Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2162899	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ku Wichita Gastroenterology	8533 E 32nd Street North, Wichita, KS	

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
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of documentation of control procedures performed, review of the patient report and interview with the Officer of Regulatory Affairs (ORA), the laboratory failed to document quality control (QC) results for histopathology staining for 1408 patient reports from 4/6/22 to 2/15/24. Findings: 1. Surveyor requested QC stain documentation for Hematoxylin & Eosin and IHC stains used for patient testing. No documentation was provided at the time of survey. 2. Surveyor asked if stain quality was documented on the patient test report. The ORA stated documentation of acceptable stain quality was not included on the patient test report. 3. Interview with the ORA on 2/15/24 at 9:10 a.m. confirmed, the laboratory failed to document QC results for histopathology staining for 1408 patient reports from 4/6/22 to 2/15/24.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: The laboratory fails to monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for histopathology testing performed. See D5805 and D5893.
D5805	TEST REPORT CFR(s): 493.1291(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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the ORA, the laboratory failed to list the correct name and address of the laboratory where the professional component of the test was performed on the patient report. Findings: 1. Review of selected patient test reports showed that the professional component of the test was performed digitally under the 8533 E 32nd Street, Wichita, KS 67226 location. 2. The surveyor asked if the digital camera and/or monitor used to review digital images was located at the Wichita, KS address listed on the patient report. The ORA stated that no components of the digital review process were located at the Wichita, KS address. 3. From 4/6/22 to 2/15/24, 1408 patient reports were released with 8533 E 32nd Street, Wichita, KS 67226 as the performing laboratory location for the professional component. 4. Interview with the ORA on 2/15/24 9:15 a.m. confirmed, the laboratory failed to list the correct name and address of the laboratory where the professional component of the test was performed on the patient report.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the incorrect performing laboratory location on patient reports, lack of documentation to identify and correct the testing location error, and interview with the ORA, the laboratory failed to take corrective action to address errors on the patient report. Findings: 1. Review of selected patient reports found the address of the performing laboratory was incorrect on all patient reports provided at the time of survey. 2. No documentation of a review process to identify the error on the patient report error was provided at the time of survey. 3. From 4/6/22 to 2/15/24, 1408 patient reports were released with 8533 E 32nd Street, Wichita, KS 67226 as the performing laboratory location (digital review) for the professional component. 4.

	Interview with the ORA on 2/15/24 at 9:15 a.m. confirmed, the laboratory failed to take corrective action to address errors on the patient report.