

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2156916	(X3) Date Survey Completed 06/05/2024
Name of Provider or Supplier Queen City Gastroenterology And Hepatology, Pc	Street Address, City, State 320 Lillington Avenue, Suite 101, Charlotte, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based upon observation inside the laboratory's refrigerator on 6/5/24, review of storage requirements printed on reagent bottles and interview with TP (Testing Personnel) #2 on 6/5/24, the laboratory failed to store its Alcian Blue/PAS (Periodic acid-Schiff) Stain kit as required by the manufacturer. Findings: Surveyor observed an unopened Alcian Blue/PAS Stain kit in the laboratory's refrigerator at approximately 10:40 a.m. Review of the storage requirements printed on the reagent bottles revealed a storage temperature of 15-30 degrees Celsius. In interview at approximately 10:40 a. m., TP#2 stated that the laboratory has always stored its PAS stain in the refrigerator.</p>
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>

This STANDARD is not met as evidenced by:
Based upon review of 2023 and 2024 maintenance logs, review of the Lab Pulse 3618 H&E (hematoxylin & eosin) Automatic Slide Stainer User Guide, review of the Lab Pulse 1550 Tissue Embedding Center User Guide and interview with TP (Testing Personnel) #2 on 6/5/24, the laboratory failed to document its humidity when operating equipment in the laboratory area. Findings: Review of 2023 and 2024 maintenance logs revealed the absence of documentation of the laboratory's humidity. Review of the Lab Pulse 3618 H&E Automatic Slide Stainer User Guide revealed in its Maintenance section: "... store in a well ventilated room with humidity levels under 80%." Review of the Lab Pulse 1550 Tissue Embedding Center User Guide revealed in its Maintenance section: "... store in a well ventilated room with humidity levels under 80%." In interview at approximately 10:25 a.m., TP#2 confirmed she does not document the humidity in the laboratory.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based upon review of the Lab Pulse 3618 H&E (hematoxylin & eosin) Automatic Slide Stainer User Guide, review of the laboratory's 2023 and 2024 automatic stainer maintenance logs and interview with TP (Testing Personnel) #2 on 6/5/24, the laboratory failed to perform and document all instrument maintenance activities required by the manufacturer. Findings: Review of the Lab Pulse 3618 H&E Automatic Slide Stainer User Guide revealed in its Maintenance section: "Lubricate the container cover front hinge pins once a week and clean the stainer after each use." Review of 2023 and 2024 automatic stainer maintenance logs revealed the following:
1. No documentation of lubricating the container cover front hinge pins once a week.
2. No documentation of cleaning the stainer after each use. In interview at approximately 10:30 a.m., TP #2 stated the following: 1. She does not lubricate the stainer. 2. The stainer is cleaned regularly; however, this task is not documented.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based upon review of training and competency records and review of the Laboratory Director's Responsibilities and Duties policy, the Laboratory Director failed to ensure the performance of competency assessments of 2 of 2 grossing staff employed in the laboratory. Findings: Review of training and competency records revealed the following: 1. Documentation of the initial training of TP (Testing Personnel)#2 from

October 2022 was observed. 2. Documentation of the initial training of TP #3 from January 2022 was observed. 3. No documentation of the assessment of competency for either employee was observed. Review of the Laboratory Director's Responsibilities and Duties policy revealed the following in section: "Non-Delegated Responsibilities": "9. Oversee the laboratory personnel performance on competency including corrective actions, training and documentation." "17. Maintaining and reviewing the competency and laboratory performance of personnel." "18. Oversees and records documentation of competency assessment of testing personnel to include new hires annual competency assessment."