

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392967	(X3) Date Survey Completed 06/05/2024
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of IQCP (Individualized Quality Control Plan) records and interview with the Technical Consultant, the laboratory did not complete the required annual quality reviews of three of three reviewed test systems with IQCP in 2023. Findings include: 1. Review of the IQCP Quality Assurance Plans (QAP) for testing on the Phoenix, Triage, and MedTox analyzers showed the QAP required an annual quality review of the IQCP for each test system. Further review showed the Laboratory Director last documented review of each of the IQCP on September 8, 2022, and the Technical Consultant documented review on May 24, 2024. The records showed no review in 2023 for the three reviewed systems. 2. Interview with the Technical Consultant on June 4, 2024, at 10:20 AM confirmed the laboratory had not completed the annual review and approval of each IQCP in 2023 as required in the laboratory's QAP.</p>