

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0393580	<b>(X3) Date Survey Completed</b>  11/12/2024
<b>Name of Provider or Supplier</b>  Ghc East Clinic	<b>Street Address, City, State</b>  5249 East Terrace Dr, Madison, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2005</b>	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Certification and Surveyor Provider Enhanced Reporting (CASPER) records and proficiency testing (PT) records and interview with the Technical Consultant, the laboratory did not report proficiency test results to Health and Human Services (HHS) for testing performed with the Quidel QuickVue Strep A Plus, a moderately complex regulated test system, for four of the last four PT events since July 2023. Findings include: 1. Review of the CASPER report 0155D (Individual Laboratory Profile) for this laboratory created on October 29, 2024, showed no Bacteriology proficiency testing data after event three in 2021. 2. Review of the laboratory's PT records from 2023 and 2024 showed the laboratory reported the QuickVue Dipstick as the test method used for Streptococcus testing to API (American Proficiency Institute). The API report identified the QuickVue Dipstick as a waived test. The records showed the laboratory tested the samples for event 2 in 2023 in June 2023. 3. Interview with the Technical Consultant on November 12, 2024, at 9:05 AM revealed the laboratory used the Quidel Quick Vue Strep A Plus test system starting in July 2023 and confirmed the test method was moderately complex. Further interview confirmed the laboratory performed PT Streptococcus testing in event three in 2023 and the three events in 2024 with the Quick Strep A Plus test but did not correct their report to API to reflect the use of a moderately complex regulated test system and confirmed results were not reported to HHS.</p>