

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2263032	(X3) Date Survey Completed 07/09/2024
Name of Provider or Supplier Dermatology And Cosmetic Physicians, Sc	Street Address, City, State 1088 S Main St, Fond Du Lac, WI	
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
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 for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records and laboratory procedures and interview with the laboratory director, the laboratory did not document the quality evaluation of the H&E (Hematoxylin and Eosin) stain used in the last six of six months, the laboratory documented the last quality control record for the H&E stain on January 10, 2024. Findings include: 1. Review of H&E QC records showed the laboratory last documented their stain quality evaluation on January 10, 2024. 2. Review of the "Mohs Surgery Laboratory Compliance Manual", page 33, showed step 6.1.5 was marked off and a modified version entered. The original 6.1.5 stated, "A control slide will be made and evaluated each day that a frozen section is prepared. A record of the control slide will be maintained". The modified version stated, "No control slide will be prepared. Each slide is its own control. Adjustments are made if any slide has deficiency". The laboratory director initialed the modification, no date is present with the modification. 3. Interview with the laboratory director on July 9, 2024, at 10:00 AM revealed the laboratory changed their process and the laboratory had not documented H&E stain quality control results since January 10, 2024.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the</p>

following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and procedures and interview with staff, the histotechnicians did not record the time the laboratory received additional specimens for six of six Mohs cases with multiple levels performed on June 5, 2024. Findings include: 1. Review of the Mohs patient log showed six of the ten cases on June 5, 2024, required multiple levels during the Mohs procedures. Review of Mohs maps for the six cases with multiple levels showed the histotechnician did not document the time of specimen receipt for any of the additional specimens. The maps included a labeled space for recording the time and initials of the histotechnician for each level. 2. Review of the procedure manual revealed the histotechnician was responsible for recording the time of receipt for each specimen and their initials on the Mohs map. 3. Interview with Staff A on July 9, 2024, at 9:30 AM confirmed the laboratory did not record the received time for each additional layer required during Mohs procedures.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the laboratory director, the director did not ensure the laboratory developed and maintained a quality assessment program to assure the accuracy and quality of laboratory reports for one of four random Mohs cases reviewed. Findings include: 1. Review of four randomly chosen Mohs patient reports from the electronic medical record (EMR) revealed the laboratory reported the tumor type as Basal Cell Carcinoma (BCC) for the sample from the left lateral forehead of patient 1. Review of the corresponding map and log showed the recorded tumor type as Squamous Cell Carcinoma (SCC). Review of the pathology report from the Department of Veteran Affairs in Madison, Wisconsin, showed the diagnosis of tissue from the left lateral forehead site as SCC. 2. Interview with the laboratory director on July 9, 2024, at 10:00 AM confirmed the tumor type reported in the EMR was not consistent with the tumor type identified in the pathology report, the map, and the patient log and that the laboratory did not have a quality assessment program to assure the accuracy of reports.