

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393950	(X3) Date Survey Completed 11/15/2022
Name of Provider or Supplier Ssm Health Dean Medical Group -Portage	Street Address, City, State 2825 Hunters Trail, Portage, 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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not maintain records of the identity of one of two testing personnel who performed hematology testing on the Sysmex XN1000. Findings include: 1. Review of maintenance logs showed testing personnel (Staff A) performed daily maintenance and quality control testing on the Sysmex XN1000 analyzer. 2. Interview with testing personnel (staff B) on November 15, 2022 at 10:45 AM revealed Staff A routinely does the daily maintenance including running quality control samples on the Sysmex XN1000. Further interview revealed Staff A occasionally performs STAT patient testing on the Sysmex XN1000 and revealed the laboratory did not document the identity of the testing person when Staff A tested patient samples on the Sysmex XN1000.</p>
D6046	<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>

This STANDARD is not met as evidenced by:
Based on surveyor review of competence evaluations and interview with a technical consultant, the technical consultant did not evaluate competence since 2020 for one of the two regularly scheduled testing personnel in performing testing with the Sysmex XN1000 analyzer. Findings include: 1. Review of competence evaluations for staff A showed Sysmex XN1000 competence evaluation was last documented in 2020. 2. Interview with a technical consultant (staff C), confirmed no documented Sysmex XN1000 competence evaluations were available for staff A since 2020 and confirmed staff A and staff B are the two regularly scheduled testing personnel at this laboratory.