

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2272086	(X3) Date Survey Completed 05/13/2025
Name of Provider or Supplier Spek Diagnostics	Street Address, City, State 155 E 50th St, Garden City, ID	
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	During an offsite paper revisit the laboratory was found to be in compliance with CLIA regulations (42 CFR Part 493 effective April 24, 2003.), all previous deficiencies found were corrected.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory director on 5/13/2025, the laboratory failed to discontinue the use of expired histopathology reagents. The findings include: 1. A direct observation of the laboratory's histopathology reagents on 5/13/2025 identified that the laboratory failed to discontinue the use of the following reagents prior to the expiration dates: 0.5% silver nitrate lot 187234 expiration 2024-12-31 0.3% gold chloride lot 194812 expiration 2025-03-31; two bottles 0.3% gold chloride lot 193805 expiration 2025-02-28 0.1% Hydroquinone lot 187236 expiration 2024-12-31 sodium borate concentrate lot 192239 expiration 2025-02-28 4% gelatin lot 183713 expiration 2024-10-31 3% hydrochloric acid lot 176970 expiration 2025-01-31 1% acid alcohol lot 163479 expiration 2024-12-31 Dako EnVision flex antibody diluent lot 11518383 expiration 2024-06-30 2. An interview with the laboratory director on 5/13/2025 at 3:24 pm confirmed the above finding. 3. The laboratory reports performing 30,000 tests annually.</p>