

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0441857	<b>(X3) Date Survey Completed</b>  10/29/2025
<b>Name of Provider or Supplier</b>  Washington County Memorial Hospital	<b>Street Address, City, State</b>  300 Health Way, Potosi, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory and nursing procedures, review of the Sysmex XN-1000, the Beckman Coulter Access 2, and the Beckman Coulter DxC 700 AU operator's guides, review of humidity records, observation of laboratory supplies and chemistry analyzers, review of calibration records for the Beckman Coulter DxC 700 AU and Beckman Coulter Access 2 chemistry analyzers, review of quality control (QC) records for gram stains, the Beckman Coulter DxC 700 AU and Beckman Coulter Access 2 chemistry analyzers, review of instrument comparisons and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure the current laboratory director approved, signed and dated laboratory procedures before use (Refer to D5407); the laboratory failed to ensure the humidity was maintained as required by the manufacturer (Refer to D5413); the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range (Refer to D5439); the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results (Refer to D5469); the laboratory failed to document positive and negative reactivity each week of use for gram stains (Refer to D5503); the laboratory failed to</p>

ensure that the laboratory and nursing transfusion reaction procedures were adequate to ensure the safety of individuals being transfused (Refer to D5559); and the laboratory failed to evaluate, define and document the relationship between test results using different instruments two times a year (Refer to D5775).

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedures and interview with the general supervisor (GS) #1, the laboratory failed to ensure the current laboratory director approved, signed and dated laboratory procedures before use. Findings: 1. Review of all laboratory procedures showed no approval by the current laboratory director who started on June 1, 2025. 2. Interview with the general supervisor (GS) #1 on October 28, 2025, at 12:30 PM confirmed the laboratory failed to ensure the current laboratory director approved, signed and dated laboratory procedures before use.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on review of the Sysmex XN-1000 operator's guide, review of the main laboratory humidity records, review of the Beckman Coulter Access 2 operator's guide, review of the Beckman Coulter DxC 700 AU operator's guide, review of the laboratory chemistry room humidity records and interview with the general supervisor #1, the laboratory failed to ensure the humidity was maintained as required by the manufacturer in the main laboratory for 117 of 181 days and in the chemistry room for 73 of 181 days. Findings: 1. Review of the Sysmex XN-1000 operator's guide states "operating environment relative humidity 30-85%." 2. Review of the main laboratory humidity records shows that the laboratory humidity in the main laboratory where the Sysmex XN-1000 is located was out of range for 117 of 181 days from November 2024 to April 2025. 3. Review of the Beckman Coulter Access 2 operator's guide states "When the system is in operation, confirm that the following requirements are met: humidity 20-80% without condensation." 4. Review of the Beckman Coulter DxC 700 AU operator's guide states "operating environment requirements humidity: operational 20% - 80%." 5. Review of laboratory chemistry room humidity records shows that the laboratory humidity in the chemistry room where the Beckman Coulter Access 2 and DxC 700 AU are located was out of range for 73 of 181 days from November 2024 to April 2025. 6. Interview with the general

supervisor (GS) #1 on October 28, 2025, at 12:30 PM confirmed the laboratory failed to ensure the humidity was maintained as required by the manufacturer.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation of laboratory supplies during the laboratory tour, and interview with the general supervisor (GS) #1, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory supplies during the laboratory tour on October 28, 2025, at 9:30 AM, showed two pediatric green top blood collection tubes lot # 416618N expiration date August 31, 2025, and forty-three 9NC coagulation sodium citrate 3.2 % blue top blood collection tubes lot # B2410338 expiration date October 1, 2025, still in use. 2. Interview with the general supervisor (GS) #1 on October 28, 2025, at 10:30 AM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.

**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 2023, 2024 and to date October 28, 2025 chemistry calibration records and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range in 2023 and 2024 and to date October 28, 2025 for 61 of 61 analytes. Findings: 1. Review of the Beckman DxC 700 AU chemistry analyzer calibration records for 2023, 2024 and to date October 28, 2025 showed no calibration every six months that included at least a minimal value, a

mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: alanine transaminase, cholesterol, total bilirubin, alkaline phosphatase, aspartate aminotransferase, direct bilirubin, amylase, lipase, high density lipoprotein, low density lipoprotein, sodium, potassium, chloride, carbon dioxide, blood urea nitrogen, creatinine, glucose, calcium, albumin, total protein, triglyceride, gamma-glutamyl transpeptidase, creatine kinase, lactate dehydrogenase, magnesium, phosphorus, uric acid, iron, transferrin, lactic acid, acetaminophen, carbamazepine, gentamicin, dilantin, phenobarbital, salicylate, vancomycin, valproic acid, c-reactive protein, ammonia, alcohol, urine sodium, urine potassium, urine chloride, urine creatinine, urine glucose, microalbumin, urine protein, cerebrospinal fluid glucose, cerebrospinal fluid protein, and hemoglobin a1c. 2. Review of the Beckman Access 2 chemistry analyzer calibration records for 2023, 2024 and to date October 28, 2025 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: thyroid stimulating hormone, free thyroxine, folate, vitamin b12, beta human chorionic gonadotropin, ferritin, myoglobin, b-type natriuretic peptide, high sensitivity troponin, and creatine kinase-myocardial band. 3. The laboratory performed 224,770 chemistry patient tests annually. 4. Interview with the GS #1 on October 28, 2025 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for 61 analytes.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:  
Based on review of QC procedures, review of Beckman Coulter DxC 700 AU chemistry analyzer quality control (QC) records for 4 of 51 analytes, review of Beckman Coulter Access 2 QC records for 3 of 10 analytes, patient results, and interview with the general supervisor (GS) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for 61 analytes. Findings: 1. Review of "Washington County Memorial Hospital Laboratory Quality Control" procedure states "The quality control limits are set on the basis of the mean + or - 2 standard deviations (S.D.) for the preceding calendar months. Cumulative data is used where possible. These values are to be posted at each work station or within instrument QC data file. Certain assayed controls retain the ranges established by the manufacturer". 2. Review of the Beckman DxC 700 AU chemistry analyzer QC records revealed MAS Omni CORE II liquid assayed chemistry control in use. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes: alanine transaminase, cholesterol,

total bilirubin, alkaline phosphatase, aspartate aminotransferase, direct bilirubin, amylase, lipase, high density lipoprotein, low density lipoprotein, sodium, potassium, chloride, carbon dioxide, blood urea nitrogen, creatinine, glucose, calcium, albumin, total protein, triglyceride, gamma-glutamyl transpeptidase, creatine kinase, lactate dehydrogenase, magnesium, phosphorus, uric acid, iron, transferrin, lactic acid, acetaminophen, carbamazepine, gentamicin, dilantin, phenobarbital, salicylate, vancomycin, valproic acid, c-reactive protein, ammonia, alcohol, urine sodium, urine potassium, urine chloride, urine creatinine, urine glucose, microalbumin, urine protein, cerebrospinal fluid glucose, cerebrospinal fluid protein, and hemoglobin a1c.

3. Review of the Beckman Access 2 chemistry analyzer QC records revealed MAS Omni IMMUNE liquid assayed immunoassay control in use. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes: thyroid stimulating hormone, free thyroxine, folate, vitamin b12, beta human chorionic gonadotropin, ferritin, myoglobin, b-type natriuretic peptide, high sensitivity troponin, and creatine kinase-myocardial band.

4. The laboratory performed 224,770 chemistry patient tests annually.

5. Interview with the GS #1 on October 28, 2025 at 11:00 AM confirmed the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for 61 analytes.

**D5503**

**BACTERIOLOGY**  
 CFR(s): 493.1261(a)(2)

(a)(2) Each week of use for Gram stains.

This STANDARD is not met as evidenced by:  
 Based on review of gram stain quality control (QC) records and interview with the general supervisor (GS) #1, the laboratory failed to document positive and negative reactivity each week of use for gram stains for 1 of 43 weeks in 2025. Findings: 1. Review of "Gram Stain Weekly QC" records showed no documentation of QC the week of July 12, 2025. 2. Interview with GS #1 on October 28, 2025 at 10:30 AM confirmed the laboratory failed to document positive and negative reactivity each week of use for gram stains.

**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 review of the laboratory's transfusion reaction procedure, the hospital

nursing transfusion reaction procedure and interview with the general supervisor (GS) #1, the laboratory failed to ensure that the laboratory and nursing transfusion reaction procedures were adequate to ensure the safety of individuals being transfused. Findings: 1. Review of the laboratory's procedure "Transfusion Reaction from Nursing Procedure Manual" showed the laboratory failed to address how staff are to document, investigate and report a transfusion reaction. 2. Review of the hospital procedure "Transfusion Reaction" showed that the hospital failed to address how staff are to recognize, document, and report a transfusion reaction. 3. Interview with the general supervisor (GS) #1 on October 28, 2025, at 12:30 PM confirmed that the laboratory failed to ensure that the laboratory and hospital transfusion reaction procedures were adequate to ensure the safety of individuals being transfused.

**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:  
Based on observation of analyzers, review of instrument comparisons, and interview with the general supervisor (GS) #1, the laboratory failed to evaluate, define and document the relationship between test results using different instruments two times a year in 2023, 2024 and to date October 28, 2025. Findings: 1. Observation of laboratory analyzers revealed the iStat analyzer and the Beckman DxC 700 AU, both analyzers perform lactic acid, blood urea nitrogen, creatinine, glucose, carbon dioxide, sodium, potassium and chloride. 2. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and the Beckman DxC 700 AU analyzer twice a year in 2023, 2024 and to date October 28, 2025. 3. Observation of laboratory analyzers revealed iStat analyzer and the ACL Elite analyzer, both analyzers perform prothrombin time. 4. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and the ACL Elite analyzer twice a year in 2023, 2024 and to date October 28, 2025. 5. Observation of laboratory analyzers revealed Beckman Access 2 chemistry analyzer and the Alere Triage analyzer, both analyzers perform b-type natriuretic peptide, myoglobin, creatine kinase-myocardial band, and troponin. 6. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the Beckman Access 2 chemistry analyzer and the Alere Triage analyzer twice a year in 2023, 2024 and to date October 28, 2025. 7. Interview with the GS #1 on October 28, 2025 at 12:00 PM, confirmed the laboratory failed to evaluate and define the relationship between blood gas test results using different instruments two times a year in 2023, 2024 and to date October 28, 2025.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on review of 2024 and 2025 proficiency testing (PT) records and interview with the general supervisor (GS) #1, the laboratory director failed to ensure appropriate staff evaluated the laboratory's performance on PT results in 2024 and 2025. Findings: 1. Review of 2024 PT records showed no corrective action documentation was available to show the laboratory investigated ungraded PT results on the following performance evaluations: American Proficiency Institute (API) 2024 Microbiology-1st Event API 2024 Hematology/Coagulation-2nd Event API 2024 Chemistry-Core-2nd Event API 2024 Microbiology-2nd Event 2. Review of 2025 PT records showed no corrective action documentation was available to show the laboratory investigated ungraded PT results on the following performance evaluations: API 2025 Chemistry-Core-1st Event API 2025 Hematology/Coagulation-2nd Event API 2025 Microbiology-2nd Event API 2025 Chemistry-Core-2nd Event 3. Interview with GS #1 on October 28, 2025 at 12:30 PM confirmed the laboratory director failed to ensure appropriate staff evaluated the laboratory's performance on PT results.