| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D2127485 | 04/24/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kansas Gastroenterology | 3121 N Webb Road, 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 |
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| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of procedure "Specimen Handling and Accessioning Procedure," lack of documentation for unacceptable specimens using the "Specimen Rejection Form" and interview with the ED, the laboratory failed to follow written procedure for the documentation of unacceptable specimens. Findings: 1. During a tour of the laboratory, the surveyor requested documentation of how the laboratory documented unacceptable specimens. The surveyor was shown a legal pad where specimen information was written down. 2. The surveyor requested the preanalytic quality assessment procedure. The document "Specimen Handling and Accessioning Procedure" was provided. Review of the procedure revealed the following: a. On page 2, under "Specimen Rejection: The following are the criteria for specimen rejection: Specimens received without labeling, patient's name and source of specimen. Specimen labels not matching requisition. Specimens left without formalin for over five (5) hours. Any specimen lacking the above sited information will be rejected and brought into attention to responsible personnel. Once the Specimen Rejection Form is completed and all errors are corrected, the specimen will then be accepted for processing. 3. The surveyor asked to review the specimen rejection form for the entries on the legal pad. No documentation was provided at the time of survey. 4. Interview with the ED on 4/24/24 at 10:35 a.m. confirmed, the laboratory failed to follow written procedure for the documentation of unacceptable specimens. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES |

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| | CFR(s): 493.1451(b)(7)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's CMS-209 Laboratory Personnel form, lack of competency assessment documentation and interview with the Executive Director (ED)), the Technical Supervisor (TS) failed to perform the six month competency for two of two high complexity testing personnel (TP). Findings: 1. Review of the CMS-209 Laboratory Personnel form found two individual listed as high complexity TP that had performed histopathology testing at this site for more than six months and were not listed on the CMS 209 for the previous survey on 7/20/22. 2. The surveyor requested the six month competency for the two new TP. No six month competencies were provided at the time of survey. 3. Interview with the ED on 4/24/24 at 9:35 a.m. confirmed, the TS failed to perform the six month competency for two of two high complexity TP. |