

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0708697	(X3) Date Survey Completed 08/12/2026
Name of Provider or Supplier Southwest Gastroenterology Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An onsite recertification survey conducted on August 12, 2026, at Southwest Gastroenterology Associates found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to ensure proper storage conditions were maintained for tissue blocks and slides in 2025 and January through July 2026. The laboratory reports 22,000 histopathology tests annually. Findings include: 1. During a laboratory tour on 08/12/2026 at 9:30 AM, no temperature or humidity monitoring equipment were observed in the tissue block and slide storage room. 2. A request was made for documentation demonstrating proper temperature and humidity was maintained in the tissue block and slide storage room in 2025 and January through July 2026, none was provided. 3. A request was made for a policy that specified proper block and slide storage conditions, none was provided. 3. During an interview with the LD on 08/12/2026 at 10:15 AM, the LD indicated temperature and humidity are not monitored in the tissue block and slide storage room. This confirmed the above findings. 4. The laboratory reports 22,000 histopathology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for

proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the Ventana Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody Manufacturer's Instructions (APK MI), review of the Cell Marque CDX-2 (EPR2764Y) Rabbit Monoclonal Antibody Manufacturer's Instructions (CDX-2 MI), review of the Tissue-Tek VIP6 AI Operator's Manual (VIP6 MI), review of the laboratory's Temperature and Humidity log, and interview with Testing Personnel 2 (TP2), the laboratory failed to document proper temperature storage conditions for the Ventana Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody (APK) and the Cell Marque CDX-2 (EPR2764Y) Rabbit Monoclonal Antibody (CDX-2) assays and failed to document proper temperature and humidity storage conditions for the Tissue-Tek VIP6 AI tissue processor for 176 days between January 2025 and July 2026. The laboratory reports 22,000 histopathology tests annually. Findings include: 1. During a laboratory tour on 08/12/2026 at 9:30 AM, immunohistochemical stains, including APK and CDX-2, were observed in the laboratory's refrigerator. A Tissue-Tek VIP6 AI tissue processor was also observed in the laboratory. 2. Review of the APK MI and CDX-2 MI revealed both stains required a storage temperature of 2-8Celsius (C). 3. Review of the VIP6 MI revealed the Tissue-Tek VIP6 AI required a storage temperature of 10-40C and humidity of 30-85%. 4. Review of the laboratory's Temperature and Humidity log revealed there was no temperature recorded for the refrigerator and no temperature or humidity recorded for the laboratory for 112 days in 2025 and 64 days between January and July 2026. 5. During an interview with the TP2 on 08/12/2026 at 10:15 AM, TP2 indicated temperature and humidity are not recorded by staff on the weekends. This confirmed the above findings. 6. The laboratory reports 22,000 histopathology tests annually.