

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0726124	(X3) Date Survey Completed 10/23/2019
Name of Provider or Supplier Illinois Dermatology Institute	Street Address, City, State 9711 Skokie Blvd, Suite J, Skokie, IL	
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review and an interview with the laboratory staff; the laboratory failed to perform and document the maintenance protocols as defined by the manufacturer and with at least the frequency specified by the manufacturer, to ensure equipment, instrument, and test system performances are accurate and reliable. Findings: 1. On 10/23/2019 at 10:40 AM during a tour of the laboratory, the surveyor observed a portable cryostat (C5) being used by the testing personnel (TP). 2. The laboratory's procedures' manual and the "Got Mohs" maintenance log were reviewed. 3. The maintenance log revealed the following: *The log states the cryostats were to be defrosted weekly. *The laboratory used 4 different cryostats (C1,C2, C3, and C4) during the months of September and October of 2019. *The cryostats were not defrosted during the above months. *The maintenance records for C5 were not documented. 4. The laboratory failed to perform and document the maintenance of all the portable cryostats brought into the laboratory for tissue processing prior to testing Mohs surgery patients. 5. On an Initial survey conducted on 10/23/2019 at 11:50 AM, the laboratory staff confirmed the above findings.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on direct observation, record review and an interview with the testing personnel (TP), the laboratory failed to establish a maintenance protocol to check the accuracy of the internal thermometer of the equipment used in Histopathology testing.

Findings: 1. On 10/23/2019 at 10:40 AM during a tour of the laboratory, the surveyor observed a portable cryostat with a built in-digital thermometer being used by the TP. 2. The laboratory's procedures' manual and the "Got Mohs" maintenance log were reviewed. 3. The maintenance log revealed the following: *The laboratory used 4 different cryostats (C1,C2, C3, and C4) during the months of September and October of 2019. *The log failed to include an accuracy check for the digital thermometers of the above portable cryostats. 4. The procedures' manual failed to establish a policy and procedure to verify the accuracy of any portable cryostats' digital thermometer when it is brought into the laboratory for tissue processing. 5. On an Initial survey conducted on 10/23/2019 at 11:50 AM, the laboratory staff confirmed the above findings.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on direct observation, lack of documentation, and an interview with the testing personnel (TP1), the laboratory failed to document each lot number of commercially prepared reagents and stains, when opened, to perform Hematoxylin and Eosin (H&E) staining procedures. Findings include: 1. On 10/23/2019 at 10:40 AM during a tour of the laboratory, the surveyor observed the following: *TP1 performing the tissue processing and H &E staining procedure for Mohs surgery tissue. *The reagents for the staining process were in individual plastic staining jars. *Each staining jar failed to indicate the reagent it contained, the reagent's lot number and expiration date. *The reagents and jars were provided by the travel Mohs service "Got Mohs" and brought with the "Got Mohs" TP on the dates Mohs surgery was performed. 2. The laboratory failed to ensure the travel Mohs service "Got Mohs" provided the laboratory with the list of reagents and their lot numbers and expiration dates when brought by the TP, to the laboratory, to perform H & E staining. 3. On an Initial survey conducted on 10/23/2019 at 11:50 AM, the TP and laboratory staff confirmed the above findings.