Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521001	10/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Memorial Hospital Lab	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory manager on 10/20/2022, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2021. The findings include: 1. A review of competency assessment records identified seven (7) of fifteen (15) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2021. 2. An interview with the laboratory manager on 10/20/2022 at 8:26 am confirmed that competency assessments were not performed in 2021. 3. The laboratory reports performing 577,980 moderate and high complexity tests annually. 4. This is a repeat deficiency from the previous inspection on 1/28/2021.
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 record review of Sysmex CA 620 coagulation documentation and an

	interview with testing personnel 2 (TP2) on 10/21/2022, the laboratory failed to perform a normal patient Prothrombin (PT) mean study for the current lot of Dade Innovin. The findings include: 1. A record review of coagulation documentation identified that the laboratory failed to perform a PT normal patient study to determine the correct mean to be used in the calculation of patient International Normalized Ratio (INR) for the current lot of Dade Innovin, 56417. 2. An interview with TP2 on 10/21/2022 at 8:31 am confirmed that the laboratory failed to perform a normal patient PT mean study for the current lot of Innovin. 3. The laboratory reports performing 200 PT/INR tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of the Biomerieux Vidas 3 maintenance logs and an interview with testing personnel 1 (TP1) on 10/20/2022, the laboratory failed to perform maintenance as required by the manufacturer. The findings include: 1. A review of the Biomerieux Vidas 3 maintenance logs identified that the laboratory failed to perform monthly maintenance, cleaning the SPR block, as required by the manufacturer in February, March, April, May, June and July of 2022. 2. An interview with TP1 on 10/20/2022 at 4:26 pm confirmed that the laboratory failed to document monthly maintenance on the Vidas 3 for six months in 2022. 3. The laboratory reports performing 689 tests annually on the Vidas 3.
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, instrument documents for the Biomerieux Vidas 3 and an interview with testing personnel 1 (TP1), the laboratory failed to verify the reportable range at least once every six months for procalcitonin in 2021 and 2022. The findings include: 1. A review of calibration records and documents for the Biomerieux Vidas 3 identified that the laboratory failed to perform verifications of the reportable range for the analyte procalcitonin at least every six months in 2021 and 2022. 2. An interview with TP1 on 10/20/2021 at 5:08 pm confirmed that the laboratory had not verified the reportable range of procalcitonin at least once every six months in 2021 and 2022. 3. The laboratory reports performing 689 procalcitonin tests annually.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review of Sysmex CA 620 coagulation quality control (QC) documentation, patient results, and an interview with testing personnel 1 (TP1) on 10 /20/2022, the laboratory failed to perform two levels of QC every eight hours of patient testing. The findings include: 1. A random record review of prothrombin time (PT) and partial thromboplastin time (PTT) QC identified that the laboratory failed to document two levels of QC every 8 hours when patient testing occurred for four days in March 2021 and three days in May 2022. 2. A review of the laboratory's patient results identified three patient PT/INRs reported on 3/27/2021, five patient PT/INRs and three PTTs reported on 3/26/2021, two patient PT/INRs and one PTT reported on 3/25/2021, one patient PT/INR reported on 3/23/2021, three patient PT/INRs and one PTT reported on 5/19/2022, two patient PT/INRs reported on 5/10/2022, and one patient PT/INR and two PTTs reported on 5/3/2022 without two levels of QC within eight hours. 3. An interview with TP1 on 10/20/2022 at 3:03 confirmed that the above patient results were reported without two levels of QC. 4. The laboratory reports performing 200 PT/INRs and 400 PTTs annually.