

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0694041	<b>(X3) Date Survey Completed</b>  05/05/2022
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology	<b>Street Address, City, State</b>  606 W Pershing Rd Ste E, Decatur, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with Testing Personnel 1 (TP 1), and Mohs surgery patient reports, the laboratory failed to follow written policies and procedures to ensure positive identification and optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing and reporting of results for one of seven patient cases reviewed for Mohs surgery in 2020 through 2022. Findings Include: 1. Review of seven Mohs surgery patient reports dated: PT 1 - 01/21/2021 PT 2 - 10/14/2021 PT 3 - 10/14/2021 PT 4 - 12/16/2021 PT 5 - 01/20/2022 (Left Lateral Forehead A) PT 5 - 01/20/2022 (Left Frontal Scalp B) PT 6 - 06/18/2020 2. Review of Mohs map documentation for PT 5 indicated Mohs surgical map DTR22 - 00013 should have two slides marked, "Left Frontal Scalp B" and Mohs surgical map DTR22 - 00017 should have two slides marked, "Left Lateral Forehead A". Date - 01/20/2022 Location - Left Frontal Scalp B Mohs Op Number - DTR22 - 00013 Case Total Number Slides - 2 (4) Date - 01/20/2022 Location - Left Lateral Forehead A Mohs Op Number - DTR22 - 00017 Case Total Number Slides - 2 (5) 3. Review of the requested Mohs surgery case slides for surgical map DTR22 - 00013 (Case Total Number Slides - 2) revealed a total of three slides on file for PT 5 marked: DTR22 - 00013 PT 5 1-20-22 Lateral I U DTR22 - 00013 PT 5 1-20-22 Frontal I IL DTR22 - 00013 PT 5 1-20-22 Frontal I 4. Review of the requested Mohs surgery case slides for surgical map DTR22 - 00017 (Case Total</p>

Number Slides - 2) revealed a total of one slide on file for PT 5 marked: DTR22 - 00017 PT 5 1-20-22 Lateral I L2 5. On 05/05/2022 at 3:17 pm, TP 1 confirmed one of the four slides for PT 5 was incorrectly labeled.

**D5603**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(b)(f)

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of patient documentation, lack of laboratory records, and interview with Testing Personnel (TP 1), the laboratory failed to retain all records and slide preparations for one of seven patient cases reviewed for Mohs surgery in 2020 through 2021. Findings Include: 1. Review of seven Mohs surgery patient reports dated: PT 1 - 01/21/2021 PT 2 - 10/14/2021 PT 3 - 10/14/2021 PT 4 - 12/16/2021 PT 5 - 01/20/2022 (Left Lateral Forehead A) PT 5 - 01/20/2022 (Left Frontal Scalp B) PT 6 - 06/18/2020 2. Review of Mohs map documentation for PT 2 revealed: Date - 10/14/2021 Location - Left malar Mohs Op Number - DTR 21 104 Case Total Number Slides - 3 (9) 3. Review of the requested Mohs surgery case slides marked DTR 21 0104 revealed a total of two of three reported slides on file for PT 2. 4. On 05/05/2022, at 2:30 pm, Testing Personnel 1 confirmed the above findings.

**D5800**

**POSTANALYTIC SYSTEMS**  
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory documentation, interview with Laboratory Director (LD), and Mohs surgery reports, the laboratory failed to monitor, evaluate, and correct identified problems for one of seven cases reviewed for Mohs surgery in 2020 through 2022. (See D5801).

**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 review of laboratory documentation, interview with Laboratory Director (LD), and Mohs surgery reports, the laboratory failed to have an adequate system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to the final report for one of seven patient cases reviewed for Mohs surgery in 2020 through 2022. Findings Include: 1. Review of seven Mohs surgery patient reports dated: PT 1 - 01/21/2021 PT 2 - 10/14/2021 PT 3 - 10/14/2021 PT 4 - 12/16/2021 PT 5 - 01/20/2022 (Left Lateral Forehead A) PT 5 - 01/20/2022 (Left Frontal Scalp B) PT 6 - 06/18/2020 2. Review of Mohs Operative Note revealed the laboratory failed to accurately and reliably report the findings of surgery results for PT 1. The Mohs map of PT 1 detailed: STAGE 3 "Superficial budding only" "Plan 5FU post healing" "# Positive 0/1" 3. Review of treatment documentation for Stage 3 Mohs Procedure Details revealed the laboratory failed to accurately relay the surgical results of the Mohs map for PT 1: "Microscopic tumor was found persisting in none of the sections of the specimens." 4. On 05/05/2022 at 3:17 pm, interview with Lab Director confirmed the above findings and no follow-up plan was initiated for PT 1.