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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2208926 | (X3) Date Survey Completed 12/12/2024 |
| Name of Provider or Supplier Greater Hazleton Gastroenterology | Street Address, City, State 10 Park Place, Hazleton, PA | |
| 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 review of laboratory records, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 OmanO Biological Microscope used to perform histopathology slide examinations from 03/21/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the OmanO biological microscope states: "microscope should be kept at temperatures between 0C-40C/32F-104F, with a maximum humidity of 85%." 2. On the date of the survey, 12/12/2024 at 12:40 pm, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for the 1 of 1 OmanO biological microscope (s/n 0814858) used to perform histopathology slide examinations from 03/21/2023 to 12/12/2024. 3. The laboratory performed 4933 histopathology slide examinations from 03/21/2023 to 12/12/2024. 4. The LD confirmed the findings above on 12/12/2024 at 12:45 pm.</p> |