

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2272086	(X3) Date Survey Completed 09/12/2023
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with laboratory histotechnician 1 on 9/12/2023, the laboratory failed to document room temperature and humidity as required for operation of the Microm HM525 cryostat and the Leica RM 2235 microtomes. The findings include: 1. A review of the manuals for the Microm HM525 cryostat identified an operational temperature of 5-35 C and humidity of less than 60% and for the Leica RM 2235 microtome an operational temperature of 10-35 C and humidity of less than 80%. 2. A review of the laboratories daily logs identified that the laboratory failed to document room temperature and humidity since beginning testing in December 2022. 3. An interview with laboratory histotechnician 1 on 9/12/2023 at 10:45 am confirmed that the laboratory fail to document room temperature and humidity. 4. The laboratory reports performing 33,000 histopathology tests annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, instrument manual, laboratory records and an interview with laboratory histotechnician 1 on 9/12/2023, the laboratory failed to perform maintenance on the Leica RM2235 microtomes as defined by the manufacturer and laboratory policy. The findings include: 1. The laboratory procedure "Microtome Procedure" states "Microtomes are cleaned daily." 2. The Leica RM2235 microtome manual states to clean the instrument daily by removing the knife holder, disassemble and clean. Clean moving parts and apply drive part oil. Detach and clean the cassette clamp. 3. A record review of laboratory logs identified that the laboratory failed to document daily maintenance as required by the manufacturer on the two Leica RM2235 microtomes. 4. An interview with laboratory histotechnician 1 on 9/12/2023 at 10:45 am confirmed that the laboratory had not document performance of daily maintenance on the two Leica RM2235 microtomes. 5. The laboratory reports performing 33,000 histopathology procedures annually.