

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2043116	(X3) Date Survey Completed 11/23/2022
Name of Provider or Supplier University Of Minnesota Genomics Center	Street Address, City, State 1-210 Ccrb 2231 6th St Se, Minneapolis, MN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of one non-regulated analyte at least twice annually in 2021 and 2022. Findings are as follows: 1. The laboratory performed Virology testing as confirmed by General Supervisor (GS) during a tour of the Oakdale facility laboratory at 9:05 a.m. on 11/23/22. 2. A ThermoFisher quantstudio 5 PCR system was observed as present and available for use during the tour. 3. The laboratory performed COVID-19 PCR testing on this analyzer beginning in November 2020. 4. A Proficiency Testing procedure requiring enrollment in Proficiency Testing (PT) for COVID-19 PCR testing by the laboratory was not found in the Laboratory SOP Binder. 5. Verification of accuracy documents for COVID-19 PCR testing were not found during review of Quality Assurance records from 2021 and 2022. The laboratory was unable to provide COVID-19 PCR verification records upon request. 6. COVID-19 PCR testing was performed on approximately 250,000 patient specimens in each of 2021 and 2022, as indicated on the CMS-116 provided by the GS on 11/22/22. 7. In an interview at 10:15 a.m. on 11/23/22, the GS confirmed the above finding. .</p>