

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2039427	(X3) Date Survey Completed 06/10/2025
Name of Provider or Supplier Park Avenue Gastroenterology And Digestive Health	Street Address, City, State 755 Park Avenue, Suite 200, Huntington, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of analytic system activities as well as interview with the Laboratory Director (LD), the laboratory failed to retain reference facility patient slide tracking form/manifest. FINDINGS: 1. There was no documentation of the Theranostix, Inc. /P4 reference laboratory patient slide tracking form/manifest. 2. LD informed the surveyor that the respective form/manifest was discarded. 3. The LD confirmed the findings on June 10, 2025, at approximately 10:30 A.M.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</p> <p>This STANDARD is not met as evidenced by: Based on the review of microscope manufacturer specifications, daily function check records, Standard Operating Procedures (SOPs), as well as interview with the LD, the</p>

laboratory failed to comply with microscope manufacturer specifications. FINDINGS:
1. Nikon microscope manufacturer specifications indicated daily function checks prior to patient testing. 2. There was no documentation of daily Nikon microscope function checks from 2024 through the survey date. 3. The current, approved SOPs did not include instructions for performing such activity. 4. It was noted that 2023 daily Nikon microscope function checks documented different laboratory name and demographics. 5. The LD confirmed findings on June 10, 2025, at approximately 11:00 A.M.