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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D2060338 | (X3) Date Survey Completed 12/12/2025 |
| Name of Provider or Supplier Housel Dermatology Pc | Street Address, City, State 235 Greenfield Parkway, Liverpool, NY | |
| 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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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interview with the Mohs technician, the laboratory failed to draft and approve procedures for calibration and calibration verification. FINDINGS: 1. There was no calibration documentation for the Extech Instruments digital thermometer model 445703 used to monitor the ambient room temperature and humidity in the Mohs laboratory. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The Mohs</p> |

technician confirmed the findings on December 12, 2025, at approximately 11:45 A. M.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(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.

This STANDARD is not met as evidenced by:

Based on direct observation, review of SOPs, as well as interview with the Mohs technician, the laboratory failed to remove from inventory reagents that have exceeded their expiration date. FINDINGS: 1. The surveyor's observations in the Mohs laboratory confirmed on December 12, 2025, at approximately 11:00 A.M., the following reagents and processing materials were not removed from inventory: a. Avantik Tissue Marking Dye Green, lot: 184540, expiration: October 31, 2025, stored in an upper cabinet near the fume hood in the Mohs processing laboratory. b. Avantik Tissue Marking Dye Orange, lot: 186726, expiration: November 30, 2025, stored in an upper cabinet near the fume hood in the Mohs processing laboratory. 2. The current, approved SOPs did not include instructions for removal of reagents, stains, solutions, and other supplies from inventory when they have exceeded their expiration date. 3. The Mohs technician informed the surveyor that the respective tissue dyes were utilized for patient specimen processing. It was noted that three hundred seventy-nine Mohs patient specimens were processed utilizing the respective expired reagents. 4. The Mohs technician confirmed the findings on December 12, 2025, at approximately 11:20 A.M.