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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>32D0708697      | <b>(X3) Date Survey Completed</b><br>01/27/2023 |
| <b>Name of Provider or Supplier</b><br>Southwest Gastroenterology Associates   | <b>Street Address, City, State</b><br>7788 Jefferson St Ne, Albuquerque, NM |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | Based upon the initial onsite survey conducted on 01/27/2023, the laboratory was found to be in substantial compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed with standard level deficiencies cited.  |
| <b>D3013</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on direct observation, record review, and confirmed by staff interview, the laboratory failed to monitor and document room conditions that ensure preservation of patient slides for 24 of 24 months (02/2021 - 01/2023). Findings included: 1. During a tour of the laboratory on 01/27/2023 at 11:30 am, the surveyor observed patient slides stored within the laboratory. Dates ranged from 02/2021 - 01/2023. 2. Review of the annual test volume submitted by the laboratory stated: a. Slide interpretation 2021 = 6355 b. Slide interpretation 2022 = 8553 3. During an interview on 01/27/2023 at 11:40 am in the laboratory, the surveyor requested environmental monitoring logs for the laboratory room. The Laboratory Director stated that the environmental conditions are not monitored and documented within the laboratory. This confirmed the above findings.</p> |
| <b>D5473</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials</p>  |

for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy, laboratory record review, and confirmed by staff interview, the laboratory failed to define the acceptable Hematoxylin and Eosin (H&E) quality control (QC) stain characteristics for 6 of 6 months (03/2021-05/2021 and 03/2022-05/2022). Findings included: 1. Review of the laboratory policy titled "4. C Histology Staining Quality Control", approved by the Laboratory Director on 02/12/2021, stated the following: "1. H&E Slide Review, a. The pathologist will assess the quality of the slides daily and initial the stain QC log for each day of staining." 2. Review of the laboratory form titled "Daily Staining QC Log", dated 03/2021-05/2021 and 03/2022-05/2022 listed criteria as: Y = Yes, adequate staining N = No, repeat /adjust The laboratory failed to define acceptable criteria for H&E stain characteristics. 3. During an interview on 01/27/2023 at 10:15 am in the conference room, after review of the above results, the laboratory director confirmed the above findings.