

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1085870	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Arkansas Dermatology	Street Address, City, State 15506 Hwy 5 Ste A, Cabot, AR	
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: Through observations made during a tour of the laboratory, review of manufacturer's instruction manual, review of the laboratory's temperature and humidity records and interviews with staff, it was determined the laboratory humidity was not monitored with the manufacturer's requirement for the laboratory's The Avantik QS12 Cryostat, Avantik QS11 Cryostat, and Thermo Scientific Cryostat HM525. Survey findings include: A) During a tour of the laboratory on 5/11/23 at 11:49 a.m., The Avantik QS12 Cryostat, Avanti QS11 Cryostat, and Thermo Scientific Cryostat HM525 was observed in the main laboratory. B) Review of the manufacturer's instruction manual for The Avantik QS12 Cryostat, Avanti QS11 Cryostat, and Thermo Scientific Cryostat HM525 revealed conditions of operating requirement "+5C up to +35C (at a max. Relative humidity of 60%)". C) Review of the laboratory's room temperature and humidity log for 2021 revealed days recorded of laboratory operation were 236. Humidity recorded 0 out of 236. D) Review of the laboratory's room temperature and humidity log and for 2022 revealed days recorded of laboratory operation were 247. Humidity recorded 0 out of 247. E) Review of the laboratory's room temperature and humidity log and for 2023 revealed days recorded of laboratory operation were 82.</p>

Humidity recorded 0 out of 82. F) In an interview on 5/11/23 at 11:49 a.m. the laboratory staff member (# 10 on the CMS 209 form) confirmed that the laboratory failed to monitor humidity.