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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0300651 | (X3) Date Survey Completed 07/30/2024 |
| Name of Provider or Supplier Total Skin And Beauty Dermatology Center | Street Address, City, State 1927 1st Avenue North, Suite 300, Birmingham, AL | |
| 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 |
|---------------------------|--|
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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: Based on a review of the lack of bi-annual accuracy verification for KOH (potassium hydroxide) documentation, the KOH Prep procedure, and an interview with the Laboratory Manager, the laboratory failed to implement a mechanism for performing accuracy verification or perform proficiency testing on KOH Prep. This was noted since the previous survey on 10/13/22 to the current survey on 7/30/24. The findings include: 1. A review of the bi-annual accuracy verification documentation for KOH Prep revealed the laboratory was utilizing DTM (Dermatologic Test Media) plates for KOH samples and sending the plates to a reference lab twice yearly for accuracy verification. The laboratory discontinued DTM testing after the date of the previous survey of 10/13/22, and failed to implement an alternative accuracy verification method for KOH. 2. A further review of the KOH Prep procedure revealed, "1. Twice yearly, a single patient has a specimen plated onto DTM to test for accuracy of KOH preparation." 2. During an interview on 7/30/24 at 3:49 PM, the Laboratory Manager confirmed the above findings.</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> |

This STANDARD is not met as evidenced by:
Based on the laboratory tour, KOH (potassium hydroxide) Prep policy and procedure, KOH patient log, and an interview with the Laboratory Manager, the laboratory used expired KOH solution for patient testing. This was noted for two days of one month reviewed in July 2024. The findings include: 1. The laboratory tour revealed the KOH solution lot#2202 expired on 7/21/24 and in use for the following days: a) 7/22/24; one patient performed. b) 7/29/24; one patient performed. 2. A further review of the KOH policy and procedure revealed, "1. KOH... is disposed of when it reaches expiration date." 3. During an interview on 7/30/24 at 3:05 PM, the Laboratory Manager confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of the lack of personnel records and an interview with the Laboratory Manager, the Technical Consultant failed to evaluate semi-annual competencies for testing personnel performing KOH (Potassium hydroxide), a moderate complexity testing. This was noted for twelve of twelve testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for the semi-annual competencies for all twelve testing personnel performing KOH testing. 2. During an interview on 7/30/2024, at 1:20 PM, the Laboratory Manager confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of the lack of personnel records and an interview with the Laboratory Manager, the Technical Consultant failed to evaluate annual competencies for testing personnel performing KOH (Potassium hydroxide), a moderate complexity testing. This was noted for twelve of twelve testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for the semi-annual competencies for all twelve testing personnel performing KOH testing. 2. During an interview on 7/30/2024, at 1:20 PM, the Laboratory Manager confirmed the above findings.