

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2089763	(X3) Date Survey Completed 08/01/2024
Name of Provider or Supplier Uf Health Dermatology Deerwood Park	Street Address, City, State 10475 Centurion Pkwy N Ste 106, Jacksonville, 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, onsite recertification survey, UF Health Dermatology Deerwood Park was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, failed to ensure the cryostat temperature was documented for 3 of 4 days reviewed in June 2024. Findings include: Review of the laboratory document titled "Cryostat Maintenance" dated June 2024 showed documentation on 6/24/24 of the temperature of cryostat #1 and #2. Review of the Mohs log showed testing was performed on 6/3/24, 6/17/24, 6/20/24, and 6/24/24. During the interview on 8/1/24 at 3:30pm with the Department Director, it was confirmed the documentation was missing for the three days.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials</p>

for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the facility failed to maintain daily quality control (QC) slide documentation for Mohs testing for 2 out of 4 testing days reviewed in June 2024. Findings include: Record review of the Mohs Accession Log showed 6 cases of Mohs were tested on 6/3/24 and 6 cases of Mohs were testing on 6/17/24. Review of the document titled "Daily Slide QA Log" showed QC documentation on 6/20/24, and 6/24/24. There was no QC documentation for 6/3/24 and 6/17/24. During the interview with the Department Director on 8/1/24 at 2:45pm, it was confirmed the QC documentation was missing.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation for 3 of 7 months reviewed in 2024. Findings include: The record review of quality control documentation showed there was no record of lot numbers and expiration dates for the Hematoxylin and Eosin (H&E) stains that were used on patient histopathology slides during processing in May, June, and July 2024. The interview with the Department Director on 8/1/24 at 3:15pm confirmed that the laboratory was missing quality control logs that record the lot number and expiration dates for the H&E stains.