

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0702730	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Great Lakes Physician Pc	Street Address, City, State 3085 Harlem Road, Suite 200, Cheektowaga, NY	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of standard operating procedures (SOPs), analyzer maintenance records, as well as interview with the Technical Consultant (TC), the laboratory failed to document Clinitek Advantus Urinalysis Analyzer monthly maintenance. FINDINGS: 1. The current, approved Clinitek Advantus Urinalysis Analyzer SOPs indicated daily and monthly maintenance performance and documentation. 2. Monthly analyzer feed table bleach solution treatment was not documented on the Clinitek Advantus Maintenance log sheet for June through September of 2022; March 2023, June through December of 2023; and February through October of 2024. 3. The TC confirmed the findings on November 19, 2024, at approximately 1:00 P.M.</p>