

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0394199	<b>(X3) Date Survey Completed</b>  02/25/2026
<b>Name of Provider or Supplier</b>  Ssm Health Dean Medical Group - Wisconsin Dells	<b>Street Address, City, State</b>  1310 Broadway, Wisconsin Dells, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory director, one of one hematology analyzer quality control procedure did not include criteria for determining acceptable control results. Findings include: 1. Review of the "HM-Sysmex XN-450 Quality Control" procedure revealed the procedure did not define the criteria for determining acceptable control results. 2. Interview with the laboratory director on February 25, 2026, at 1:52 PM confirmed the procedure did not include criteria for determining acceptable control results.</p>

**D6010**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(2)

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

This STANDARD is not met as evidenced by:

Based on surveyor review of documented humidity readings in the laboratory and interview with the laboratory director, the laboratory director did not ensure the humidity levels in the laboratory were appropriate for the testing performed for 43 of 43 operating days in December 2025 and January 2026, two of two winter months reviewed. Findings include: 1. Review of the "Temperature Log" indicated the laboratory's acceptable humidity range was 30% to 65%. Review of the log records from December 2025 and January 2026, showed the laboratory documented daily humidity readings on working days. Testing personnel documented readings that were less than 30% on 43 of 43 operating days in December 2025 and January 2026. 2. Interview with the laboratory director on February 25, 2026, at 1:45 PM confirmed the laboratory's acceptable humidity range was 30% to 65%, that the daily humidity readings were less than 30% for all working days of the two months reviewed, and that the laboratory director did not ensure the humidity levels in the laboratory were appropriate for the testing performed.