

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2235273	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Dkp Gastrointestinal Laboratory	Street Address, City, State 26 E Red Bank Ave, Woodbury, NJ	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Leica DM2000 LED and DM 750 Microscopes, Leica ASP 300S, Leica HistoCore Spectra ST Stainer, Leica HistoCore Arcadia C Cold Plate, Leica Autocut Rotary Microtome and Leica Bond-Max Instruction Manuals (IM) and interview with the Laboratory Director (LD) and Testing Personnel (TP) provided on the CMS-209, the laboratory failed to provide the correct room temperature and humidity per the IM's requirements in the laboratory from 9/8/21 to the date of the survey. The findings include: 1. The surveyor observed that the strictest requirements for room temperature was 20-26C and humidity was 30-80% based on the IM's specifications. 2. The LD and TP confirmed on 8/15/23 at 11:00 am that the acceptable laboratory room temperature and humidity provided on the daily log was not strict enough.</p>