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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>38D0935145 | <b>(X3) Date Survey Completed</b><br>10/18/2021 |
| <b>Name of Provider or Supplier</b><br>Broadway Medical Clinic-Dermatology   | <b>Street Address, City, State</b><br>4212 Ne Broadway, Portland, OR   |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of records and discussion with staff RN, no record of bi-annual verification for potassium hydroxide (KOH) could be produced. Finding include: 1. During survey on 10/18/2021, no written record of bi-annual verification for KOH interpretations could be produced.</p>  |
| <b>D5291</b>              | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory documents and discussion with staff, no Quality Assessment plan (QA) could be produced. Findings include: 1. When asked to share the laboratory's QA plan or procedure during survey 10/18/2021, none could be produced. 2. When staff RN and one other staff member were asked about the laboratory's QA plan during interview at approximately 1400 on 10/18/2021, neither staff member was aware of a QA plan.</p> |
| <b>D5407</b>              | PROCEDURE MANUAL   |

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of procedures on line for this facility and discussion with staff, no procedure for potassium hydroxide (KOH) wet mounts could be produced for review. Findings include: 1. During survey 10/18/2021 at approximately 1330, staff were asked to share their procedure for KOH mounts. None could be produced. 2. When asked to see the current Laboratory Director's signature on current procedures, none could be produced.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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 inspection of currently used potassium hydroxide reagent (KOH) and discussion with staff during survey 10/18/2021, the laboratory was using expired KOH reagent. 1. Upon inspection of the KOH used for skin scrapings, it was revealed that the bottle of KOH had expired 05/28/2020. 2. During interview with staff at approximately 1330, staff member responsible for ordering supplies confirmed that she had just noticed it was expired by 15 months.