| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D1027742 | 10/17/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Foothill Dermatology Medical Center | 2301 E Foothill Blvd Ste 100, Glendora, CA | |

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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| **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 the surveyor's observation during the laboratory tour, lack of laboratory's policies and procedures, and interviews with office manager (OM) and laboratory technician (LT), the laboratory failed to: A) Establish safety procedures to ensure protection from physical, chemical, and biochemical materials. B) Establish formaldehyde and xylene exposure limits by providing testing performed by an outside company. No exposure testing for formaldehyde and xylene records were found. C) Have an eye wash solution/area up to date and ready to use. The findings include: 1. Based on the survey on October 17, 2025, at approximately 11:30 a.m. the laboratory failed to provide a written policy and procedure for laboratory safety; including environmental testing for formaldehyde and xylene exposure in the laboratory for testing personnel. 2. Based on the observations during the laboratory tour, where the Mohs processing and staining of samples took place, it was found that the laboratory lacked an eye wash that was ready to use. 3. The OM and LT affirmed by interviews October 17, 2025, at approximately 11:45 a.m., that the laboratory lacked safety procedures, formaldehyde and xylene exposure testing records, and ready to use eyewash in the Mohs processing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 10/16/ 2025, the laboratory processed and reported annually approximately 8,000 Mohs patients' test samples. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250 |

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| | Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on severity of the deficiencies cited herein, the Condition for Analytic Systems was not met. The findings included: The laboratory failed to: A) Establish policies and procedures for the laboratory such as: Mohs procedure, quality assurance, peer review, retention and storage of slides, quality control, turn-around time, microscope and equipment preventive maintenance, safety plan, reagent log, corrective action, and complaint investigation. See D5401 and D5403 B) Establish and follow a policy for the use of expired reagents. See D5417 C) Establish policies and procedures for preventive maintenance and temperature recording each time the cryostat is used for Mohs sample processing. See D5429 |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of a laboratory's policies and procedures manual and interviews with the office manager (OM) and testing personnel (TP) on October 17, 2025; the laboratory failed to provide a procedure manual for policies and procedures. The findings included: 1. It was the practice of the laboratory to perform Dermatopathology -Mohs processing in house with no policies and procedures approved, signed, and dated by the laboratory director available for: Mohs specimen processing, quality assurance, preventive maintenance, peer review, reagent use, reagent log, microscope use, safety procedures etc. 2. All CLIA compliant protocols for histopathology practice were not available on the day of the survey. 3. The OM and TP confirmed by interview on October 17, 2025, at approximately 1:00 p.m., that the laboratory had no CLIA compliant histopathology policies and procedure manual to reflect current practices approved, signed and dated by the laboratory director. 4. The laboratory's testing declaration form, signed by the laboratory director on October 16, 2025, stated that the laboratory performed approximately 8,000 histopathology tests annually with no CLIA compliant policies and procedures available to be followed by the testing personnel. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for |

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| | specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, the lack of laboratory written procedures, and interview with the office manager (OM); it was determined that the laboratory failed to have written requirements for specimen management, written procedures for managing laboratory records with regularly scheduled self-audits for quality assessment, and a process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. Findings included: 1. The laboratory failed to have written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation, transportation and referral of Biopsy specimen, and criteria for specimen acceptability and rejection. 2. The laboratory failed to have written procedures for managing laboratory records, including receipt and retention of Histopathology reports and records relating to Mohs procedures. 3. The laboratory failed to have written policy and procedure for at least twice annually verifying the accuracy of tests performed onsite, including but not limited to Mohs to clear tumor and as applicable, Frozen Biopsy sections to identify pathology during Mohs procedures. 4. The laboratory failed to have a written policy and procedure for regularly scheduled self-audits of laboratory records to assess the quality of preanalytic, analytic, and postanalytic processes, apply remedial corrections as appropriate, and monitor for quality assurance and compliance. 5. The laboratory failed to have any other written policies and procedures pertinent to a Dermatopathology laboratory. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's observation during the laboratory tour, examination of laboratory reagent materials and solutions, and interviews with the office manager (OM) and laboratory testing personnel (TP); the laboratory failed in using reagent materials and solutions when it had exceeded its expiration date. The findings include: 1. The laboratory performed Mohs and used reagent materials such as marker dyes |

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| | beyond their expiration: a) Violet dye Lot # 164384 Exp: 12/31/2024 b) Orange dye Lot # 165231 Exp: 2/28/2025 2. The laboratory had an eye wash solution in place expired since March 2022. 3. The OM and TP affirmed by interview on October 17, 2025 at approximately 12:30 p.m. that the laboratory used the reagent materials and solutions beyond its expiration date for patients' sample processing and testing without checking the expiration date of the reagents used. 4. According to the testing declaration submitted at the time of survey, October 17, 2025, the laboratory tested and reported approximately 8,000 patient samples for Mohs during the time when reagent materials and solutions used were past its expiration date. Thus, the quality and accuracy of patient results cannot be assured. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's direct observation during the laboratory tour, lack of laboratory's policies and procedures, review of preventive maintenance (PM) documentation, five (5) patient histopathology and Mohs test records, and interviews with the laboratory's office manager (OM) and laboratory testing personnel (LT); the laboratory fail to establish and follow policies and procedures in place for the calibration and preventive maintenance (PM) of the cryostat as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing. The findings include: 1.The laboratory failed to provide PM and temperature checks documentation for the cryostat used in the laboratory for Mohs sample processing since July 23, 2024. 2. No corrective action report for the lack of cryostat PM and temperature documentation was available for review at the time of the survey. 3. For five (5) out of (5) patients' Mohs records reviewed; preventive maintenance for the cryostat and temperature recordings were not documented. 4. The OM and TP affirmed by interviews on October 17, 2025, at approximately 12:00 noon, that the laboratory failed to document/ find PM records and document temperature readings since 7/23/2024 for the cryostat used to process Mohs sample processing. 5. According to the testing volume declaration submitted at the time of the survey, the laboratory performed and reported approximately 8,000 tests results annually for Histopathology- Mohs during the time PM for the cryostat and temperature documentation were missed to be performed and/or documented. |
| **D5779** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(a)<br><br>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of the laboratory's policies and procedures, five (5) randomly selected Mohs patient records, and interview with the office manager (OM) and testing personnel (TP); the laboratory failed to have an established and approved policy and procedure for corrective action. Findings include: 1. Based on the lack of |

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| | policies and procedures, no corrective action policy or documentation log were found, including any criteria necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 2. The OM and TP affirmed by interview that the laboratory did not have a corrective action log for quality assessment that included the corrective action procedure as mentioned in statement #1. 3. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 8,000 tests annually during the time that no corrective action policy and procedure was implemented; thus, the quality and accuracy of patient records cannot be assured. |
| **D5819** | TEST REPORT<br>CFR(s): 493.1291(j)<br><br>(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of laboratory policies and procedures, five (5) randomly selected patient records, preventive maintenance log, and interviews with the office manager (OM) and laboratory testing personnel (TP), the laboratory failed to establish and follow policies and procedures in maintaining reports or records in a manner that permits ready identification and timely accessibility. The findings include: 1. During the patient review audit, for one (1) out of five (5) randomly selected Mohs patient records, the documentation of Mohs final stage and number of slides was incomplete. 2. The laboratory's standard practice is to document the Mohs log at the end of the MD microscopic examination of the slides to document the final Mohs stage and number of slides prepared. 3. During an interview on October 17, 2025, at approximately 12:30 p.m., the OM and TP affirmed missing documentation for Mohs sample processed on 10/7/2025 for sample ID number 482. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory reported approximately 8,000 patient tests for Dermatopathology-Mohs for which no policy or procedure was established for documentation that permits ready identification and timely accessibility. |
| **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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory Director was not met. The laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored: D3011, D5401, D5403, D5417, D5429, D5779, D5819, D6106; and the establishment and maintenance of acceptable level of analytical performance for each test system. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14) |

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| | (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's policies and procedures, survey findings and an interviews on October 17, 2025, the laboratory director is herein cited for failure to ensure that a CLIA compliant, approved, signed, and dated, procedure manual and laboratory policies that accurately reflects current laboratory practices is available for all personnel. See D5401 and D5403. |