

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1021071	<b>(X3) Date Survey Completed</b>  09/04/2024
<b>Name of Provider or Supplier</b>  Dundee Dermatology	<b>Street Address, City, State</b>  1201 Water Tower Road, West Dundee, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policies and procedures, lack of documentation, review of laboratory records, and interview with laboratory administrator; the laboratory failed to perform bi-annual method accuracy verifications for histopathology testing from April 2022 through May 2024. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the procedure titled, "Mohs Micrographic Surgery Skin specimens", which stated, "In the absence of an accredited Proficiency testing program in the Mohs Micrographic Cutaneous Oncology, this laboratory has instituted its own External Quality Control Program. Semi-Annually, the Mohs Microscopic tech, RN, or Risk Manager will send up to ten percent of completed cases containing the original slides for microscopic examination by a board-certified Dermatologist. No differential diagnosis will be offered with the specimen. The slide will be labeled with the case number for the records of the reference laboratory. Upon receipt of the pathology report from the Dermatopathologist, Diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in "proficiency testing" located in the quality control manual." 2. Review of laboratory records found no bi-annual method accuracy verifications for histopathology from April 2022 through May 2024. 3. Review of laboratory records identified a letter dated 08/20/2024 from the technical supervisor of Dundee Dermatology to North Suburban Dermatology Associates in regard to reviewing Mohs micrographic surgery slides as part of Dundee Dermatology's bi-annual method accuracy for the Mohs histopathology testing. The letter confirmed that samples from Dundee Dermatology had not been sent out bi-annually starting in April of 2022 and continuing until May of 2024. The communication stated:</p>

"Enclosed are random samplings of my Mohs Micrographic Surgery slides that have been prepared in Dundee Dermatology's Mohs laboratory. Travel Tech Mohs prepares the slides in our lab with their cryostat, inks, and histology technicians. The cases you are reviewing are from April 19, 2022 - May 17, 2024. It would be greatly appreciated if you could use the enclosed Mohs Surgery quality assurance and proficiency testing form to evaluate the diagnosis, sectioning quality, and staining quality. Please document each individual case." 4. Interview with laboratory administrator on 09/04/2024 at 1:06 pm confirmed the facility had not sent out bi-annual evaluations from April 2022 through May 2024. 50842 Based on laboratory policies and procedures, lack of documentation, review of laboratory records, and interview with laboratory administrator; the laboratory failed to perform bi-annual method accuracy verifications for histopathology testing from April 2022 through May 2024. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the procedure titled, "Mohs Micrographic Surgery Skin Specimens", which stated, "In the absence of an accredited Proficiency testing program in the Mohs Micrographic Cutaneous Oncology, this laboratory has instituted its own External Quality Control Program. Semi-Annually, the Mohs Microscopic tech, RN, or Risk Manager will send up to ten percent of completed cases containing the original slides for microscopic examination by a board-certified Dermatologist. No differential diagnosis will be offered with the specimen. The slide will be labeled with the case number for the records of the reference laboratory. Upon receipt of the pathology report from the Dermatopathologist, Diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in "proficiency testing" located in the quality control manual." 2. Review of laboratory records found no bi-annual method accuracy verifications for histopathology from April 2022 through May 2024. 3. Review of laboratory records identified a letter dated 08/20/2024 from the technical supervisor of Dundee Dermatology to North Suburban Dermatology Associates in regard to reviewing Mohs micrographic surgery slides as part of Dundee Dermatology's bi-annual method accuracy for the Mohs histopathology testing. The letter confirmed that samples from Dundee Dermatology had not been sent out bi-annually starting in April of 2022 and continuing until May of 2024. The communication stated: "Enclosed are random samplings of my Mohs Micrographic Surgery slides that have been prepared in Dundee Dermatology's Mohs laboratory. Travel Tech Mohs prepares the slides in our lab with their cryostat, inks, and histology technicians. The cases you are reviewing are from April 19, 2022 - May 17, 2024. It would be greatly appreciated if you could use the enclosed Mohs Surgery quality assurance and proficiency testing form to evaluate the diagnosis, sectioning quality, and staining quality. Please document each individual case." 4. Interview with laboratory administrator on 09/04/2024 at 1:06 pm confirmed the facility had not sent out bi-annual evaluations from April 2022 through May 2024.