

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2262657	(X3) Date Survey Completed 06/20/2024
Name of Provider or Supplier Dermatology Southeast	Street Address, City, State 1807 3rd Street North, Jacksonville Beach, FL	
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
D0000	At the time of the announced, on-site recertification survey, Dermatology Southeast was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to retain the daily quality control (QC) slide for the Hematoxylin and Eosin stain for one of four testing days in March 2024. The findings include: The record review of the "Mohs Quality Control Staining" log provided by the facility for January 2024 through June 2024 showed that slide quality for the Hematoxylin and Eosin stained specimens was documented as "ok" on 3/5/24, 3/12/24, 3/19/24, and 3/26/24. The facility was unable to provide the 3/12/24 quality control slide for verification of retention. Interview with the Office Manager on 6/20/24 at 11:15 AM confirmed that the QC slide was missing.</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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document the room temperature and humidity of the laboratory for 1 of 2 days reviewed in July 2023, 1 of 4 days reviewed in March 2024; and failed to ensure the cryostat temperature was documented for 1 of 2 days reviewed in July 2023, 1 of 4 days in March 2024, and 1 of 3 days in April 2024. Findings include: 1. The review of the laboratory document titled "Hematoxylin & Eosin Quality Control & Maintenance Linistat Linear Stainer" dated July 2023 showed the room temperature, humidity, and cryostat temperature was not documented on July 16, 2023. Review of the Mohs specimen log showed patient testing was performed on 7/16/23 and 7/31/23. 2. The review of the laboratory document titled "Hematoxylin & Eosin Quality Control & Maintenance Linistat Linear Stainer" dated March 2024 showed the room temperature, humidity, and cryostat temperature was not documented on March 26, 2024. Review of the Mohs specimen log showed patient testing was performed on 3/5/24, 3/12/24, 3/19/24 and 3/26/24. 3. The review of the laboratory document titled "Hematoxylin & Eosin Quality Control & Maintenance Linistat Linear Stainer" dated April 2024 showed the cryostat temperature was not documented on April 16, 2024. Review of the Mohs specimen log showed patient testing was performed on 4/2/24, 4/16/24, and 4/30/24. During the interview on 6/20/24 at 11:00am with the Office Manager, it was confirmed the documentation was missing.