

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2028950	(X3) Date Survey Completed 07/10/2023
Name of Provider or Supplier Center For Dermatology, Pllc	Street Address, City, State 14275 N 87th St Suite 110, Scottsdale, AZ	
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: Based on lack of temperature records for review and interview with the facility personnel, the laboratory failed to monitor and document the room temperature and humidity of the area where dermatopathology stain reagents are stored and used for patient testing and where the cryostat is utilized. Findings include: 1. Each day patient testing occurred during 2021, the laboratory failed to monitor and document the room temperature of the area where dermatopathology stain reagents are used and stored. 2. The laboratory's daily temperature log showed an acceptable room temperature range of 70 degrees Fahrenheit (F) to 74 degrees F. 3. Each day of patient testing during 2021 and 2022, the laboratory failed to monitor and document the humidity of the area where the cryostat is used. 4. The manufacturer's instructions for the cryostat reviewed during the survey listed an acceptable operating relative humidity range of 0 - 60%. 5. The laboratory's reported annual test volume is 1,500. 6. The facility personnel interviewed on July 10, 2023 at 11:03 AM confirmed the laboratory failed to monitor and document the room temperature and humidity as indicated above.</p>
D5607	<p>HISTOPATHOLOGY CFR(s): 493.1273(d)(f)</p>

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of tissue pathology reports and interview with the facility personnel, the qualified individual who performed the examination and made the diagnosis failed to sign the Mohs test report for one patient. Findings include: 1. The laboratory performs patient testing in the subspecialty of Histopathology, with an approximate annual test volume of 1,500. 2. One out of one Mohs test reports (YSM21-402) reviewed in the Electronic Health Record (EHR) failed to include the electronic signature of the individual who performed the examination and made the diagnosis. 3. The facility personnel interviewed on July 10, 2023 at 10:30 AM confirmed the tissue pathology report indicated above was not signed by the individual who performed the examination and made the diagnosis.

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of pathology test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure test results are reliably sent to the patient's electronic health record (EHR). Findings include: 1. The laboratory performs patient testing in the subspecialty of Histopathology, with an approximate annual test volume of 1,500. Pathology reports are scanned into the patient's EHR by laboratory personnel. The EHR is the final report destination. 2. The laboratory failed to provide evidence of the pathology test report maintained in the patient's EHR for biopsy# PS23-FBX-05. 3. The laboratory failed to have a system in place to ensure patient test results are reliably sent to the patient's EHR. 4. The facility personnel interviewed on July 10, 2023 at 11:19 AM confirmed the laboratory failed to have a system in place to ensure patient test results are reliably sent to the patient's EHR.