

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0441828	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier Madison Medical Center	Street Address, City, State 611 West Main, Fredericktown, MO	
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
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 immunohematology procedures, patient immunohematology testing, chemistry procedures, and interview with the technical supervisor (TS) #2, the laboratory failed to provide procedures for patient tube method, to provide procedures for acceptability of chemistry quality control (QC). Findings: 1. Review of immunohematology procedures showed no procedure for patient tube method for blood bank. 2. Review of immunohematology patient testing showed one patient tested on 6/10/26 by tube method. 3. Review of chemistry procedures revealed no procedures for acceptability of QC for the Vitros XT 7600 analyzer. 4. Interview with TS #2 on August 11, 2026 at 11:00 AM confirmed the laboratory failed to provide procedures for patient tube method, and acceptability of chemistry QC.
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 observation of Maytag Freezer #1 and Helmer Freezer #2, review of laboratory logs, laboratory humidity records for January 2026 to date August 11, 2026, laboratory temperature records for July 2026 to date August 11, 2026 and Centers for Medicare and Medicaid Services Form 116 (CMS-116) and interview with the technical supervisor (TS) #2, the laboratory failed to ensure the freezer temperature and humidity was maintained for 130 of 223 days. Findings: 1. Observation of Maytag Freezer #1 on August 11, 2026 showed: 1 box of MAS Omni-IMMUNE quality control (QC) Lot OIM26121A exp 12/31/26, 1 box of MAS Omni-IMMUNE QC Lot OIM26122A exp 12/31/26, and 1 box of MAS Omni-IMMUNE QC Lot OIM26123A exp 12/31/26 with temperature storage requirements of -15 to -20 degrees Celsius 3 boxes of BioRad Immunoassay Plus QC Lot 1003921 exp 02/28/27, 3 boxes of BioRad Immunoassay Plus QC Lot 1003922 exp 02/28/27, and 3 boxes of BioRad Immunoassay Plus QC Lot 1003923 exp 02/28/27 with temperature storage requirements of -20 to -70 degrees Celsius 1 pack of Vitros High Sensitivity Troponin calibrator Lot 0050 exp 11/02/2026 with temperature storage requirements of -4 to -20 degrees Celsius 2. Review of "Refrigerator and Freezer Temperature Log" states acceptable range "#1 Freezer Maytag Range -20 to -70 degrees Celsius". 3. Review of the temperature records shows that the freezer temperature was out of range for Maytag Freezer #1 for 39 of 42 days from July 2026 and to date August 11, 2026. 4. Observation of Helmer Freezer #2 on August 11, 2026 showed: 2 boxes of Vitros Alcohol reagent Lot 5534-0114-1995 exp 08/01/2027 with temperature storage requirements of less than or equal to -18 degrees Celsius 1 box of Vitros CKMB (CKMB2) calibrator Lot 0210 exp 10/31/26 with temperature storage requirements of -4 to -20 degrees Celsius. 5. Review of "Refrigerator and Freezer Temperature Log" states acceptable range "Chemistry #2 Freezer Helmer Range: -20 to -70 degrees Celsius". 6. Review of the temperature records shows that the freezer temperature was out of range for Helmer Freezer #2 for 42 of 42 days from July 2026 and to date August 11, 2026. 7. Review of the "Humidity Log-Main Lab" log states acceptable range 30-80%. 8. Review of the laboratory humidity records shows that the humidity in the laboratory was out of range for 88 of 223 days from January 2026 to date August 11, 2026. 9. Review of CMS-116 showed the laboratory performs approximately 189,771 patient tests annually. 10. Interview with the TS #2 on August 11, 2026 at 11:00 AM confirmed the laboratory failed to ensure the freezer temperature and humidity was maintained for 130 days.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on review of procedures, review of troponin patient testing, review of Polymedco Pathfast quality control (QC) for January 2026 to date August 11, 2026, review of Abaxis Piccolo chemistry QC for January 2026 to date August 11, 2026, review of patient results and interview with technical supervisor (TS) #2, the laboratory failed to include two controls materials of different concentrations each day of patient testing for 1 of 5 troponin patient testing days, and 2 of 8 Piccolo chemistry

	patient testing days. Findings: 1. Review of "Quality Assessment Process-Quality Control Processes and Quality Assurance and Performance Improvement" procedure stated "If the test is considered non-waived by CLIA regulations: a) A two level set (minimum) is performed each day of testing". 2. Review of Polymedco Pathfast troponin testing showed: June 4, 2026 one patient resulted for troponin and no QC performed. 3. Review of Abaxis Piccolo chemistry testing showed: March 20, 2026 one patient resulted for sodium, potassium, tCO₂, chloride, glucose, calcium, BUN, creatinine, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, total bilirubin, albumin, total protein and no QC performed. June 25, 2026 one patient resulted for sodium, potassium, tCO₂, chloride, glucose, calcium, BUN, creatinine, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, total bilirubin, albumin, total protein and no QC performed. 4. Interview with the TS #2 on August 11, 2026 at 1:00 PM confirmed the laboratory failed to include two controls materials of different concentrations each day of patient testing for Polymedco Pathfast troponin and Piccolo chemistry.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Sure-View serum human chorionic gonadotropin (hCG) test quality control (QC) records for 2025 to date August 11, 2026, patient results and interview with the technical supervisor (TS) #2, the laboratory failed to perform positive and negative controls for serum hCG for 2 of 44 patient testing days. Findings: 1. Review of "Pregnancy Test-Serum & Urine Qualitative" procedure states "External procedural controls are to be tested each day of testing for SERUM qualitative pregnancy testing. A positive hCG control (containing >25 mIU/hCG in serum) and a negative hCG control are to be performed". 2. Review of "Serum HCG Testing Worksheet" records showed: 03/28 /2026 one patient resulted for serum hCG and no QC performed 06/21/2026 one patient resulted for serum hCG and no QC performed 3. Review of patient results showed the laboratory performs approximately 30 serum hCG patient tests annually. 4. Interview with the technical supervisor #2 on August 11, 2026 at 2:30 PM confirmed the laboratory failed to perform a positive and negative control each day of patient testing.
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:

A. Based on review of the Vitros XT 7600 chemistry analyzer quality control (QC) records for 2 of 59 analytes, patient results, and interview with the technical supervisor (TS) #2, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for alkaline phosphatase (ALP) and direct bilirubin. Findings: 1. Review of the Vitros XT 7600 chemistry analyzer QC records showed the laboratory used BioRad liquid assayed multiquant QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC when the QC ranges were not within the manufacturer's assayed ranges for the analytes: acetaminophen, albumin, alcohol, ALP, alanine transaminase, aspartate transferase, ammonia, amylase, direct bilirubin, total bilirubin, calcium, chloride, high density lipoprotein, cholesterol, carbon dioxide, creatine phosphokinase, creatinine, c-reactive protein, ferritin, glucose, glycohemoglobin, iron, lactic acid, lactate dehydrogenase, lipase, magnesium, phosphorus, potassium, prostate specific antigen, sodium, total protein, triglyceride, blood urea nitrogen, uric acid, beta human chorionic gonadotropin, thyroid stimulating hormone, FT4, troponin I, amphetamines, B12, barbiturates, benzodiazepines, CKMB, cocaine, folate, FT3, methadone, microalbumin, NT-proBNP, opiates, phenylephrine, prolactin, rheumatoid factor, salicylates, THC, TIBC, TT4, valproic acid, vancomycin, and vitamin D. 2. Review of chemistry QC in the computer where testing personnel accept QC results showed the range for ALP MQ4: 30.50-42.86. 3. Review of manufacturer's instructions for BioRad liquid assayed multiquant QC ranges showed lot #46051 ALP MQ4: 31.8-50.3. The laboratory could not address the discrepancy in ALP ranges. 4. Review of Vitros XT 7600 chemistry analyzer patient results showed approximately 5,948 ALP patient results reported annually. 5. Review of chemistry QC in the computer where testing personnel accept QC results showed the range for direct bilirubin level 2: .79-1.07. 6. Review of manufacturer's instructions for BioRad liquid assayed multiquant QC ranges showed lot #46052 direct bilirubin level 2: .84-1.16. The laboratory could not address the discrepancy in ALP ranges. 7. Review of Vitros XT 7600 chemistry analyzer patient results showed approximately 92 direct bilirubin patient results reported annually. 8. Interview with the TS #2 on August 11, 2026 at 12:10 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. B. Based on review of the Sysmex CA-600 coagulation analyzer quality control (QC) records for 2 of 2 analytes, coagulation QC study for 2 of 2 lot numbers, patient results, and interview with the technical supervisor (TS) #2, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for prothrombin time (PT) and activated partial thromboplastin time (APTT). Findings: 1. Review of the Sysmex CA-600 coagulation analyzer QC records showed Dade Ci-Trol Coagulation Level 1 Lot 564903 exp 08/18/2027 and Dade Ci-Trol Coagulation Level 3 Lot 55659024 exp 11/26/2026 controls 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: prothrombin time (PT) and activated partial thromboplastin time (APTT). 2. Review of coagulation QC in the laboratory information system (LIS) where testing personnel accept QC results showed the range for PT level 1: 9.58-13.26 and PT level 3: 47.77-61.77. 3. Review of coagulation QC in the laboratory information system (LIS) where testing personnel accept QC results showed the range for APTT level 1: 25.58-30.22 and APTT level 3: 50.4-60.4. 4. Review of acceptable QC ranges established during the QC study for Lot 564903 exp 08/18/2027 on 04/24/2026 show the range for PT level 1: 10.85-11.65 and APTT level 1: 26.6-29.0. 5. Review of acceptable QC ranges established during the QC study for Lot 55659024 exp 11/26/2026 on 09/25/2024

	show the range for PT level 3: 36.2-56.2 and APTT level 3: 44.5-64.5. 6. Review of coagulation patient results showed approximately 916 PT and 353 APTT patient results reported annually. 7. Interview with the TS #2 on August 11, 2026, at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
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 laboratory analyzers, review of instrument comparisons for 2025 and to date August 11, 2026, review of Centers for Medicare and Medicaid Services Form 116 (CMS-116) annual test volumes and interview with the technical supervisor (TS) #2, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2025 and to date August 11, 2026. Findings: 1. Observation of the laboratory analyzers showed an Abaxis Piccolo analyzer and Vitros XT 7600 chemistry analyzer, both analyzers perform sodium, potassium, tCO₂, chloride, glucose, calcium, BUN, creatinine, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, total bilirubin, albumin, and total protein. 2. Review of 2025 instrument comparisons showed the laboratory could not provide Abaxis Piccolo analyzer and Vitros XT 7600 chemistry analyzer instrument comparisons. 3. Observation of the laboratory analyzers showed a Vitros XT 7600 chemistry analyzer and Polymedco Pathfast analyzer, both analyzers perform CKMB and BNP testing. 4. Review of 2025 and to date August 11, 2026 instrument comparisons showed the laboratory could not provide Polymedco Pathfast analyzer and Vitros XT 7600 chemistry analyzer instrument comparisons. 5. Review of CMS-116 test volumes showed the lab performs approximately 121,687 chemistry patient tests annually. 6. Interview with the TS on August 11, 2026 at 11:00 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (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 on review of Vitros XT 7600 chemistry analyzer quality control (QC) for 3 of 59 analytes from June 1, 2026 to date August 11, 2026, review of patient results and interview with technical supervisor (TS) #2, the technical supervisor failed to establish a chemistry quality control program that included parameters for acceptable

levels of analytic performance. Findings: 1. Review of Vitros XT 7600 QC showed: 6/7/26 Folic Acid level 1 QC not within acceptable limits and no patients resulted 7/9/26 Folic Acid Level 2 QC not within acceptable limits and no patients resulted 6/13/26 Direct bilirubin level 5 QC not within acceptable limits and no patients resulted 6/19/26 Direct bilirubin level 5 QC not within acceptable limits and no patients resulted 6/3/26 Alkaline phosphatase level 4 QC not within acceptable limits and 23 patients resulted 6/5/26 Alkaline phosphatase level 4 QC not within acceptable limits and 21 patients resulted 6/8/26 Alkaline phosphatase level 4 QC not within acceptable limits and 21 patients resulted 6/10/26 Alkaline phosphatase level 4 QC not within acceptable limits and 38 patients resulted 6/13/26 Alkaline phosphatase level 4 QC not within acceptable limits and 5 patients resulted 6/14/26 Alkaline phosphatase level 4 QC not within acceptable limits and 2 patients resulted 6/19/26 Alkaline phosphatase level 4 QC not within acceptable limits and 23 patients resulted 2. Interview with the TS #2 on August 11, 2026, at 1:00 PM confirmed the technical supervisor failed to establish a chemistry quality control program that included parameters for acceptable levels of analytic performance.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(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; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, training and competency documents and interview with the technical supervisor (TS) #2, the technical supervisor (TS) failed to identify and document initial and annual training needs for 5 of 12 testing personnel (TP) performing laboratory testing. Findings: 1. Review of "Laboratory Quality Management System" policy states "Training must be documented and specific to assigned duties. Personnel must demonstrate ability to perform testing prior to reporting patient results. Competency must be assessed semiannually during the first year and annually thereafter". 2. Review of training and competency documents showed the laboratory could not provide documentation for initial training and competency for TP #9 with a hire date of 09/02/2024 for the Gem Premier 4000 blood gas analyzer. 3. Review of training and competency documents showed the laboratory could not provide documentation for annual training and competency for TP #2, TP #8, and TP #12 for 2025. 4. Review of training and competency documents showed the laboratory could not provide documentation for annual training and competency for TP #6 for 2026. 5. Interview with the TS #2 on August 11, 2026 at 3:00 PM, confirmed the technical supervisor failed to identify and document training needs for five TP performing laboratory testing.