

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0924324	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier Alabama Dermatology And Rejuvenation Center, Pc	Street Address, City, State 1606 Hwy 78 West, Jasper, AL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of potassium hydroxide (KOH) records and an interview with the Laboratory Director, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) at least twice annually. This was noted from 2019 to 2021. The findings include: 1. A review of the potassium hydroxide (KOH) records revealed a lack of accuracy verifications being performed at least twice annually. 2. During an interview on 06/17/2021 at 11:20 AM, the Laboratory Director stated when a patient is performed the slide is split and reviewed twice by the same person, as quality control; but the accuracy is not being verified at least twice a year for KOH.</p>
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 review of the Avantik QS11 and QS11UV Cryostats Instruction Manual,</p>

lack of room temperature and humidity records, and an interview with the histology tech, the laboratory failed to monitor and document room temperature and humidity in the laboratory. The findings include: 1. A review of the Avantik QS11 and QS11UV Cryostats Instruction Manual stated "...Operating conditions: +5 degrees Celsius up to +35 degrees Celsius (at a maximum relative humidity of 60%)..." 2. A review of temperature records revealed room temperature and humidity for the laboratory had not been documented. 3. During an interview conducted on 06/17/2021 at 11:40 AM, the histology tech confirmed that the laboratory had not monitored room temperature and humidity.