

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2009726	(X3) Date Survey Completed 08/22/2018
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to develop and follow a function check protocol for laboratory microscopes used for histopathology and mycology testing for 2 years of testing reviewed from August 2016 to August 2018. The laboratory performed approximately 1700 histopathology tests and 15 to 20 mycology tests per year. Findings include: 1. The laboratory lacked documentation the microscopes used for potassium hydroxide (KOH) mycology tests and for histopathology permanently fixed slides and frozen section testing from Moh's surgery were maintained from August 2016 to August 2018. 2. In an interview with the laboratory manager on 08/22/2018 at approximately 3:15 P.M., staff stated the laboratory did not document microscope maintenance nor have a procedure stating the frequency maintenance was to be performed and documented.</p>
D5607	<p>HISTOPATHOLOGY CFR(s): 493.1273(d)(f)</p> <p>(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who</p>

performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on patient test records review and interview with staff, tissue test reports failed to include documentation of a signature, or computer generated electronic signature for 8 of 16 histopathology (dermatopathology) test reports reviewed for formalin fixed paraffin embedded tissue specimen reports reviewed for testing performed from August 2016 to August 2018. Findings include: 1. Test reports for histopathology biopsies ending in numbers (as recorded in the specimen log book) for specimens collected in 2016: #1389 and 1413, collected in 2017 for #451, 598, 1067 and for specimens collected in 2018 or #435, 271, and 1064 failed to include the signature of the qualified histopathology testing person. 2. Test reports reviewed were reports generated by laboratory personnel and added to the same test report received from the preparatory laboratory performing the gross analysis and did not include the signature of the person qualified to perform histopathology testing. 3. In an interview conducted on 08/22/2018 at approximately 3:00 P.M., staff confirmed histopathology reports failed to include the board certified dermatologist's signature or computer generated signature for the 8 histopathology reports performed by the laboratory.