

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2009726	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Teton Dermatology, Llc DbA Epiphany Dermatology	Street Address, City, State 984 W Broadway, Ste 4, Jackson, WY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory director failed to ensure the laboratory had a policy and procedure in place to ensure competency of testing personnel performing test procedures for 6 of 6 testing personnel (PA-C #1, PA-C #2, MD #1, MD #2, MD #3). The findings were: Review of the CMS-209 Laboratory Personnel Report dated 5/4/21 showed 6 employees were listed as testing personnel. Interview with the laboratory director on 5/4/21 at 4:45 PM revealed the laboratory did not have a policy and procedure in place to ensure testing personnel competency.</p>
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 lack of documentation and staff interview, the laboratory failed to verify histopathology frozen section analysis test accuracy at least twice annually for 1 of 2 years (2020) of testing reviewed. In addition, the laboratory failed to verify the accuracy of KOH (potassium hydroxide) testing at least twice annually for 1 of 2 years (2019) of testing reviewed. The laboratory performed approximately 230 Mohs</p>

surgery procedures in 2020 and approximately 40 KOH preps per year. The findings were: 1. Review of the laboratory case log showed a peer review of the histopathology frozen section analysis was performed on 8/13/20 for a sample collected on 3/27/20. There was no documentation the laboratory had verified the accuracy of the frozen section analysis a second time in 2020. Interview with the lab director on 5/4/21 at 4:45 PM revealed he was aware of the required twice a year accuracy review, however had not implemented the review until recently. 2. Review of the laboratory's 2019 KOH testing log sheet and Quality Assessment KOH/Scabies Preps Peer Review log showed no evidence KOH testing had been verified for accuracy at least twice annually for 5 of 5 testing personnel. Interview with the laboratory director on 5/4/21 at 4:45 PM revealed the laboratory had performed the KOH accuracy evaluations, however they had not documented the results

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 observation and staff interview, the facility failed to ensure staining reagents were not used beyond their expiration date for 2 of 2 procedures (potassium hydroxide (KOH) and Mohs surgery histopathology). The findings were: 1. Observation on 5/4/21 at 2 PM showed 1 container of Eosin Y Stain lot #1801907 had an expiration date of 1/26/2020; 1 container of Hematoxylin Stain lot #1801909 had an expiration date of 1/26/2020; and 1 bottle of Chlorazol Black E fungal stain had a lot # of 6259, an open date of 2/2016, and an expiration date of 9/15/18. 2. Review of the laboratory's billing log sheet from 6/2/19 through 5/4/21 showed the laboratory had performed 84 KOH procedures. 3. Review of the laboratory's case log from 1/26/20 through 5/4/21 showed the laboratory performed 22 Mohs surgery frozen sections. 4. Interview with the laboratory director on 5/4/21 at 4:45 PM revealed he was unaware the stains had expired.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory director failed to ensure the competency of personnel performing test procedures for 3 of 3 testing personnel (PA-C #1, PA-C #2, MD #1).The findings were: 1. Review of the CMS-209 Laboratory

Personnel Report showed 3 additional testing personnel were listed from the prior CLIA survey conducted on 8/22/18. Interview with the clinic manager on 5/4/21 at 4:30 PM revealed PA-C #1 was hired in 2016; PA-C #2 was hired in April 2019; and MD #1 was hired in March 2019. 2. There was no documentation to show PA-C #1, PA-C #2, or MD #1 had been evaluated for competency prior to testing patient samples. 3. Interview with the laboratory director on 5/4/21 at 4:45 PM revealed he had educated, trained, and evaluated the testing personnel, however he had not documented the process.