

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2163901	(X3) Date Survey Completed 03/28/2024
Name of Provider or Supplier Desert Sky Dermatology PLLC	Street Address, City, State 1688 E Boston Street Suite 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 and the Sakura Tissue-Tek Prisma Automated Slide Stainer, and interview with the facility personnel, 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 2,880. 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 reviewed during the survey listed an operating relative humidity range of 30%-85%. 4. 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. 5. The facility personnel interviewed on 3/28/2024 at 10:20 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on 3/28/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1231 through 493.1236. 2. The facility personnel interviewed on 3/28/2024 at 10:40 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.