

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393163	(X3) Date Survey Completed 08/12/2021
Name of Provider or Supplier Ssm Health Dean Medical Group - Stoughton	Street Address, City, State 225 Church St, Stoughton, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of hematology proficiency testing (PT) records from 2020 and 2021 and interview with the laboratory director, the director or a qualified designee did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for four of five events. Findings include: 1. Review of the laboratory's hematology PT records from 2020 (three events) and 2021 (two events) showed the attestation statements did not include the signature of the laboratory director or qualified designee for the three events in 2020 or the first event in 2021. The laboratory did not retain the attestation statement for event one in 2020 with the PT records. Review of the attestation statement for event three in 2020 showed a testing person (staff A) had signed the document both as a testing person and as the director designee. 2. Interview with the laboratory director on August 12, 2021 at 2:00 PM confirmed staff A was not qualified or delegated the responsibility to sign PT attestation statements as a designee of the director. Further interview confirmed the PT attestation statements were not signed by the director or a qualified designee for the three hematology events in 2020 or the first event in 2021 and that the director did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>