

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2132149	<b>(X3) Date Survey Completed</b>  06/09/2025
<b>Name of Provider or Supplier</b>  Dermatology Center Of Indiana Mohs	<b>Street Address, City, State</b>  824 Edwards Dr Suite 100, Plainfield, IN	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to ensure three out of four bottles of the orange and violet tissue marking dyes, one out of two bottles of Cryoseal XyL and one of two Surgipath SelecTech Blue Buffer 8 concentrate solution bottles were not expired for MOHS Microscopic Surgery (MOHS) testing performed on ten of eleven patients (PT#2-PT#11) reviewed. Findings included: 1.) During a laboratory tour on 6/9/2025 at 9:45am, the following supplies used for MOHS testing were expired: a.) Tissue Marking Dyes (Orange) had one open bottle in use with Lot 126932 expired 7/31/2023; and two unopened bottles Lot 148374 Expired 4/30/2024 and Lot 161406 expired 1/31/2025. b.) Tissue Marking Dyes (Violet) had one open bottle in use with lot 122227 in use expired 5/31/2023, and two unopened bottles Lot 123480 expired 6/30/2023 and lot 144871 expired 2/29/2024. c.) Cryoseal XyL one open bottle in use with Lot 129143 expired 4/17/2025. d.) Surgipath SelecTech Blue Buffer 8 concentrate open bottle in use with Lot 121020 expired 12/10/2024. 2.) During an interview on 5/9/2025 at 10:08 AM, SP-1 (Histo Tech) confirmed the tissue marking dyes orange and violet, Cryoseal XyL and Surgipath SelecTech Blue Buffer 8 solutions were expired. 3.) Review of patient records revealed the following testing was performed when the open bottles of orange and violet tissue marking dyes had expired: a.) PT#2 was tested on 1/25/2024 for MOHS. b.) PT#3 was tested on 2/12/2024 for MOHS. c.) PT#4 was tested on 1/29/2024 for MOHS. d.) PT#5 was tested on 4/4/2024 for MOHS. e.) PT#6 was tested on 5/19/2025 for MOHS f.) PT#7 was tested on 4/16/2025 for MOHS. g.) PT#8 was tested on 4/15/2025 for MOHS. h.) PT#9 was tested on 11/14/2024 for MOHS. i.)</p>

PT#10 was tested on 5/30/2025 for MOHS. j.) PT#11 was tested on 6/4/2025 for MOHS. 4.) The annual MOHS test volume is 11,000.