Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521001	09/18/2018
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to enroll in PT for Syphilis, Rubella, Hepatitis B surface antigen (HbsAg), and Anti-human immunodeficiency virus (HIV) analytes since the last survey on July 21, 2017. Findings: 1. A review of PT records from the American Proficiency Institute (API) revealed the laboratory failed to enroll in PT for the analytes Syphilis, Rubella, HbsAg, and HIV since the last survey. 2. An interview on September 18, 2018 at 8:30 AM, with the laboratory manager, confirmed the laboratory was not enrolled in a CMS-approved PT program for the listed analytes since the last survey.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory director and/or designee failed to sign the attestation statements from the American Proficiency Institute (API) for the specialty of hematology, immunohematology, microbiology, and chemistry from since last survey on July 21, 2017. This is a repeat deficiency. Findings: 1. A review of API PT records from 2017 and 2018, revealed the laboratory director and/or designee failed to sign the attestation statements for the specialty of hematology, immunohematology, microbiology, and chemistry for the 2017 and 2018 events. 2. An interview on September 18, 2018 at 8:30 AM, with the laboratory manager, confirmed the laboratory director or designee failed to sign the attestation statements.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to verify the accuracy of fetal screen, semen count, Hepatitis C (HepC), and vitamin D at least twice a year since the last survey on July 21, 2017. Findings: 1. A record review of proficiency testing revealed the laboratory failed to document the accuracy of fetal screen, semen count, HepC, and vitamin D at least twice a year since the last survey. 2. An interview on September 18, 2018 at 8:30 AM, with the laboratory manager, confirmed the laboratory failed to document the accuracy of fetal screen, semen count, HepC, and vitamin D at least twice a year.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 a record review and an interview with the microbiology lead, the laboratory director failed to approve, sign, and date the MicroScan Walkaway bacteria identification system and the 6 analytes tested on the Cepheid Gene Xpert Individualized Quality Control Plan (IQCP) since the last survey on July 21, 2017. This is a repeat deficiency. Findings: 1. A review of the IQCPs for the Walkaway and tests performed on the Cepheid Gene Xpert, revealed the laboratory director failed to approve, sign, and date the IQCPs. 2. An interview on September 18, 2018 at 4:00 PM, with the microbiology lead, confirmed the laboratory director failed to sign and date the IQCPs.
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 record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification activities at least once every 6 months, after major maintenance or parts replacement, issues with quality control, or verification of reportable range on the Siemens Centaur XP Immunoassay analyzer since the last survey on July 21, 2017. Findings: 1. A review of calibration records revealed the laboratory failed to perform calibration verification activities on vitamin D, vitamin B-12, testosterone, parathyroid hormone, insulin, folate, cortisol, follicular stimulating hormone, progesterone, prolactin, phenytoin, valproic acid, total triiodothyronine, Luteinizing hormone, and carbamazepine on the Siemens Centaur immunoassay analyzer since the last survey. 2. An interview on September 18, 2018 at 9:50 AM, with the laboratory manager, confirmed the laboratory failed to perform calibration verifications activities for the listed analytes.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to meet the manufacturer's requirements for performing the mean closure time since the last survey on July 17, 2017. Findings: 1. A review of the Siemens PFA-100 instruction manual revealed the laboratory failed to meet the

	quality control testing requirement that the control group values should be between 110-160 seconds. 2. An interview on September 18, 2018 at 9:50 AM, with the laboratory manager, confirmed the laboratory failed to follow the manufacturer's instructions for donor control testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to perform control procedures at least once each day of patient testing on the Siemens PFA-100 instrument used for the detection of platelet dysfunction since the last survey on July 17, 2017. Findings: 1. A review of the quality control records for the PFA-100 instrument revealed the laboratory failed to perform quality control at least once each day of patient testing since the last survey. 2. An interview on September 18, 2018 at 9:50 AM with the laboratory manager, confirmed the laboratory failed to perform quality control each day of patient testing and did not write an Individualized Quality Control Plan for the test system.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory manager, the laboratory failed to test two levels of quality control material for both Hepatitis B surface antigen (HbsAg) and D-dimer prior to reporting patient results between February 26, 2018 through May 16, 2018. Findings: 1. A review of the HbsAg quality control records performed on the Siemens Centaur immunoassay between February 26, 2018 through March 6, 2018 revealed the laboratory failed to test two levels of quality control materials prior to 8 patients HbsAg results reported. 2. A review of the D-dimer quality control records performed on the Sysmex CA-500 coagulation between May 14 through May 16, 2018, revealed the laboratory failed to test two levels of quality control materials prior to 6 patients D-dimer results being reported during that time. 3. An interview on September 18, 2018, at 2:30 PM, with the laboratory manager, confirmed 8 HbsAg and 6 D-dimer tests were reported without two levels of quality control performed.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to establish or verify the criteria for acceptability of control materials for Hepatitis B surface antigen (HbsAg) performed on the Centaur immunoassay analyzer during the dates reviewed from February 26 through March 6, 2018. Findings: 1. A review of quality control records for HbsAg revealed the laboratory failed to establish and verify the acceptability of unassayed quality control material. 2. An interview on September 18, 2018, at 10:30 AM, with the laboratory manager, confirmed the laboratory failed to verify a patient sample used as quality control material.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 record review and an interview with the bloodbank lead, the laboratory failed to perform compatibility testing to detect IgM antibodies using the Ortho Workstation since the last survey on July 17, 2017. Findings: 1. A review of quality control records revealed the laboratory failed to perform an immediate spin crossmatch for the detection of IgM antibodies for ABO incompatibilities. 2. An interview on September 18, 2018, at 5:05 PM, with the bloodbank lead, confirmed the laboratory failed to perform an immediate spin to demonstrate ABO incompatibilities.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the microbiology lead, the laboratory failed to establish and follow a written policy or procedure to monitor, assess, and correct problems in the MicroScan Walkaway system for bacteria identification and antimicrobial susceptibility testing since the last survey on July 17, 2017. Findings: 1. A review of the Individualized Quality Control Plan (IQCP) for the Walkaway microbiology system revealed the laboratory failed to write a Quality Assessment Plan (QAP) for the test system. 2. An interview on September 18, 2018, at 4:00 PM, with the microbiology lead, confirmed the laboratory failed to write a QAP to provide a system that reviews the functions of the Walkaway system.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the laboratory manager, the laboratory failed to document quality assessment activities in the analytic systems during the dates reviewed from February through May 2018. Findings: 1. A review of quality control records revealed the laboratory testing personnel failed to document corrective actions when quality control material for the prothrombin time (PT), partial thromboplastin time (PTT), D-dimer, and hepatitis B surface antigen (HbsAg) failed to meet the manufacturer's and laboratory's established quality control criteria during the dates reviewed. 2. An interview on September 18, 2018, at 3:00 PM, with the laboratory manager, confirmed the laboratory testing personnel failed to document corrective actions when problems occurred in quality control testing.