

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0911386	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Pinnacle Dermatology Brighton	Street Address, City, State 6888 Grand River Avenue, Brighton, MI	
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 record review and interview with the Clinical Manager, the laboratory failed to ensure Potassium Hydroxide (KOH) preparations for 2 (January 2020 to January 2022) of 2 years. Findings include: 1. A review of the laboratory's "KOH Competency Log Sheet" revealed the secondary results were initialed by staff not listed on the CMS-209 form. 2. An interview on 1/13/22 at 10:14 am with the Clinical Manager revealed the secondary results were initialed by staff that ensured the results were entered into the patients' charts and the staff did not review the test for accuracy at least twice annually. ***This is a repeated deficiency from the 12/16/19, 7/27/17, and 8/22/13 recertification surveys***</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Clinical Manager, the laboratory failed to ensure mohs surgery maps used in histopathology testing were sent to the final report destination for 1 (Patient M20-186) of 9 patient test reports reviewed. Findings include: 1. A review of patient test records revealed Patient M20-186 did not have a mohs surgery map used in histopathology testing for surgery performed on 8/31/20. 2. An interview on 1/13/22 at 10:37 am with the Clinical Manager confirmed the laboratory did not have the mohs surgery map for the patient listed above.