

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2064353	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Madison Memorial Satellite Clinic	Street Address, City, State 255 N 3rd E, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to maintain a copy of records for proficiency testing. Findings: 1. A record review of proficiency testing records revealed that the laboratory failed to maintain the attestation statement, raw data from the hematology analyzer and results for the 3rd event of hematology in 2017. 2. An interview on September 12, 2019 at approximately 10:25 A.M., with the technical consultant confirmed that the laboratory did not have proficiency testing documents for the 3rd event of hematology for 2017.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the technical consultant, the laboratory failed to follow their approved quality assurance policy to review quality control and maintenance activities month to month. Findings: 1. A record review of quality control for 4 months in 2019 and one month in 2018 revealed that quality control was not being reviewed for shifts, drifts or trends by the technical consultant monthly. 2. A record review of maintenance and temperature logs revealed that the technical consultant did not review these activities since January 2019. 3. An interview on September 12, 2019 at approximately 10:00 A.M., with the technical consultant, confirmed that the laboratory failed to document reviews of quality control and maintenance activities from month to month in 2019.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the technical consultant, the laboratory failed to document calibration procedures at the frequency specified by the manufacturer. Findings: 1. A record review of calibration documentation revealed that the laboratory failed to maintain records of a calibration after a major preventative maintenance on May 20, 2019. 2. An interview on September 12, 2019 at approximately 10:15 A.M., with the technical consultant confirmed that the laboratory failed to document a calibration as required by the manufacturer.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the technical consultant, the

	<p>laboratory failed provide the correct name of the testing laboratory on the final reports. Findings: 1. A review of final patient test reports for complete blood cell counts (CBCs) performed in the laboratory revealed that the laboratory was using "MDSN TMG Laboratory" as the testing location. 2. An interview on September 12, 2019 at approximately 9:55 A.M., with the technical consultant, confirmed the name of the performing location was not correct.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to establish and follow a written procedure to monitor and assess the accuracy of reference ranges on the final reports generated through the laboratory's computer interface. Findings: 1. A review of final patient test reports for a male, female and a pediatric patient revealed that the laboratory was using different reference ranges on their final reports than what the laboratory had established for male, female and pediatric patients. 2. An interview on September 12, 2019 at 9:55 AM with the technical consultant, confirmed the laboratory did not have a mechanism in place to verify the accuracy of results generated through the laboratory's computer interface.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (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.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to evaluate the competency of testing personnel. Findings: 1. A review of personnel records for 3 of 3 testing personnel revealed that competency assessments had not been documented in 2018. 2. An interview on September 12, 2019 at approximate 10:45 A.M. with the technical consultant, confirmed that competency of testing personnel had not been documented in 2018.</p>