

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2171640	(X3) Date Survey Completed 09/08/2025
Name of Provider or Supplier Dermatology And Skin Cancer Consultants, Pllc	Street Address, City, State 96 Physicians Drive, Jackson, TN	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 laboratory observation, a review of the manufacturer's operator's manuals, a review of laboratory environmental records, patient test reports, and staff interview, the laboratory failed to monitor laboratory humidity readings in 2024 and 2025. The findings include: 1. Laboratory observation on 09/08/25 at 8:15 a.m. revealed an Avantik cryostat, Linistat automated stainer, inks, stains, and reagents used to process tissue removed during Mohs surgery in preparation for slide interpretation. 2. A review of the manufacturer's operator's manual and environmental requirements revealed the following: For the Linistat Automated Stainer, the maximum relative humidity was up to 80%. For the Advantik cryostat, the maximum relative humidity was up to 60%. 3. A review of the laboratory's 2024 and 2025 environmental records revealed no documentation that the laboratory monitored humidity readings. 4. A review of randomly selected test records revealed the following patient case numbers performed during the period when humidity was not monitored: J24-0282 on 04/01/24, J24-0932 on 11/06/24, J25-205 on 03/05/25, J25-543 on 06/23/25, and J25-758 on 09/04/25. 5. The lead histotech confirmed the survey findings during an interview on 09/08/25 at 10:30 a.m.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on laboratory observation, staff interview, and review of an electronic mail communication, the laboratory failed to ensure expired hematoxylin and eosin stains were not used past the expiration date from 11/11/24 to the date of the survey on 09/08/25. The findings include: 1. Laboratory observation on 09/08/25 at 8:15 a.m. revealed an Avantik cryostat, Linistat automated stainer, inks, stains, and reagents used to process tissue removed during Mohs surgery in preparation for slide interpretation. During observation, containers of stains were noted that had expired: hematoxylin lot number 2229905, expiration date of 11/10/24, and eosin lot number 2304107, expiration date of 02/21/25. 2. The lead histotech confirmed the expired stains were being used to stain patient tissue during an interview on 09/08/25 at 8:20 a.m. 3. A review of an email received on 09/15/25 at 2:48 p.m. revealed that 811 Mohs surgery patients had slides stained during the period of expired stain use.