

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2284271	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 3273 Davison Rd Unit 5, Lapeer, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to perform and document the staining characteristics for its Hematoxylin and Eosin staining materials used in histopathology testing at least each date of patient testing for 2 (8/18/24 and 9/15/24) of 10 testing dates reviewed. Findings include: 1. A review of the laboratory's patient testing records revealed a lack of assessment of staining characteristics for its Hematoxylin and Eosin staining used in histopathology testing on 8/18/24 and 9/15/24. 2. A review of the laboratory's patient testing log revealed a total of 24 patients received testing using Hematoxylin and Eosin staining materials when staining characteristics were not assessed and documented on 8/18/24 and 9/15/24. 3. An interview on 5/22/24 at 10:55 am with the Mohs Technician confirmed documentation showing the assessment of staining characteristics for Hematoxylin and Eosin staining materials was not present for 8/18/24 and 9/15/24.</p>