Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2162899	04/25/2024
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on the review of the allegation of compliance (AOC), onsite revisit, lack of written procedure for the transport of histopathology slides and interview with the officer of regulatory affairs (ORA), the laboratory failed to have procedures for the transportation of histopathology slides from the technical laboratory to the professional laboratory. Findings: 1. Review of the AOC, signed by the laboratory director on 3/14/24 states under D5805 the following: "The slides are then shipped to the professional lab (17D2162899), and a pathologist visits on a monthly schedule to review all cases and issue the Final medical reports with the diagnosis and CPT

	codes." 2. The surveyor asked to see the procedure for the shipping of the slides to the professional lab. No procedure was provided at the time of survey. 3. In interview with the ORA via a Teams meeting on 4/24/24 at 1 p.m. confirmed, the laboratory failed to have procedures for the transportation of histopathology slides from the technical laboratory to the professional laboratory.