

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0885058	(X3) Date Survey Completed 03/31/2022
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 2685 Jolly Road, Okemos, 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 Moh's Supervisor (MS), the laboratory failed to verify the accuracy of its microscopic tissue examination testing at least twice annually for 1 (2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy documentation revealed a lack of documentation for 1 (2021) of 2 years reviewed. 2. An interview on 3/31/2022 at 8:55 am, the MS confirmed the verification of accuracy testing for its microscopic tissue examinations was not completed in 2021.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs' Supervisor (MS), the laboratory failed to maintain a record system that included the specimen receipt time into the laboratory for each stage of the Mohs' tissue specimens for 7 of 13 Mohs'</p>

patient charts audited. Findings include: 1. Record review for 7 of 13 Mohs' cases reviewed, the laboratory failed to include the specimen receipt time into the laboratory for each stage of the Mohs' tissue specimen recorded on the final Mohs' map as follows: a. OPM21 - 0006 performed on 1/26/2021 b. OPM21 - 0124 performed on 5/25/2021 c. OPM21 - 0162 performed on 7/28/2021 d. OPM21-0026 performed on 9/13/2021 e. OMS21-0090 performed on 11/08/2021 f. OMS21 - 0010 performed on 1/03/2022 g. OMS22-0090 performed on 3/14/2022 2. During the interview on 3/31/2022 at 10:12 am, the MS confirmed the recording of the specimen receipt time into the laboratory for processing was not present on the Mohs' map.

D5801

TEST REPORT
CFR(s): 493.1291(a)

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.

This STANDARD is not met as evidenced by:
. Based on document review and interview with the Mohs' Supervisor (MS), the laboratory failed to establish a system to ensure the transcribed Mohs' surgery site were accurately reported for 7 of 13 Mohs' cases reviewed. Findings include: 1. Record review revealed for 7 of 13 Mohs' cases reviewed, the Mohs' surgical site on the pre-op biopsy report, the Mohs' map, the Mohs' log did not match the location on the final report in the LIS system as follows: a. OPM20-0206 performed on 12/15/2020 i. Pre-op biopsy report and the Mohs' map - left central postauricular skin ii. Mohs' log and LIS report - left central postauricular b. OPM21-0006 performed on 1/26/2021 i. Pre-op biopsy report and the LIS report - left proximal pretibial region ii. Mohs' map and Mohs' log - left proximal pretibial c. OPM21-0055 performed on 3/30/2021 i. Pre-op biopsy report, Mohs' map, and the Mohs' log - right lateral eyebrow ii. LIS report - right inferior lateral forehead d. OPM21-0162 performed on 7/28/2021 i. Pre-op biopsy report and Mohs' map - right superior crus of antihelix ii. Mohs' log - right superior crus of helix iii. LIS report - right inferior posterior helix e. OMS21-0026 performed on 9/13/2021 i. Pre-op biopsy report, Mohs' map, and Mohs' log - right lateral trapezial neck ii. LIS report - right medial trapezial neck f. OMS21-0010 performed on 1/03/2022 i. Pre-op biopsy report and the LIS report - left distal pretibial region ii. Mohs' map and Mohs' log - left distal pretibial g. OMS22-0090 performed on 3/14/2022 i. Pre-op biopsy report and LIS report - right distal pretibial region ii. Mohs' map and Mohs' log - right distal pretibial 2. An interview on 3/31/2022 at 10:15 am, the MS confirmed the locations on the pre-op biopsy report, Mohs' map, Mohs' log and the final LIS report were not consistent with the original tumor site.