Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393534	04/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health Dean Medical Group-South Madison Campus	1211 Fish Hatchery Rd, Madison, WI	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the chemistry freezer, review of chemistry freezer temperature log, and interview with the general supervisor, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the Maine Standards calibration verification material stored in Freezer 1 and two hundred eighty-two days of two hundred eighty-three days were out of acceptable range in 2022 and 2023 Findings include: 1. Observation of Maine Standards Validate GC3, GC4, and GC1 calibration verification material in Freezer 1 on April 11, 2023, at 1:50 PM showed the manufacturer required storage at -10 to -25 Celsius (C). 3. Review of the temperature logs for 2022 and 2023 showed the defined acceptable temperature range for Freezer 1 was less than or equal to 20 C. Two hundred eighty-two days of two hundred eighty-three days showed recorded temperatures were colder than -25 C. 4. Interview with the general supervisor on April 11, 2023, at 1:54 PM confirmed the laboratory's acceptable range for Freezer 1 was not consistent with the manufacturer's acceptable range for the Maine Standards calibration material.
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 surveyor review of calibration verification records, patient testing reports and interview with a technical specialist, staff A, the laboratory did not perform calibration verification every six months on the Abbott Alinity chemistry analyzer in 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Abbott Alinity chemistry analyzer on January 24, 2022, and August 3, 2022. Further review showed no evidence of additional calibration verification performed on the analyzer in 2022 when calibration verification was due on July 24, 2022. 2. Review of patient testing reports showed two hundred and nine patient tests were performed between July 25, 2022, and August 3, 2022. 3. Interview with the staff A on April 11, 2023, at 1:53 PM confirmed the laboratory did not perform calibration verification every six months on the Abbott Alinity chemistry analyzer in 2022.