

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392170	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 2600 N Mayfair Rd, Ste 810, Milwaukee, 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
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of retained slides in the laboratory and interview with the regional manager, the laboratory did not maintain slides in a manner that ensured their preservation; staff could not separate multiple stored slides from three of six Mohs cases performed in 2022 and 2023. Findings include: 1. Observation on May 24, 2023 at approximately 2:00 PM of retained slides from six Mohs cases performed in 2022 and 2023 showed slides from the following three cases were stuck together and could not be separated to view individually: Patient 1: The patient had two Mohs cases on July 12, 2022, one set of two slides and a second set of six slides could not be separated for review. Patient 2: The patient had a Mohs case on December 30, 2022, two slides from the first stage could not be separated, and two slides from the second stage and a slide from the following Mohs case could not be separated for review. 2. Interview with the regional manager (staff A) on May 24, 2023 at approximately 2:00 PM confirmed the laboratory did not store the slides in a manner that ensured proper preservation to allow review of individual slides.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

This CONDITION is not met as evidenced by:
Based on surveyor review of laboratory records and interview with the regional manager, the laboratory director did not ensure the established quality assessment program was sufficient to identify and correct failures in quality as they occurred in charting patient results for two of six Mohs cases and one of two frozen section cases reviewed. See D6094.

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 regional manager, the laboratory director did not ensure the established quality assessment program was sufficient to identify and correct failures in quality as they occurred in charting patient results for two of six Mohs cases and one of two frozen section cases reviewed. Findings include: 1. Review of laboratory quality assurance records from 2022 monitoring the accuracy of entry between the patient log, 'Mohs Micrographic Surgery Maps', medical records, and slides showed the laboratory evaluated three patient records each quarter in 2022. Results from the third and fourth quarters showed the reviewer determined five of the elements evaluated were not acceptable. No record of review of additional records or corrective actions taken was evident. 2. Review of 'Visit Notes' and 'Mohs Micrographic Surgery Maps' showed the following discrepant results: Patient One: Mohs surgery one: left mid back, one stage completed. The 'Visit Notes' result from stage 1 included, "Frozen section analysis showed: residual tumor seen. Histology: There were numerous aggregates of basaloid cells." The 'Mohs Micrographic Surgery Map' showed the laboratory director identified the result as "Neg" in Stage 1. The laboratory director signed the map. Mohs surgery two: right posterior shoulder, two stages completed. The 'Visit Notes' documentation for stage 1 included: "Frozen section analysis showed: residual tumor seen." The note showed no histology description. The 'Visit Notes' documentation for stage 2 included: "Frozen section analysis showed: residual tumor seen. Histology: The pattern and morphology of the tumor is as described in the first stage." The 'Mohs Micrographic Surgery Map' showed the laboratory director identified tumor present in Stage 1 and resulted "Neg" in Stage 2. The laboratory director did not sign the map. The laboratory director electronically signed the 'Visit Note' on July 13, 2022, at 4:32 PM. Patient Three: Frozen Section performed on a papule located on the left temple. Review of the 'Visit Note' showed the physician entered no microscopic description result. 3. Interview with the regional manager (staff A) on May 24, 2023, at 2:15 PM confirmed the results in the 'Visit Note' for patient one did not correlate with the results on the Mohs map. The Manager also confirmed the 'Visit Note' showed no frozen section microscopic results for patient three, confirmed the laboratory did not identify failures in quality when they occurred, and confirmed the laboratory did not address the issues identified through the quality assurance program to ensure additional patients were not affected.