| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 34D0981311 | 08/06/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wilmington Gastroenterology Associates, Pa | 5115 Oleander Drive, Wilmington, NC | |

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** |
|---|---|
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on policy and procedure reviews, and interview with testing personnel (TP) 08 /06/2024, the laboratory's competency assessment polices had not been updated to reflect the current competency performed by pathologist. Findings: Review of Histology Quality Control/Quality Assurance Policy, page 3, 2. f., revealed, "Quarterly, a blind review of 15 cases signed by each pathologist will be performed. Results are kept in QA/QC book for year." Review of Peer Education Programs /Proficiency Testing for Pathologists, page 1, "PURPOSE: ...Proficiency testing to assess competency will occur quarterly for pathologists," and "POLICY: ...2. To |

| | |
|---|---|
| | assess Competency of pathologists, a blind review of 5 cases every 6 months will be performed." During interview at approximately 1:01 p.m. TP-1 confirmed the competency assessment for pathologists do not match in both documents. TP-1 stated the pathologists are doing blind reviews of 5 cases every 6 months for competency assessment and not 15 cases per quarter. TP-1 stated the quality policy isn't the current process and needs to be updated to match 5 cases every 6 months. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies and procedures, review of 2022, 2023, and 2024 maintenance logs, and interview with testing personal (TP) 08/06/2024, the laboratory failed to establish humidity ranges for proper functioning of equipment and slide storage. Findings: Review of policy WG100 "Histology Quality Control/Quality Assurance Policy" revealed, page 2, "k. A daily temperature and humidity check ...to ensure proper functioning of equipment and slide storage...humidity between 30 to 70%." Review of "Temperature/Humidity Log" revealed, "Room Temp 50-86F... Humidity Range 20-85%." The laboratory's established humidity range 20 - 85% does not meet the specification requirements listed in policy WG100 30-70%. During interview at approximately 1:22 p.m. TP-2 stated she did not notice the document was outdated and the humidity ranges do need updating. |