| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D2277655 | 12/04/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Institute Of Dermatology & Oculoplastic Surgery | 1617 South Tuttle Ave Floor 3, Sarasota, FL | |

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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Institute of Dermatology & Oculoplastic Surgery on 12/2/2025-12/4/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 493.1441 Condition: Laboratory Director |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the laboratory failed to ensure protection from chemical hazards from 06/09/2023 through 10/30/2025. Findings included: 1. During a tour of the laboratory on 12/2/2025 at 11:05 a.m., no fume hood was observed in the laboratory. 100% Reagent Alcohol and Safe-Clear Xylene Substitute for Histology was use and stored in the safety cabinet. Hazard labeling on the 100% Alcohol stated "Do not breathe dust/fumes/gas/mist/vapors/spray" and the Safe-Clear Xylene Substitute for Histology indicated may cause respiratory irritation. 2. The MOHS Manual was approved by the Laboratory Director on 3/25/2025. The Laboratory Facility policy stated the laboratory should have hoods. 3. During an interview on 12/02/2025 at 11:05 a.m., the Histology Tech acknowledged there was no fume hood and they did not monitor the exposure to the chemicals. 4. The Laboratory Director indicated via email on 12/04/2025 at 12:32 p.m. he was not aware the laboratory needed a fume hood due to the chemicals in use. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to verify accuracy twice annually from 01/2024 to 07/2025 for Testing Person (TP) A, the only TP performing testing in the subspecialty of Histopathology. Findings included: 1. The laboratory's Policies and Procedure Manual reviewed and signed by the Laboratory Director on 03/25/2025, indicated proficiency testing was to be performed twice a year and that once results returned to the laboratory they were to be reviewed to ensure diagnosis match. 2. The CMS-209 signed by the Laboratory Director on 12/02/2025 listed only himself as TP A. 3. Quality Assurance-Proficiency records were reviewed from 01/2024 to 12/2025, revealed no records were presented for 2024 and results of what had been sent for verification in 02/2025 failed to have documentation of review of results to ensure diagnosis matched by the Laboratory Director or other qualified staff. 4. The Laboratory Director on 12/04/2025 at 12:32 p.m. confirmed via email the twice yearly verification of Histopathology testing failed to have documentation of review of results to ensure diagnosis matched by the Laboratory Director or other qualified staff. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, it was determined the laboratory failed to monitor the cryostat and testing room temperature and the testing room humidity for one (10/28/25) of three patient testing days (10/14/25, 10/21/25, and 10/28/25) in October 2025. Findings included: 1. The MOHS Daily Quality Control Worksheet documented monitoring of the cryostat and testing room temperature and the testing room humidity on 10/14/25 and 10/21/25. 2. The patient log documented Histology testing was performed on 10/14/25, 10/21/25, and 10/28/25. 3. The Laboratory Director on 12/4/2025 at 12:32 p.m. stated via email he was not aware that the laboratory failed to monitor the cryostat and testing room temperature and the testing room humidity for 10/28/25 when there was Patient testing performed. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to maintain documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for three of three months reviewed (March 2025, July 2025, and October 2025). Findings included: 1. Review of the MOHS Daily Quality Control Worksheets for March 2025, July 2025, and October 2025 showed a column to document H&E Control slide number and if quality was good. The worksheets indicated the H&E Control slide number but not if the slide was of good quality or who had reviewed the QC slide. 2. The CMS-209 signed by the Laboratory Director on 12/2/25 listed only himself as TP A. 3. The laboratory's Policies and Procedure Manual reviewed and signed by the Laboratory Director on 3/25/2025 indicated under Monitoring of Quality Control Testing: "Prior to patient specimen testing, a slide is prepared (stained) and reviewed by the Laboratory Director". There was no documentation for March 2025, July 2025, and October 2025 that this policy was followed. 4. The Laboratory Director on 12/4/2025 at 12:32 p.m. stated via email he provided verbal assessment of staining quality and did not document the quality of the QC slide as the Testing Personnel. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview, and record review, the Laboratory Director failed provide overall management and direction of the laboratory from 01/16/24 to 12/02 /25. (See D6093) |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred from 01/16/24 to 12/02/25. Findings included: 1. The laboratory's Policies and Procedure Manual were reviewed and signed by the Laboratory Director on 03/25/2025. The Quality Assurance (QA) policy stated the QA program was designed to monitor and evaluate the quality of services and it was the responsibility of the Laboratory Director and "Lab Supervisor" to oversee the plan to identify problems. 2. The CMS-209 signed by the Laboratory Director on 12/02/2025 listed only himself as the Laboratory Director, Technical Supervisor, and General Supervisor, there is no CLIA position of "Lab Supervisor". 3. QA reports for March 2025, July 2025, and October 2025 were reviewed. No problems were identified through the QA plan. There was no evidence the laboratory QA had identified the |

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| | following problems found during the survey- a. The laboratory failed to ensure protection from chemical hazards from 06/09/2023 through 10/30/2025. (See D3011) b. The laboratory failed to verify accuracy twice annually from 01/2024 to 07/2025 for Testing Person (TP) A, the only testing personnel, for testing performed in the subspecialty of Histopathology. (See D5217) c. The laboratory failed to monitor the cryostat and testing room temperature and the testing room humidity for one (10/28 /25) of three patient testing days (10/14/25, 10/21/25, and 10/28/25) in October 2025. (See D5413) d. The laboratory failed to maintain documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for three of three months reviewed (March 2025, July 2025, and October 2025). 4. The Laboratory Director on 12/04/2025 at 12:32 p.m. via email confirmed the above listed problems found during the survey. |