2025 and the cause of the prolonged transfusion and resolution was not documented. This was confirmed with laboratory staff on April 9, 2025 during the review at 12:00 pm.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual and the "AU5800 #2 Lot to Lot Reports" binder and interview with the chemistry department supervisor, the laboratory failed to follow written procedures for performing lot to lot reagent verifications when new lot numbers of chemistry reagents were received. Findings: 1. The procedure, "Chemistry Lot to Lot Verification" provides instructions for how to verify new lot numbers (#) of chemistry reagents before using them for testing. Testing personnel (TP) are instructed to choose two patient specimens as well as two levels of quality control (QC) which were previously run with the current lot # of reagent, and test them using the new lot # of reagent to be verified. 2. The procedure states that TP are to fill out the "Lot to Lot Chemistry" form to record the "current" and "new" lot numbers of the reagent, the expiration date of each, and the results of both QC ("QC low" and "QC High"), a "Normal" and "Abnormal" patient, the "Allowable Diff."

	(difference), "Lower limit accept" (acceptability), "Upper limit accept," and whether the evaluation was acceptable ("Acceptable Y/N"). The procedure also states that "If results are within 10%, the new lot is okay to put into use." 3. A review of "Lot to Lot Chemistry" forms from May 2023 through February 2025 showed that on 06/18/2023 the "current" lot # of glucose reagent (lot # 2687, expiration date 09/01/2024) was compared with the "new" lot # (lot # 2688, expiration date 10/01/2024). The results for the glucose test run on the two levels of QC and the "Allowable Diff." for each were entered on the form, however the lab did not calculate the lower and upper limit of acceptability or document whether the verification was "acceptable." 4. The results for the "Normal" patient's glucose test run on the "current" lot # was "89.000" and was "87.000" when run on the "new" lot # of reagent. The "Allowable Diff." entered on the form was "17.600," which is approximately 20% of the result obtained with the current lot #, not 10%; and 5. The results for the "Abnormal" patient's glucose test run on the "current" lot # was "192.000" and was "188.000" when run on the "new" lot # of reagent. The "Allowable Diff." entered on the form was "47.500," which is approximately 25% of the result obtained with the current lot #, not 10%. 6. The lower and upper limits of acceptability entered on the form were calculated using the stated "Allowable Diff." which meant that the calculated acceptable range did not match the criteria in the laboratory's procedure. The results on the form were documented as "Acceptable." 7. The next available "Lot to Lot Chemistry" form was from 11/27 /2023 for the comparison between the "current" lot # of glucose reagent (lot # 2695, expiration date 03/01/2025) and the "new" lot # (lot # 2698, expiration date 06/01 /2025). There was no "Lot to Lot Chemistry" worksheet, showing that a comparison had been performed between lot # 2688 and the next "new" lot #, or documentation that any lot to lot verifications had been performed since 06/18/2023 for the glucose reagent. 8. During an interview on 04/10/2025 at 2:30 PM, the chemistry department supervisor confirmed that the laboratory failed to follow the written procedure for performing lot to lot verifications on new lot # of chemistry reagents.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

Based on review of the "Media Quality Control" procedure manual, the "Quality Control - Plated Media" worksheets for January 2024, and interview with the technical supervisor (TS), the laboratory's procedure manual and worksheets failed to have the same incubation times for the media being quality controlled. Findings: 1. The "Media Quality Control" procedure for Campylobacter agar states, "Divide a plate into thirds and inoculate with Campylobacter jejuni, to show the media's to isolate and support growth of this pathogen, and Proteus mirabilis and Staphylococcus aureus to show the media's ability to inhibit the growth of mixed flora which may be present in the specimen. Also incubate an uninoculated plate at 42 [degrees] C [Celsius] for 48 hours in a Campy bag." 2. The "Quality Control - Plated Media" worksheet for Campylobacter agar states, "1. Divide one plate in thirds, inoculate with the following and incubate for 24 hours at 42C:" and "2. Incubate one uninoculated plate at 42C for 48 hours days and examine for microbial contamination." 3. The worksheet shows that two different lot numbers of Campylobacter agar were received on 1/17/24. The observations were recorded for the three organisms plated and the sterility check. The completion date is listed as 1/21/24 along with the initials of the "Tech." The worksheet does not show that the three QC organisms were evaluated at 24 hours per the instructions listed on the worksheet and who performed the evaluation. The worksheet shows that all the evaluations were performed and documented 96 hours after the initial inoculation of the agar plates instead of 48 hours. The "Media Quality Control" procedure for Campylobacter agar does not state that the QC organisms are evaluated at 24 hours. 4. The "Media Quality Control" procedure for Lowenstein-Jensen slants states, "Inoculate one slant with Mycobacterium fortuitum ATCC 6841, and another E. coli 25922. Also incubate one uninoculated slant at 35C for 5 days to show sterility." 5. The "Quality Control - Plated Media" worksheet for Lowenstein-Jensen Medium slants states, "1. Prepare a 0.5 McFarland Standard using the appropriate organism in the chart below and inoculate the tube using a 1/1000 inoculation loop." The Escherichia coli 25922 is incubated for 48 hours, the Mycobacterium fortuitum ATCC 6841 and Uninoculated /Sterile tube are incubated for 7 days. 6. The worksheet shows that the slants were received on 12/28/23 and the completion date is listed as 1/9/24 along with the initials of the "Tech." The worksheet shows that all the evaluations were performed and documented 12 days after the initial inoculation of the slants instead of at 48 hours for the Escherichia coli 25922 and 7 days for the Mycobacterium fortuitum ATCC 6841 and Uninoculated/Sterile tube. The "Media Quality Control" procedure for Lowenstein-Jensen slants does not state that the Escherichia coli 25922 QC organism is evaluated at 48 hours and the Mycobacterium fortuitum ATCC 6841 and Uninoculated/Sterile tubes are evaluated at 7 days. The "Media Quality Control" procedure for Lowenstein-Jensen slants does not mention preparation of a 0.5 McFarland standard for inoculation of the QC slants. 7. The "Media Quality Control" procedure for MacConkey II Agar with Sorbitol states, "Divide a plate in half and inoculate one side with E. coli 0157 35150 and the other side with E. coli 5922 and incubate overnight to show the media's ability to differentiate between sorbitol and non-sorbitol fermenting strains of E. coli. Also incubate an uninoculated plate at 35C for 72 hours to show sterility." 8. The "Quality Control - Plated Media" worksheet for MacConkey II Agar with Sorbitol states, "1. Divide one plate in half, inoculate with the following, and incubate for 24 hours at 35C:" and "2. Incubate one uninoculated plate at 35C for 72 hours and examine for microbial contamination." 9. The worksheet shows that the agar was received on 1/17/24 and the completion date is listed as 1/22 /24 along with the initials of the "Tech." The worksheet shows that all the evaluations were performed and documented 5 days after the initial inoculation of the agar instead of at 48 hours for the Escherichia coli 0157 35150 and Escherichia coli 25922 and 72 hours for the sterility. 10. During the survey on 04/10/25 at 12:45 PM, the TS

	confirmed that the "Media Quality Control" procedures and the "Quality Control - Plated Media" worksheet instructions did not match. The dates received and the completion dates listed on the worksheets did not reflect the incubation times listed in the procedure and the worksheets.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 on review of the procedure, review of maintenance forms, and interview with the lead histotech and pathology supervisor, the laboratory failed to document maintenance tasks for the immunohistochemistry (IHC) and special stainers with at least the manufacturer's recommended frequency. Findings: 1. The "Maintenance of the Ventana/Roche Benchmark ultra Automated Immunohistochemistry and Special Stainer" procedure stated that: a. "Monthly and quarterly recommended maintenance is performed by laboratory staff." b. "Daily and monthly maintenance performed is documented on the monthly charts." c. Documentation of "The quarterly temperature checks" should be printed and filed "in the maintenance binder in the corresponding tab." d. "A maintenance binder is located in an upper cabinet in the IHC/Staining Room. Locate the corresponding tab, find the appropriate form, and fill in the date with your initials after you have completed the task." 2. The monthly maintenance forms for the IHC stainers contained four monthly tasks and four quarterly tasks and for the special stainer contained five monthly tasks and seven quarterly tasks. 3. At 12: 15 PM on 04/08/2025 the lead histotech confirmed that all monthly and quarterly maintenance tasks should be performed at the designated frequency and should be documented on the maintenance logs. 4. Maintenance logs for the IHC stainer "Stewart" were reviewed for five months (10/2024-02/2025): a. Monthly maintenance was not documented in one of five months (10/2024). b. One or more monthly maintenance tasks were not completed in 11/2024. c. Quarterly maintenance was not documented. 5. Maintenance logs for the IHC stainer "Bernadette" were reviewed for nine months (06/2024-02/2025): a. Monthly maintenance was not documented in four of nine months (10/2024, 09/2024, 07/2024, and 06/2024). b. One or more monthly maintenance tasks were not completed in 11/2024 and 08/2024. c. Quarterly maintenance was documented as performed once in nine months. i. 11/11/2024: three of four tasks were completed 6. Maintenance logs for the IHC stainer "Leonard" were reviewed for 24 months (03/2023-02/2025): a. Monthly maintenance was not documented in six of 24 months (10/2024, 09/2024, 07/2024, 06/2024, 02/2024, and 09/2023). b. One or more monthly maintenance tasks were not completed in 11/2024, 08/2024, 04/2024, 03/2024, 12/2023, 08/2023, 07/2023, and 05/2023. c. A printout of 2023 quarterly maintenance activities showed that maintenance for the 3rd quarter was not performed. d. Quarterly maintenance for 2024 was documented as performed two times: i. 01/20/2025: two of four tasks were completed ii. 06/03/2024: three of four tasks were completed 7. Maintenance logs for the IHC stainer "Raj" were reviewed for 15 months (03/2023-05/2024): a. Monthly maintenance was not documented for 3 of 15 months (02/2024, 09/2023, and 08/2023). b. One or more monthly maintenance tasks were not completed in 05/2024, 04/2024, 03/2024, 12 /2023, 07/2023, and 05/2023. c. Quarterly maintenance was documented as performed three times in 15 months: i. 11/05/2023: all tasks were completed ii. 05/20/2023: two of four tasks were completed iii. 03/23/2023: three of four tasks were completed 8.

	Maintenance logs for the special stainer "Sheldon" were reviewed for 24 months (03 /2023-02/2025): a. Monthly maintenance was not documented for 14 of 24 months (02 /2025, 11/2024, 09/2024, 08/2024, 07/2024, 06/2024, 05/2024, 04/2024, 03/2024, 02 /2024, 12/2023, 09/2023, 07/2023, and 06/2023). b. One or more monthly maintenance tasks were not completed in 10/2024. c. Quarterly maintenance was documented as performed five times in 24 months. i. 10/30/2024: five of seven tasks were completed ii. 01/18/2024: one of seven tasks were completed iii. 08/24/2023: five of seven tasks were completed iv. 04/06/2023: one of seven tasks were completed v. 03/22/2023: five of seven tasks were completed 9. Printouts for the quarterly maintenance tasks were only available for 2023 for the IHC stainer "Leonard." The quarterly temperature checks were not printed and filed in the maintenance binder as stated in the procedure. 10. The maintenance logs were reviewed (initialed and dated) monthly by the pathology supervisor. 11. During the survey on 04/08/2025 at 12:30 PM, the pathology supervisor confirmed that monthly and quarterly maintenance was not documented as performed with the frequency recommended by the manufacturer. The pathology supervisor stated that they would speak with the testing personnel if maintenance activities were not documented and confirmed that the conversations were not documented.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: I. Based on review of the hematology proficiency testing (PT) records for comparison of analyzers and interview with the technical consultant (TC), the laboratory failed to perform a comparison of test results between the hematology analyzers used in the core laboratory and the stat laboratory to ensure the accuracy and reliability of the test results of the analyzers. Findings: 1. The laboratory had three identical Sysmex analyzers in 2023. The PT records for 2023 showed that there had been no comparison of test results between the three analyzers. The TC confirmed that in 2023 the laboratory had no policies and procedures for comparing the three hematology analyzers that evaluated and defined the relationship between the three analyzers twice a year. 2. In 2024 the laboratory had four Sysmex analyzers. The PT records from the first event showed that three of the four analyzers performed the comparison PT. The PT records for the second event showed that two of the three analyzers performed the comparison along with the analyzer that had not participated in the first event. Therefore, two of the two analyzers had a comparison evaluation performed in 2024 and the other two analyzers only had a comparison evaluation performed once in 2024. 3. During the survey on 04/10/2025 at 2:30 PM, the TC confirmed that all four Sysmex analyzers had not been evaluated using the PT comparison materials in 2024. 38127 II. Based on record review and interview with the chemistry department supervisor, the laboratory failed to accurately evaluate and define the relationship between test results using the laboratory's different chemistry analyzers. Findings: 1. The laboratory subscribes to its proficiency testing (PT) provider for three samples, twice a year in order to monitor instrument performance and assess comparability across multiple instruments in the laboratory and to identify potential issues before they affect patient results. The PT provider evaluates and compares the submitted

	results, and issues the laboratory a report, "General Chemistry and Therapeutic Drug Monitoring Quality Cross Check" (Cross Check) which shows if the results of the three samples were within acceptable "peer group" limits, and reports the "Instrument Comparisons" between the analyzers as a calculation, "Absolute Difference (%)." 2. Review of one of two Cross Check events in 2024 (CZQ-B 2024) showed that the laboratory ran three samples (CZQ-04,CZQ-05, and CZQ-06) and submitted the results to the PT provider for evaluation. The "Original Evaluation Date" on the report was 10/02/2024. 3. The test analyte "Ammonia" was run on two identical "Beckman AU/DXC" analyzers ("Instrument #2 and #3"). The results reported by the laboratory for Cross Check specimen CZQ-05 for two of two analyzers was 600 umol/L and were evaluated to be "outside limit" in the peer group (acceptable "limit" for CZQ-05: 841-1362 umol/L) and the results reported by the laboratory for Cross Check specimen CZQ-06 for two of two analyzers was 600 umol/L and were evaluated to be "outside limit" in the peer group (acceptable "limit" for CZQ-06: 691-1168 umol/L). The comment, "OK. Mean greater than linearity of 600" was hand-written on the report. 4. During an interview on 04/10/2025 at 11:45 AM, the chemistry department supervisor stated that the ammonia results for CZQ-05 and CZQ-06 should have been reported as ">600 umol/L." Record review showed that there was no corrective action performed for the failed Cross Check evaluation. 5. The test analyte "Bilirubin, direct" was run on three identical "Beckman AU/DXC" analyzers ("Instrument #1, #2, and #3"). The result reported by the laboratory for Cross Check specimen CZQ-04 on "Instrument #1" was 3.9 mg/dL and was evaluated to be "outside limit" in the peer group for one of three analyzers (acceptable "limit": 0.8-1.6 mg/dL). There was no corrective action performed for the failed Cross Check evaluation. 6. The test analyte "Lactate" was run on two identical "Beckman AU/DXC" analyzers ("Instrument #2 and #3"). The result reported by the laboratory for Cross Check specimen CZQ-06 on "Instrument #2" was 6.4 mmol/L and was evaluated to be "outside limit" in the peer group for one of two analyzers (acceptable "limit": 6.5-7.7 mmol/L). There was no corrective action performed for the failed Cross Check evaluation. 7. The "Absolute Difference" between the analyzers ranged between 0.0% to 105.9% for the analytes mentioned above. A note below the Instrument Comparisons on each page of the report stated, "Consult your laboratory director/designee to evaluate the acceptability of instrument comparisons." There was no procedure available for performing the biannual Cross Check, listing what the acceptable "Absolute Difference" was for each analyte. 8. During an interview on 04/10/2025 at 11:45 AM, the chemistry department supervisor confirmed that the laboratory failed to accurately assess comparability when running the same analyte on multiple identical chemistry analyzers.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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, the laboratory director did not ensure that blood bank quality assurance reviews were conducted in a timely manner. Findings: 1. The blood bank laboratory performs monthly quality assurance reviews as an ongoing check of pre and post activities for transfusion medicine. Each month the blood bank reviews a sampling of patient records to ensure patient positive identification and accurate administration of blood and blood components and provides a mechanism to

	correct any problems identified through this review. The following audits for the months of March 2024 to June 2024 were all performed late and occurred on August 5, 2024: a) The June 2024 Final Disposition- Component Trace Audit and Typenex Band Audit. b) The May 2024 Final Disposition- Component Trace Audit and Typenex Band Audit and Issue and Administration Audit. c) The April 2024 Final Disposition- Component Trace Audit and Typenex Band Audit and Specimen Collection Audit. d) The March 2024 Final Disposition- Component Trace Audit and Typenex Band Audit and Specimen Collection Audit. 2. The delay of the monthly reviews was confirmed during interview with laboratory staff member #1 on April 10 at 11:00 am.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: I. Based on review of the "Media Quality Control" procedure manual, the "Quality Control - Plated Media" worksheets for January 2024 and interview with the technical supervisor (TS), the TS failed to ensure that the testing personnel followed the written procedures for performing and documenting media quality control. Cross-refer to D5403 for details. 43123 II. Based on review of the "Maintenance of the Ventana /Roche Benchmark ultra Automated Immunohistochemistry [IHC] and Special Stainer" procedure, review of the IHC and special stainer maintenance logs, and interview with the pathology supervisor, the supervisor failed to ensure that testing personnel performed maintenance on the IHC and special stainers with at least the frequency recommended by the manufacturer. Cross-refer to D5429 for details.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: I. Based on review of the "Media Quality Control" procedure manual, the "Quality Control - Plated Media" worksheets for January 2024, and interview with the technical supervisor (TS), the testing personnel (TP) failed to follow written procedures for performing and documenting media quality control. Cross-refer to D5403 for details. 43123 II. Based on review of the "Maintenance of the Ventana /Roche Benchmark ultra Automated Immunohistochemistry [IHC] and Special Stainer" procedure, review of the IHC and special stainer maintenance logs, and interview with the pathology supervisor, the testing personnel failed to perform maintenance on the IHC and special stainers with at least the frequency recommended by the manufacturer. Cross-refer to D5429 for details.