

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0394199	<b>(X3) Date Survey Completed</b> 12/13/2021
<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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory did not retain records of the calibration performed on the Sysmex KX-21 hematology analyzer on May 24, 2021. Findings include: 1. Review of laboratory records showed a calibration of the Sysmex KX-21 analyzer was performed on May 24, 2021; the calibration report was not included in the laboratory records. 2. Interview with the laboratory director on December 13, 2021 at 11:25 AM confirmed the laboratory did not retain the calibration report from May 24, 2021. Further interview at 11:45 AM revealed the calibration was performed by a Sysmex employee and confirmed the records were not available through Sysmex.</p>
<b>D6069</b>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(a)</p> <p>Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, testing personnel (staff A) performed testing and entered and verified test results for three complete blood counts (CBC) without differential, two CBCs with</p>

automated differentials and one CBC with a manual differential on December 2, 2021 that were not authorized by the director. Findings include: 1. Review of test records from the laboratory information system (LIS) showed staff A performed a CBC with manual differential on patient one on December 2, 2022 and verified the results at 12:55 PM. Review of additional records showed staff A also performed CBCs with automated differentials on patients two and five and CBCs without differentials on patients three, four, and six. 2. Review of the CMS209 'Laboratory Personnel Report' provided for this survey showed staff A was not included on the form. The form was signed by the director on December 13, 2020. 2. Interview with the laboratory director on December 13, 2021 at 12:20 PM revealed staff A was in the laboratory on December 2, 2021 supporting an instrument 'go live' and the director had not authorized staff A to perform hematology testing in this laboratory.