

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392967	(X3) Date Survey Completed 08/25/2022
Name of Provider or Supplier Ghc-Scw Sauk Trails Laboratory	Street Address, City, State 8202 Excelsior Dr, 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
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 American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical supervisor, staff A, the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for four of four immunohematology events in 2021 and 2022. Findings include: 1. Review of the API immunohematology PT records showed staff A signed the immunohematology attestation statements as the designee. Further review showed the laboratory director, who is the immunohematology technical supervisor, did not sign four of four immunohematology attestation statements in 2021 and 2022. 2. Interview with staff A on August 24, 2022 at 10:20 AM confirmed the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for four of four immunohematology events in 2021 and 2022.</p>