Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405516	05/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Healthcare Services	900 2nd Ave, Madison, MN	

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
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 observation, document review, and interview with laboratory personnel, the laboratory failed to include one accurate Hematology reference range in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 05/23/22. 2. A HemaTechnologies ESR Stat 6 automated sedimentation rate analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer in December 2020 as indicated in laboratory records. 3. The Erythrocyte Sedimentation Rate (ESR) reference range for

	male patients was inaccurate in the Erythrocyte Sedimentation Rate ESR Stat 6 procedure and the Hematology/Coagulation Testing Reference range table, both found in the Hematology Coagulation Manual, when compared to a 70 year old male patient test report from 03/29/21 and the performance verification (PV) records from 2020. See below. Male ESR reference ranges Procedure 0-20 (no age indicated) Table 0-20 (> 50) Test report 0-15 PV 0-15 (no age indicated) 4. In an interview at 2:30 p.m. on 05/23/22, the Technical Consultant confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform calibration verification on an analyzer performing bacterial and viral detection at least once every 6 months in 2021 and 2022. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 05/23/22. 2. A Qiagen QIAstat-Dx real-time PCR analyzer was observed as present and available for use during the tour. The laboratory began Respiratory Panel testing for detection of 21 bacteria and viruses (or their subtypes) using this analyzer in October 2020 as indicated in laboratory records. 3. QIAstat-Dx calibration verification was required every six months as indicated in the QIAGEN QIAstat-Dx Respiratory Panel procedure found in the Chemistry Procedure Manual. 4. QIAstat-Dx calibration verification documentation from 2021 and 2022 was not found in laboratory records. The laboratory was unable to provide calibration verification documentation upon request. 5. The Technical Consultant (TC) indicated 98 patient samples received Respiratory Panel testing between April 2021 and date of survey, 05/23/22. 6. In an interview at 4:00 p.m. on 05/23/22, the TC confirmed the above finding.