

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0521001	<b>(X3) Date Survey Completed</b>  11/06/2024
<b>Name of Provider or Supplier</b>  Madison Memorial Hospital Lab	<b>Street Address, City, State</b>  450 E Main St, Rexburg, ID	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the technical supervisor (TS) on 11/5/2024, the laboratory failed to follow written procedures to assess testing personnel competency and to establish a procedure for competency assessments for the TS and general supervisor (GS) in 2023 and 2024. The findings include: 1. The CMS 209 identified 34 testing personnel (TP) performing moderate and high complexity testing of which 12 were new since the last inspection on 10/21/2022. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency but failed to establish a procedure for competency assessment performance for the TS and GS. 3. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments for six (6) TP. 4. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for 16 TP performing EPOC testing in 2023 and one (1) in 2024. 5. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for three (3) TP performing testing in the main laboratory in 2024. 6. A review of training and competency assessment records identified that the laboratory failed to have competency assessments for the TS and GS. 7. An interview with the TS on 11/5/2024 at 8:57 am confirmed the above findings. 8. The laboratory reports performing 564,424 tests annually. 9. This is a repeat deficiency from the previous inspections on 1/28/2021 and 10/21/2022.</p>

**D5300**

**PREANALYTIC SYSTEMS**

CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This **CONDITION** is not met as evidenced by:

Based on review of the laboratory's patient test records, laboratory's policy, manufacturer's instructions, and interview, the laboratory failed to meet the requirements of for the preanalytic system for seven of twenty lactic acid specimens and six of twenty ammonia specimens reviewed as evidenced by: 1. The laboratory failed to follow laboratory policy and manufacturer's instructions for specimen collection and handling with the 15 minute centrifugation time frame prior to analysis for seven of twenty lactic acids and six of twenty ammonia specimens. (See D5311)

**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 review of the laboratory's patient test records, laboratory's policy, manufacturer's instructions, and interview with technical consultant of chemistry, the laboratory failed to follow laboratory policy and manufacturer's instructions for specimen collection and handling with the 15 minute centrifugation time frame prior to analysis for seven of twenty lactic acid and six of twenty ammonia specimens reviewed as evidenced by: Ammonia: 1. In review of the manufacturer instructions for use (the Vitros chemistry system 7200) for ammonias states under special precautions, "Centrifuge specimens and remove plasma from the cellular material within 15 minutes of collection." 2. In review of the laboratory's policy and confirmed with testing person #1 at 1022 on Nov. 5, 2024, he stated that the lab uses the manufacturer's instructions as part of their policy. 3. The following patients, six of twenty reviewed were outside the 15 minute time frame: a. patient #8325490 collected 11/2/2024 at 0448 received into the laboratory at 0516, 28 minutes. b. patient #8325462 collected 10/29/2024 at 2146 received into the laboratory at 2211, 25 minutes. c. patient #8323838 collected 10/29/2024 at 1144 received into the laboratory at 1204, 20 minutes. d. patient #8323501 collected 10/13/2024 at 2047 received into the laboratory at 2132, 45 minutes. e. patient #8323390 collected 10/14/2024 at 1515 received into the laboratory at 1541, 26 minutes. f. patient #8323178 collected 10/15/2024 at 1749 received into the laboratory at 1904, 75 minutes. 4. The laboratory performs 198 ammonias per year according to their test volume report. 5. In interview with testing person #1 at 1022 on Nov. 5, 2024 stated that they follow

manufacturer's instructions for ammonias testing and confirmed they may not be following their procedure and manufacturer's instructions. Lactic Acid: 1. In review of the manufacturer's instructions for use (the Vitros chemistry system 7200) for lactic acid states under special precautions, "Centrifuge specimens and remove plasma from the cellular material within 15 minutes of collection." 2. The following patients seven of twenty reviewed were outside of the 15 minute time frame: a. patient # 8325878 collected on 11/1/2024 at 1724 received in the laboratory at 1819, 55 minutes. b. patient # 8325415 collected on 10/29/2024 at 1542 received in the laboratory at 1607, 25 minutes. c. patient # 8325201 collected on 10/29/2024 at 0440 received in the laboratory at 0459, 19 minutes. d. patient # 8323957 collected on 10/17/2024 at 0739 received in the laboratory at 0828, 49 minutes. e. patient # 8323782 collected on 10/15/2024 at 1748 received in the laboratory at 1816, 28 minutes. f. patient #8323772 collected on 10/15/2024 at 1510 received in the laboratory at 1533, 23 minutes. g. patient #8323512 collected on 10/13/2024 at 2119 received in the laboratory at 2135, 16 minutes. 3. The laboratory performs 1068 lactic acid test per year according the their test volume report. 4. In interview with testing person #1 0945 on Nov. 5, 2024, stated that they follow manufacturer's instructions and that lactic acids tests had to be separated cells from the plasma within 15 minutes. He confirmed that they were not following the procedure or instructions.

**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 the laboratory procedures, testing records, and interview, the laboratory failed to have included in their procedures the interpretation of results and define each range per high power field within the grading scale points of +1, +2, +3, +4 for microscopic urinalysis as evidence by: 1. In review of the laboratory procedure, titled Urinalysis -Microscopic Urinalysis, the laboratory did not define the range or interpretation of results for each grading scale point of +1, +2,+3,+4 for mucous, coars Gran, and amorph Urate. 2. In review of testing record MRN: 129176 tested on 10/5/2024 the following UA microscopic urine interpretation : UA mucous +1 UA

coarse Gran +1 UA amorph Urate +1 3. In interview with testing person #1 on 11-5-2024 at 1306 he stated that they did not define in the procedure the grading scale of +1, +2,+3,+4 for microscopic urinalysis.

**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 a review of the Cardinal Health Rapid Plasma Reagin (RPR) Card Test package insert, laboratory policy, patient test results, quality control (QC) log and an interview with testing personnel 1 (TP1) on 11/6/2024, the laboratory failed to follow the manufacturer's instructions for Syphilis Serology testing. The findings include: 1. A review of the Cardinal Health RPR package insert and laboratory policy, "Serology-RPR", the speed of the rotator is to be verified at 100 +/- 5 revolutions per minute. 2. A review of patient test results and the QC log identified that the laboratory failed to verify and document the rotator speed used for testing met the manufacturer's requirements since May 2024. 3. An interview with TP1 on 11/6/2024 at 8:57 am confirmed the above findings. 4. The laboratory reports performing 763 RPR tests annually.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 a review of calibration records, linearities, instrument documents for the Ortho Vitros 7600 and an interview with the chemistry technical consultant (TC) on 11

/5/2024, the laboratory failed to verify the reportable range at least once every six months for Hepatitis B surface antigen (HBsAg) in 2024. The findings include: 1. A review of calibration records for the Vitros 7600 identified that HBsAg had a one point calibration. 2. A review of instrument documents and a lack of linearities for HBsAg identified that the laboratory failed to perform verifications of the reportable range for HBsAg at least every six months in 2024. 3. An interview with the chemistry TC on 11/5/2024 at 2:53 pm confirmed that the laboratory failed to verify the reportable range of HBsAg at least once every six months in 2024. 4. The laboratory reports performing 791 HBsAg tests annually.

**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 Services (CMS) 209 personnel form, competency assessments, educational documents, testing experience and an interview with the technical supervisor on 11/6/2024, the laboratory failed to have a technical consultant that qualified with the minimum educational and testing experience requirements for epoc Blood Analysis System testing. See 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 Services (CMS) 209 personnel form, competency assessments, educational documents and an interview with the technical supervisor (TS) on 11/6/2024, the laboratory failed to have a qualified technical consultant performing epoc Blood Analysis System testing competency assessments in 2024. The findings include: 1. A review of the CMS 209 identified 22 testing personnel (TP) performing epoc Blood Analysis System testing. 2. A review of competency assessments for epoc Blood Analysis System testing in 2024 identified TP 2 performing the assessments. 3. A review of educational documents and testing experience available during the inspection for TP 2 identified that the laboratory failed to hire a technical consultant with a bachelor's degree or higher in chemical, physical, biological science or medical technology with the required testing experience for epoc Blood Analysis System testing. 4. An interview with the TS on 11/6/2024 at 9:36 am confirmed that the laboratory failed to have a qualified technical consultant for epoc Blood Analysis System testing. 5. The laboratory reports performing 2,076 tests on the epoc Blood Analysis System annually.