

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2046062	(X3) Date Survey Completed 03/28/2024
Name of Provider or Supplier Southwest Skin Laboratory Pllc	Street Address, City, State 1688 E Boston St, Ste 101, Gilbert, AZ	
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 lack of humidity records for review from 2022, 2023 and 2024, review of the manufacturer's specifications for the Avantik QS12 Cryostat, Sakura Tissue-Tek Prisma Automated Slide Stainer, Sakura Tissue-Tek VIP Vacuum Infiltration Processor, Roche Ventana Benchmark Ultra and Roche Ventana Benchmark Special Stains, and interview with the testing personnel (TP-2), the laboratory failed to monitor and document the humidity of the room where the above instrumentation is utilized. Findings include: 1. The laboratory utilizes the Avantik QS12 Cryostat and the Sakura Tissue-Tek Prisma Automated Slide Stainer in conjunction with Mohs testing under the subspecialty of Histopathology with a reported annual test volume of 2880. 2. The manufacturer's specifications for the Avantik QS12 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. The manufacturer's specifications for the Sakura Tissue-Tek Prisma Automated Slide Stainer and the Sakura Tissue-Tek VIP Vacuum Infiltration Processor reviewed during the survey listed an operating relative humidity range of 30%-85%. 4. The manufacturer's specifications for the Roche Ventana Benchmark Ultra reviewed during the survey listed an operating relative humidity range of 10%-90%. 5. The manufacturer's specifications for the Roche Ventana Benchmark Special Stains reviewed during the survey listed an operating relative humidity range of 20%-80%.</p>

6. On the survey date of 3/28/2024, no documentation was provided for review to indicate the laboratory monitored and documented the humidity of the room where the above instrumentation is utilized on each day of patient testing during 2022, 2023 and 2024 through the date of the survey. 7. The TP-2 interviewed on 3/28/2024 at 12:00 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.