| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D1092736 | 01/30/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Frederick Dermatology Associates Llc | 45 Thomas Johnson Drive, Suite 209, Frederick, MD | |

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** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 standard operating procedure manual (SOPM) review and interview with the office staff, the laboratory did not ensure that there was an approved policy for performing potassium hydroxide (KOH) testing. Findings: 1. During an interview with the office staff, he/she stated that the laboratory performs KOH testing to diagnose fungal infections in the skin and nails. 2. A review of the SOPM showed that there was not an approved policy (signed and dated by the laboratory director) for performing KOH testing. The office staff member was able to locate 2 pages of information in a binder meant for the Medical Assistants and kept in an adjacent |

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| | office titled, "KOH Test for Diagnosing Fungal Infections of the Skin," however this was not a procedure for how to perform the test, nor was it approved by the laboratory director. 3. During an interview on 01/30/2023 at 12:30 PM, the office staff confirmed that there was no approved policy for performing KOH testing available at the time of the survey. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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 record review, observation, and interview with the office staff, the laboratory failed to ensure that reagents used for potassium hydroxide (KOH) testing were not used after they exceeded their expiration date. Findings: 1. The laboratory performs KOH testing to diagnose fungal infections in the skin and nails. During a tour of the laboratory at 11:00 AM, it was observed that the in-use bottle of 10% KOH (lot number 9220-03) expired on 01/31/2021 and that the bottle of "sterile water" (lot number 1402094) expired 3/2016. 2. A review of reagent logs from 2020 to 2021 showed that the KOH reagent was not documented on the log. 3. During an interview on 01/30/2023 at 12:30 PM, the office staff confirmed that the laboratory failed to ensure that supplies were not used when they had exceeded their expiration date, had deteriorated, or were of substandard quality. |