

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2071988	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier Greater Cincinnati Digestive Health Network	Street Address, City, State 3648 Werk Road, Cincinnati, OH	
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: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity diagnostic slide interpretations performed in 2024. This deficient practice had the potential to affect 15,016 out of 15,016 patients tested in the subspecialty of Histopathology from 01/01/2024 through 12/31/2024. Findings Include: 1. Review of the laboratory policy and procedure titled, "Quality Assurance Plan" approved by the the LD on 03/21/2024, found the following statement: "...4) Results of the proficiency/accuracy verification (performed twice annually as per procedure in April and October) will be summarized and reported on the end of year assurance meeting..." 2. Further review of an untitled black three-ring binder containing laboratory policies and procedure found no other mention of TAV for high complexity diagnostic slide interpretations. 3. Review of "Proficiency Testing" documents found high complexity diagnostic slide interpretation TAV for 2025 only. 4. The Inspector requested the high complexity diagnostic slide interpretation TAV documents for 2024 from the LD. The LD confirmed the laboratory did not follow the policy and procedure for high complexity diagnostic slide interpretation TAV activities at least twice annually in 2024 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/18/2025 at 11:00 AM.</p>