

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0054055	(X3) Date Survey Completed 01/08/2025
Name of Provider or Supplier Memorial Medical Center	Street Address, City, State 815 Virginia N Street, Port Lavaca, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's records and staff interview, the laboratory failed to have documentation of performing two of two accuracy assessments in 2024 for one non-regulated analyte, C-reactive protein (CRP). Findings include: 1. A review of the laboratory's records revealed the laboratory performed CRP testing on the Beckman Coulter DxC AU 700 chemistry analyzers. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing two accuracy assessments for the non-regulated analyte CRP in 2024. 3. In an interview on 1/8/25 at 8:40 a.m. in the office, after review of the records, the general supervisor confirmed the above findings.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:</p>

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of the 'Preventive Maintenance and Quality Control Checklist for Centra-W Cell Washer' records from 2024, the laboratory's records, and staff interview, the laboratory failed to ensure the quarterly checks of the Centra-W cell washer's motor speed fell within the acceptable range for two of four times quarterly maintenance was performed in 2024. Findings include: 1. A review of the 'Preventive Maintenance and Quality Control Checklist for Centra-W Cell Washer' records revealed the Centra-W cell washer (serial number: 23923389) required a quarterly check of the motor speed with an acceptable range of 3400 - 3600. 2. Further review of the 'Preventive Maintenance and Quality Control Checklist for Centra-W Cell Washer' records revealed the laboratory performed the quarterly checks on the following dates and the readings were outside of the acceptable range: Date: 10/3/24 Actual reading: 2720 Date: 12/12/24 Actual reading: 2590 3. A review of the laboratory's records revealed the laboratory estimated performing 3,506 immunohematology tests annually. 4. In an interview on 1/8/25 at 10:55 a.m. in the laboratory, after review of the records, the general supervisor confirmed the above findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(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 the laboratory's calibration verification records from 2023 and 2024, and staff interview, the laboratory failed to have documentation of performing

calibration verification every six months. The findings included: 1. A review of the laboratory's calibration records from 2023 and 2024 identified studies were preformed at the following times: a) GC1 analytes: Potassium, Chloride, Sodium, Calcium, Glucose, Albumin, Creatinine, Blood Urea Nitrogen, Total Protein, Magnesium, Phosphorus, Cholesterol, Triglycerides, Lactate Perform: 06/2023 and 12/2024 Elapsed time: 18 months b) GC4 analytes: Direct Bilirubin, Total Bilirubin Performed: 08/2023 and 08/2024 Elapsed time: 12 months 2. General supervisor number 1 confirmed the finding in an interview on 01/07/2024 at 1445 hours in the Inpatient Surgery waiting room.

D5559

IMMUNOHEMATOLOGY

CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the facility's policies, the laboratory's policies, patient transfusion records, and staff interview, the laboratory failed to have documentation of reviewing and investigating suspected transfusion reactions (per the facility's defined criteria) for six of twenty patient's transfusions reviewed from July 2023 to December 2024. Findings include: 1. A review of the facility's policy titled 'Blood Product Transfusion' revealed the following: "Review possible transfusion reaction symptoms: - Blood pressure changes either hypertension or hypotension: - Hypotension: defined as drop in systolic blood pressure of greater than or equal to 30 mmHg - Hypertension: defined as systolic or diastolic increase by at least 30 mmHg during the transfusion. When a transfusion reaction is suspected the nurse must: - Stop the transfusion - Keep the IV open with 0.9 percent normal saline - Report the reaction to both the laboratory and attending physician immediately." 2. A review of the laboratory's policy titled 'Investigation of Possible Transfusion Reactions' revealed the following: "Irrespective of the reason, all transfusion reactions should be investigated to attempt to determine the cause. This requires a re-check of every aspect of the transfusion including clerical records as well as the serological procedures." 3. A review of patient transfusion records from July 2023 to December 2024 identified the following six transfusions where the patients' vital signs met the criteria for a suspected transfusion reaction, however the transfusions were not stopped and the transfusion reactions were not reviewed and investigated by the laboratory: a) Patient ID: 1571158 Transfusion date: 7/25/23 Blood pressure at 15 minutes: 110/55 Blood pressure at 30 minutes: 149/65 (increase in systolic blood pressure of 39 mmHg) Blood pressure at 60 minutes: 145/67 Blood pressure at 90 minutes: 87/59 (decrease in systolic blood pressure of 58 mmHg) b) Patient ID: 1571616 Transfusion date: 7/27/23 Blood pressure at 15 minutes: 94/55 Blood pressure at 45 minutes: 131/69 (increase in systolic blood pressure of 37 mmHg) c) Patient ID: 1591327 Transfusion date: 1/25/24 Baseline blood pressure: 117/58 Blood

pressure at 2 hours: 152/75 (increase in systolic blood pressure of 35 mmHg) d) Patient ID: 1594083 Transfusion date: 2/20/24 Baseline blood pressure: 110/58 Blood pressure at 3 hours: 149/52 (increase in systolic blood pressure of 39 mmHg) e) Patient ID: 1605749 Transfusion date: 6/5/24 Blood pressure at 60 minutes: 182/52 Blood pressure at 90 minutes: 109/71 (decrease in systolic blood pressure of 73 mmHg) f) Patient ID: 1627914 Transfusion date: 12.27/24 Baseline blood pressure: 136/70 Blood pressure at 90 minutes: 167/52 (increase in systolic blood pressure of 31 mmHg) 4. In an interview on 1/8/25 at 10:55 a.m. in the laboratory, after review of the records, the general supervisor confirmed the above findings.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, the laboratory's competency assessment documents, and staff interview, the technical supervisor failed to document the assessment of problem-solving skills for two of eleven testing personnel performing high complexity testing in 2024. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 11 testing personnel performing high complexity testing in the specialty of Immunohematology in 2024. 2. A review of the laboratory's Competency Assessment documents revealed that the technical supervisor failed to document the assessment of problem-solving skills for the following testing personnel: - Testing person #10 competency assessment performed April 2024 - Testing person #11 competency assessment performed October 2024 3. In an interview on 1/7/25 at 11:00 a.m. in the inpatient surgery waiting room, after review of the records, the general supervisor confirmed the above findings.