| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 39D1022348 | 04/08/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Upmc Falk Dermatology | 3601 Fifth Avenue, Pittsburgh, PA | |

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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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's PS-L-001 Physician Office Laboratory Quality Assurance Surveillance Review Policy, record review, and interview with the Laboratory Director (LD), the Laboratory failed to follow the Laboratory's written policies and procedures to assess the competency for 1 of 12 testing personnel (TP) who performed potassium hydroxide (KOH) microscopic examinations in 2021. Findings include: 1. The laboratory's PS-L-001 Physician Office Laboratory Quality Assurance Surveillance Review Policy under Pre-analytic Aspects of Care states "Physicians and APPs who perform any microscopic testing must also complete staff competencies annually". 2. On the day of the survey, 4/08/2022, review of the competency assessment records revealed the laboratory could not provide the annual competency for 1 of 12 TP (CMS 209 personnel #12) who performed KOH microscopic examinations in 2021. 3. The laboratory performed 79 KOH microscopic examinations in 2021. 4. The LD confirmed the findings above on 04/08/202 at 1:45 p. m. . |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual, review of peer review records, and interview with the Laboratory Director (LD), the laboratory failed to verify twice annually the accuracy of potassium hydroxide (KOH) scabies and Tzancks microscopic examinations performed by 12 of 12 testing personnel (TP) in 2020 and 2021. Findings include: 1. The Laboratory procedure manual states: " peer review are to be done twice annually for each interpreting physician/App" for KOH, scabies and Tzancks microscopic examinations. 2. On the day of survey, 04/08/2022, review of peer review records revealed, the laboratory did not separate peer review by analyte (KOH, Scabies and Tzanck microscopic examinations) performed by 12 of 12 TP in 2020 and 2021. 3. 125 KOH, 21 scabies, and 7 Tzancks microscopic examinations were analyzed in 2020. 4. 79 KOH, 18 Scabies, and 0 Tzanck microscopic examinations were analyzed in 2021. 5. The LD confirmed the findings above on 04 /08/2022 at 01:45 pm. |
| **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 review of the laboratory procedure and interview with Laboratory Director (LD), the laboratory failed to establish a Quality Control (QC) procedure to assess Potassium Hydroxide (KOH), scabies and Tzancks microscopic examinations from 04 /08/2020 to the day of survey. Findings Include: 1. On the day of survey, 04/08/2022, reviewed of the KOH, scabies, and Tzancks microscopic examinations procedure manuals revealed that a daily quality control was not included in the procedure. 2. The LD confirmed the finding above on 04/08/2022 around 01:45 p.m. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and interview with the Laboratory Director (LD), the Laboratory Director (LD) failed to approve and sign 2 of 6 procedure manuals in the laboratory from 07/01/2021 to the date of survey. Findings included: 1. On the day of survey 04/08/2022, a review of the manuals revealed, the following procedures were not approved and signed by the LD prior to patient testing: - Quality Assurance Surveillance Review Policy. - Laboratory Specimen collection. 2. The LD confirmed the finding above on 04/08/2022 at 1:45 p.m. |