

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2151774	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Woseth Dermatology, Pc	Street Address, City, State 4040 West Daybreak Pkwy, Ste 200, South Jordan, UT	
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
D5393	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on mycology proficiency testing records review, lack of documentation, and interview with the office manager, the laboratory failed to evaluate their corrective actions taken for failed Potassium Hydroxide (KOH) test scores for 3 of 6 proficiency testing events and for failed fungi culture presence or absence for 1 of 6 testing events reviewed from January 2019 to January 2021. The laboratory performed approximately 90 KOH and cultures per year. Findings include: 1. A. The laboratory failed American Proficiency Institute (API) proficiency tests the 1st and 3rd events of 2020 with scores of 50% and 0% respectively. For the 1st event of 2020 the laboratory reported specimen KOH 01 as No Fungal Elements seen. The correct response was Fungal elements present. B. The laboratory failed the third API event of 2020 reporting KOH 05 as No Fungal Elements present. The acceptable response was Fungal Elements Present. KOH 06 was reported as Fungal Elements present. The acceptable response was No Fungal Elements Present. C. The laboratory failed the 1st API - KOH event of 2019 with a score of 50 % reporting KOH 02 as No Fungal element present. The acceptable response was Fungal elements present. D. The laboratory failed the 3rd API -KOH event of 2019 with a score of 50% reporting No Fungal elements present. The acceptable response was Fungal Elements present. The corrective action taken was to change proficiency testing to another company but before the first event of 2020 the laboratory decided to continue using API for both</p>

KOH and fungal culture testing for the presence or absence of dermatophytes. E. The laboratory failed the 2nd API fungal culture event of 2019 with a score of 60%. The laboratory mixed up 2 samples. 2. In an interview conducted on 01/20/2020 the laboratory staff stated the laboratory complained about the poor quality of KOH specimens sent for testing. The laboratory failed to identify the problem in identification fungal element presence in KOH specimens.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on proficiency testing records review and lack of documentation the laboratory technical consultant failed to ensure the laboratory did not report potassium hydroxide (KOH) until corrective actions have been taken and the KOH test system is functioning properly. The laboratory performed approximately 90 tests per year. Findings include: 1. The laboratory failed 5 of 6 proficiency KOH proficiency tests from January 2019 to January 2021. 2. The laboratory failed to document they took corrective actions to verify KOH testing was accurate and functioning properly. 3. In an interview conducted on 01/20/2021 at approximately 3:15 P.M. staff confirmed KOH proficiency did not have corrective actions documented to verify KOH testing was functioning properly. (See D5393).