| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D1038526 | 04/08/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ne Gastroenterology Associate Pc | 2812 Scranton-Carbondale Hwy, Blakely, 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 |
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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory temperature and humidity records, lack of documentation and interview with Testing Personnel (TP) #3, the laboratory failed to monitor and document temperature and humidity to ensure proper test system operating conditions were met for instrumentation used to perform histopathology testing for 188 of 631 days from 07/17/2023 to 04/08/2025. Findings include: 1. On the day of survey, 04/08/2025, review of the laboratory's temperature and humidity logs revealed the laboratory failed to monitor and document room temperature (laboratory's acceptable range: 20 to 26 degrees Celsius) and humidity (laboratory's acceptable range: 30 to 80%) to ensure proper test system operating conditions were met for 188 of 631 days from 07/17/2023 to 04/08/2025 for the following: - 1 of 1 Tissue-Tek VIP Processor - 1 of 1 Leica EG1160 Embedder - 1 of 1 Leica ST 5020 Stainer - 1 of 1 Leica RM2235 Microtome 2. The hours of laboratory testing are Monday-Friday 08:00 am to 05:00 pm (CMS 116). The laboratory could not provide documentation of temperature and humidity taken on days the laboratory was closed. 3. TP#3 confirmed the above findings on 04/08/2025 at 1:58 pm. |
| **D5805** | TEST REPORT |

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| | CFR(s): 493.1291(c)<br><br>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 1 of 1 patient test report and interview with Testing Personnel (TP) #3, the laboratory failed to include the address of the laboratory location where histopathology testing was performed from 07/17/2023 to the day of survey. Findings Include: 1. On the day of survey, 04/08/2025 at 12:50 pm, review of 1 of 1 patient test report revealed the laboratory failed to include the address of the laboratory location where histopathology examinations were performed from 07/17/2023 to 04/08/2025. 2. The laboratory reported an estimated annual volume of 4844 histopathology examinations performed in 2024. (CMS 116) 3. TP #3 confirmed the findings above on 04/08/2025 at 12:50 pm. |