Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2156916	11/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Queen City Gastroenterology And Hepatology, Pc	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, review of laboratory records and absence of documentation, and phone interview with the LD(laboratory director) 11/15/21, the laboratory failed to verify accuracy of testing for the tissue microscopic examination at least twice a year in 2019, 2020, and 2021. Findings: Review of the laboratory's Quality Assurance procedure revealed, " 3. Pre-analytic, Analytic, and Post Analytic Systems....3. the following areas are included under these policies and procedures for Post-analytic Systems. a. Peer Review- Quarterly a review will be conducted on 5 surgical cases. Any issues or discrepancies will be noted and sent to another pathologist. b. Consultation review- A review of all consultations for pathology cases will be conducted to verify diagnostic consistency and maintain the highest standard of reporting accuracy possible. In addition, this will serve as a feed-back mechanism for the pathologist to evaluate their diagnostic skills." Review of the laboratory's records revealed there was no documentation that the laboratory had sent out cases for verification of accuracy in 2019 and 2021. There were 2 cases that were sent out to other laboratories for consultation in August and October 2020, but no other records to indicate the laboratory had verified accuracy of testing twice a year since the laboratory opened in January 2019- a period of approximately 34 months. During phone interview with the LD at approximately 3:45pm on 11/15/21, the LD confirmed there was no record on file that verification of accuracy was performed twice a year. He stated that he had shared slides for a second pathologist to review during 1st of 2021, but there was no record of that review on file.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with TP #1(testing personnel)11/15/21, the laboratory failed to discard reagents when they had exceeded their expiration date. Findings: During tour of laboratory and storage area at approximately 3:15pm., the surveyor observed the following reagents that had expired: a. One bottle of Bluing Reagent- Lot # 511093, expiration date: 10/21- located in safety storage cabinet in laboratory, available for use; b. One bottle of Clear Rite 3- lot #511060, expiration date: 10/21- located in safety storage cabinet in laboratory and two bottles of Clear Rite 3 with same lot number located in safety storage cabinet in storage room, available for use; c. One opened box of 10% Neutral Buffered Formalin- lot #068220, expiration date: 8/1/21- located in safety storage cabinet in storage room, available for use; d. Six unopened boxes of 10% Neutral Buffered Formalin- lot# 1714303, expiration 5/30/19-located in safety storage cabinet in storage room, available for use; TP#1 confirmed at approximately 3:20pm. that the reagents were expired.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, review of the laboratory's quality control records and absence of documentation, and interview with TP#1(histology technologist) 11/15/21, the laboratory failed to document control procedures for each special stain performed in 2019, 2020, and 2021. Findings: The laboratory performs manual Giemsa and AB-PAS(Alcian blue/periodic acid- Schiff) special staining procedures. Review of the laboratory's procedures revealed "Section 4. Staining... Policy: 1. All special stains must be run with a known positive control...4. All special stains will be entered on the Special Stain Quality Assurance Log and reviewed by the Pathologist. a. The Histology Special Stain Quality Assurance log was designed to keep a record of all special stains done and a check for acceptability of results. b. The slide accession number, date, and stain are to be logged. c. If the stain needs to be repeated or is unacceptable, it will be noted on this log." Review of stain Quality control logs revealed absence of documentation for the control slides for each special stain performed in 2019, 2020, and 2021. At approximately 2 p.m., TP#1 confirmed the laboratory only began documenting the positive control for the special stains in August 2021-(a period of approximately 31 months from the time the laboratory began testing until August 2021 when documentation started). She stated before that, they were performed but were not documented.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, verification of accuracy records, Quality control and Quality Assessment records, and TP(testing personnel) training and competency records 11/15/21, the LD(laboratory director) failed to provide overall management and direction of the laboratory. Findings: 1. The LD failed to ensure responsibilities were delegated to personnel that met the qualifications to perform the responsibilities. See D6079. 2. The LD failed to ensure verification procedures for the tissue microscopic examination was adequate to determine the accuracy of the testing performed. See D6086. 3. The LD failed to ensure the QA program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D6096. 4. The LD failed to ensure that TP had documented training for the performance of the gross examination of patient specimens. See D6102. 5. The LD failed to ensure TP competency procedures were established. See D6103. 6. The LD failed to evaluate the competency of TP. See D6120.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures and personnel records, review of the Medical Director job description, and review of the Delegation of responsibility 11/15 /21, the LD(laboratory director) failed to ensure responsibilities were delegated to personnel that met the qualifications to perform the responsibilities. Findings: Review of the laboratory's procedures revealed the Medical Director's Job description signed by the laboratory director 4/1/19 that stated, "...Delegation: The Medical director need not perform all responsibilities personally, Technical duties may be delegated to qualified laboratory personnel. Administrative duties may be delegated to qualified laboratory personnel. The Medical Director, however, remains responsible for the overall operation and administration of the laboratory." Review of the "Laboratory Director Responsibilities Delegation/Non-delegation" revealed the laboratory director delegated some responsibilities to TP#1(histology technologist) on 4/1/19. Some of the delegated responsibilities are duties that would be performed by the Technical

	Supervisor or General Supervisor in Histopathology. For example, the delegation stated, "Delegated Responsibilities: As Director, I delegate the following to the Histotechnologist: 1. Observation and review of monthly QC...3. Review of performance on Proficiency Testing results, including: recommendations on corrective actions and documentation....12. Overseeing laboratory personnel performance and competency...13. Planning for training or continuing education needs..." Review of personnel records revealed TP#1 has a Bachelor's Degree in a Biological Science and does not qualify to perform these responsibilities in Histopathology.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory QA(Quality Assessment)polices and procedures, review of laboratory records and absence of documentation 11/15/21, and the deficiency cited at D5217, the LD failed to ensure verification procedures for the tissue microscopic examination was adequate to determine the accuracy of the testing performed. 1. The LD failed to ensure the laboratory had a policy that stated specifically what the verification of accuracy for the tissue microscopic examination would consist of and failed to ensure the laboratory performed a bi-annual verification of accuracy for the microscopic examination. Findings: Review of the "General QA Plan" revealed. "1. Histopathology Second Pathologist Review: a. As a general rule, any clinically unsuspected malignancy, rare or unusual malignancy, or any case deemed appropriate by the pathologist should be reviewed by a second pathologist.... b. All unusual cases should have a second pathologist review and concur, for example: Any case where the pathologist determines a second opinion is warranted..... c. Pathologists will be responsible for documenting consultations and case reviews..." Under Pre-Analytic, Analytic, and Post- Analytic System....."A. Peer Review-Quarterly a review will be conducted on 5 surgical cases...." The laboratory had a policy for processing the slides for consultation review, but the policy failed to include what is reviewed by the Second pathologist. For example: Are the slides reviewed for correct staining? Are they reviewed to confirm diagnosis? The laboratory also failed to include in the policy the name of the second pathologist who will perform the review and the address where the slides will be sent. Review of verification of accuracy records for the tissue microscopic examination revealed no documentation for performance of a verification of accuracy in 2019, 2020, and 2021. See D5217.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	Based on review of the Medical Director Job Description, review of the laboratory's QA(Quality Assessment) procedures, review of QA records, and interview with TP#1 (Histology technologist) 11/15/21, the LD(laboratory director) failed to ensure the QA program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: The Medical Director Job Description stated, "Supervision exercised: Responsible for direction of the Laboratory...Essential Duties and Responsibilities include the following but not limited to:....Assumes responsibility for implementation of the quality assurance plan.... Review of the laboratory's QA procedure revealed, "Section 6. Quality Assurance...Program: A. Assign Responsibilities. The Medical Director is responsible for the complete Quality Assurance(QA) program. The histology department will be responsible for the data collection and reporting. The data will be reviewed by the Medical Director.... D. Collect/Organize data. 1. Daily.....2.. Weekly... 3. Quarterly: The Medical Director(or his designee) is to review the following: a. Monthly QA Documentation Checklist- Complete all appropriate sections. This will be reviewed monthly...." For example, the laboratory collects data on a daily and weekly basis, and completes a Monthly QA Documentation Checklist that is reviewed by the Medical Director. The QA procedure also revealed under 6.0 General Guidelines, "Assessment required for: 1. Patient test management. 2. Quality Control. 3. Proficiency Testing. 4. Test comparisons. 5. Relate results to clinical data. 6. Personnel. 7. Communications. 8. Complaints. 9. Staff Review. 10. Records." Review of the laboratory's 2019, 2020, and 2021 QA records revealed: 1. The LD failed to ensure the laboratory's QA program was maintained. A Monthly Quality Assessment Report was completed for August 2021, September 2021, and October 2021. There was no other documentation of QA records from the time the laboratory opened in January 2019 until August 2021- a period of approximately 31 months. At approximately 2 p.m., TP #1 confirmed the laboratory only began completing the QA reports in August of 2021. 2. The laboratory's QA program failed to identify problems that were identified during the survey in the following areas: a. Proficiency Testing/Verification of accuracy of testing. See D5217; b. Expired Reagents. See D5417; c. Quality Control. See D5601; d. Testing personnel training. See D6102; e. Testing personnel competency. See D6103 and D6120.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Medical Director's job description, review of personnel records, absence of documentation, and interview with TP#1(histology technologist) and outside consultant 11/15/21, the LD(laboratory director) failed to ensure that testing personnel had documented training for the performance of the gross examination of patient specimens. Findings: The Medical Director's job description stated, ..."Ensures that there are sufficient qualified personnel with adequate documented training and experience...." Review of personnel records revealed the only documented training for TP#1 was for H&E(Hematoxylin & Eosin) Autostainer (staining) verification that was performed by the outside consultant on 1/30/19. There

	was no additional training documented for TP#1 for the gross examination of patient specimens. Interview with TP#1 at approximately 12:45pm confirmed there was no documentation of her training for the gross examination. She and the outside consultant confirmed that her training included the gross examination procedure but documentation of the training was not completed.
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 on review of laboratory's procedures, review of personnel records and absence of documentation 11/15/21, and the deficiency cited at D6120, the LD(laboratory director) failed to ensure TP(testing personnel) competency procedures were established that meet the regulations as stated in section 493.1451(b)(8) of 42 CFR Part 493 Requirements for Laboratories. Section 493.1451(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Findings: 1. Review of the laboratory's procedures revealed no procedures established for the competency assessment of the TP. Review of personnel records revealed there was no documentation of competency assessments performed for TP#1 in 2019, 2020, and 2021. See D6120.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the Histology technician job description, review of the laboratory's QA(quality assessment) plan, review of personnel records, and phone interview with the laboratory director 11/15/21, the technical supervisor failed to evaluate the competency of 1 of 3 TP(testing personnel

	#1) as required in 2019, 2020, and 2021. Findings: The laboratory director serves as TS(technical supervisor) for the laboratory. The laboratory's procedure Section 3. General Histology. 1. Grossing of Surgical Specimens stated, "Purpose: To clearly define the guidelines set forth for the evaluation of the grossing personnel to ensure the quality /clarity of gross descriptions and the specimens examined and dissected.... Pathologist: Supervises indirectly all gross examinations and evaluates the performance of all grossing personnel on a periodic basis. Reviews all gross descriptions at the time of performing the microscopic tissue examination and diagnosis." Review of the job description for they Histology Technologist revealed, "Reports to: Reports directly to the Laboratory Director for grossing task and specific histological techniques....Supervision Received: ...Reports to the Laboratory Director for responsibilities that include the biopsy dissecting tasks and histology procedures..." Review of the laboratory's General QA plan revealed, "...4. Annually: a. Employee evaluations will be performed....c. Competency Assessments will be completed by the immediate supervisor at 90 days of hire and then annually as required by CLIA and CAP..." Review of personnel records revealed TP#1 was hired in January 2019 before the laboratory began testing that month. There was no documentation of competency assessments being performed to evaluate the competency of TP#1 twice in the first year of her performing gross examinations in 2019, or any documentation of annual competency assessments in 2020 and 2021- a period of approximately 34 months since TP#1 began testing. Phone interview with the laboratory director at approximately 3:40 p.m. confirmed there was no documentation of competency assessments for TP#1 in 2019, 2020, and 2021. He stated he has indirectly observed her performance by review of the grossing reports and has directly observed her a few times, but there was no documentation available.