

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2140742	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 10720 W 165th St, Orland Park, IL	
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
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory procedure manual, Mohs accessioning logs, Mohs maps, patient slides, proficiency testing (PT) records, CMS-209 (Laboratory personnel Report), the laboratory's quality assurance documents for Mohs Micrographic Surgery, Mohs "Quality Control Staining" log, lack of documentation, and interview with a laboratory representative, the laboratory failed to meet the requirements of this condition. The laboratory failed to ensure positive identification of patient specimens throughout the testing process by failing to properly label histopathology slides for two of nine cases reviewed (See D5203). The laboratory failed to follow the written policy for bi-annual method accuracy of Mohs histopathology testing for one of one events performed in 2023 (See D5291 part A). The laboratory failed to follow the written policy for bi-annual method accuracy for Mohs histopathology for two of two events in 2022 (See D5291 part B). The laboratory failed to follow the "Mohs Slide Labeling" procedure for Mohs histopathology testing for five of five Mohs histopathology cases reviewed in 2023 (See D5311). The laboratory failed to check hematoxylin and eosin (H&E) staining material for intended reactivity each day of use for one of seven patient testing dates reviewed for Mohs histopathology testing (See D5473).</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure</p>

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.

This STANDARD is not met as evidenced by:
REPEAT DEFICIENCY Based on review of Mohs accessioning logs, Mohs maps, patient slides, and interview with a laboratory representative, the laboratory failed to ensure positive identification of patient specimens throughout the testing process by failing to properly label histopathology slides for two of nine cases reviewed. Findings Include: 1. Patient testing records were reviewed for nine patients that had a Mohs surgery performed. a. Medical Record Numbers (MRN):749627, 611171, 665768, 9254411, 664239, 637074, 747738, 629570, and 658329. 2. Review of the Mohs accessioning log for 1-18-2023 and the corresponding Mohs maps identified the following information for the slide accession numbers (SAN) for the three patients reviewed on this date. MRN SAN 9254411 OP23-0040 747738 OP23-0039 629570 OP23-0041 3. Review of the corresponding patient slides from the Mohs procedures found the following: MRN SAN on Mohs Map SAN On Slide 9254411 OP23-0040 OP23-0039 747738 OP23-0039 OP23-0040 629570 OP23-0041 OP23-0041 4. On survey date 8-14-2023, at 1:35 pm, the laboratory representative confirmed two of three sets of patients slides from Mohs testing performed on 1-18-2023 were mislabeled according to the information found on the Mohs accession log and Mohs maps.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
A. Based on review of proficiency testing (PT) records, CMS-209 (Laboratory personnel Report), the laboratory's quality assurance documents for Mohs Micrographic Surgery, and interview with the laboratory representative, the laboratory failed to follow the written policy for bi-annual method accuracy for Mohs histopathology testing for one of one events performed in 2023. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Quality Assurance-Proficiency Testing", which stated the following under the sub section for Mohs Micrographic Surgery: "In compliance with section 493.1709, each Mohs surgeon will have 6 slides from each year (3 from Jan-June and 3 from July-Dec) in which Mohs surgery is performed pulled at random...A reviewing Mohs surgeon will verify the diagnosis and sign off on the paperwork." 2. Review of the CMS-209 (Laboratory Personnel Report) identified three testing personnel (TP#1, TP#2, and TP#3) performing Mohs micrographic surgeries. 3. Review of PT testing records for Mohs Micrographic Surgery found for the first bi-annual method accuracy evaluation of 2023 (January through June) a total of 3 patient cases were reviewed. a. TP#1 - Zero cases selected (Zero slides) b. TP#2 - One case selected (Two total slides) c. TP#3 - Two cases selected (Four total slides) 4. Interview with the laboratory representative on 8-24-2023 at 1:35 pm confirmed the laboratory failed to follow the "Quality Assurance-Proficiency Testing" policy for Mohs micrographic surgery for the first

event of 2023. B. Based on review of proficiency testing (PT) records, the laboratory's quality assurance documents for Mohs Micrographic Surgery, lack of documentation, and interview with the laboratory representative, the laboratory failed to follow the written policy for bi-annual method accuracy for Mohs histopathology for two of two method accuracy assessments in 2022. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Quality Assurance-Proficiency Testing", stated the following under for Mohs Micrographic Surgery: "If the reviewing Mohs surgeon and the performing Mohs surgeon disagree on the diagnosis a full review will be done of the case. First, we will check to make sure that there are no additional notes in the operation note stating why a positive case would be called clear. If there are no such notes both Mohs surgeons will re-read the case with notes from the other to see if they agree. If no agreement can be achieved a third Mohs surgeon will read the slides. If two surgeons agree that the case is still positive, they will work on a plan to get the information to the patient with a plan of action on how to take care of the remaining cancer. All the steps along this process will be documented. All quality assurance documentation is maintained in the laboratory Quality Assurance section of the Mohs Manual." 2. Review of 2022 PT testing records for Mohs micrographic surgery found for the following disagreements: a. Event Two of 2022 - One of six cases reviewed had a differing diagnosis by the reviewing dermatopathologist. i. MRN:730445 b. Event One of 2022 - Two of six cases reviewed had a differing diagnosis by the reviewing dermatopathologist. i. MRN: 9076815 ii. MRN: 674706 3. Review of the laboratory Quality Assurance section of the Mohs Manual found no documentation of reviews for the three cases identified in the above finding as outlined in the "Quality Assurance-Proficiency Testing" procedure. 4. Interview with the laboratory representative on 8-24-2023, at 1:35 pm, confirmed the laboratory failed to follow the "Quality Assurance-Proficiency Testing" policy for Mohs micrographic surgery and identify and investigate diagnostic discrepancies for Mohs cases reviewed in 2022.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of the "Mohs Slide Labeling" procedure, patient slides, and interview with a laboratory representative, the laboratory failed to follow the "Mohs Slide Labeling" procedure for Mohs histopathology testing for five of five Mohs histopathology cases reviewed in 2023. Findings include: 1. Review of the laboratory procedure, "Mohs Slide Labeling", stated the following: "Slides will be labeled according to office location they originate from: ...followed by the Mohs Surgeon performing the procedure:" 2. Review of five of five Mohs histopathology cases performed in 2023 found the slides failed to include the Mohs surgeon performing the procedure. Medical Record Numbers 9254411 664239 637074 747738 629570 3. Interview with the laboratory representative on 8-24-2023, at 1:35 pm, confirmed in September of 2022 the laboratory changed how Mohs slides were labeled but the slide labeling procedure failed to be updated.

<p>D5409</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedures manual and interview with a laboratory representative, the laboratory failed to document the discontinuance of two of two microbiology procedures, "Potassium Hydroxide (KOH)" and "Ectoparasites". Findings Include: 1. Review of the laboratory procedure manual identified the procedures, "Potassium Hydroxide (KOH)" and "Ectoparasites" 2. On survey date 8-24-2023, at 1:35 pm, the laboratory representative confirmed that KOH and ectoparasite testing were not performed at this location but had not been discontinued by the laboratory director.</p>
<p>D5473</p>	<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: REPEAT DEFICIENCY Based on review of laboratory procedures, Mohs accession logs, Mohs "Quality Control Staining" log, and interview with a laboratory representative; the laboratory failed to check hematoxylin and eosin (H&E) staining material for intended reactivity each day of use for one of seven patient testing dates reviewed for Mohs histopathology testing. Findings Include: 1. Review of the laboratory's policy, "Policy On Quality Assurance and Procedure -Mohs Surgery", revealed that the laboratory will produce a control slide each day of testing for H&E staining and is assessed for the quality of staining and technique. 2. A random review of patient testing dates for Mohs histopathology found for one of seven patient testing dates reviewed the Mohs surgeon failed to document the acceptability of H&E stain reactivity on the Mohs "Quality Control Staining" log for 4-22-2022. 3. Review of the Mohs accession log identified five patients who had Mohs histopathology testing performed on 4-22-2022. 4. On survey date 8-24-2023, at 1:35 pm, the laboratory representative confirmed the laboratory director or Mohs surgeon failed to sign off on the H&E control for 4-22-2022.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on review of proficiency testing (PT) records, the laboratory's quality assurance documents for Mohs Micrographic Surgery, lack of documentation, the laboratory policy "Policy on Quality Assurance-Quarterly Checklist", competency assessment records, and interview with the laboratory representative, the laboratory director failed to meet the requirements of this condition. The laboratory director failed to identify problems that required corrective actions for bi-annual method accuracy of Mohs histopathology for three of three events in 2022 and 2023 (See D6091). The laboratory director failed to ensure the quality assessment program was maintained for Mohs histopathology testing in 2022 and 2023 (See D6094). The laboratory director failed to ensure the competency assessments were performed as described for the laboratory director and the two additional Mohs surgeons identified on the CMS-209 (Laboratory Personnel Report) that perform Mohs histopathology testing (See D6103).

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records, the laboratory's quality assurance documents for Mohs Micrographic Surgery, lack of documentation, and interview with the laboratory representative, the laboratory director failed to identify problems that required corrective actions for bi-annual method accuracy of Mohs histopathology for three of three events in 2022 and 2023. Findings Include: 1. The laboratory failed to follow the PT procedure for Mohs histopathology testing in 2023 and two of three testing personnel failed have the appropriate number of slides reviewed, as outlined by the laboratory's procedure. See D5291 part A. 2. The laboratory failed to identify differential diagnoses by the reviewing pathology for the 2022 bi-annual method accuracy evaluations performed for Mohs histopathology testing. See D5291 part B.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy "Policy on Quality Assurance-Quarterly Checklist", lack of documentation, and interview with a laboratory representative, the laboratory director failed to ensure the quality assessment program was maintained for Mohs histopathology testing in 2022 and 2023. Findings include: 1. Review of the laboratory procedure manual identified the policy, "Policy on Quality Assurance-Quarterly Checklist", approved by the laboratory director on 9-12-2022, which stated: "Quarterly, the technician will select on Mohs surgical case for a process quality assurance check. The patient chart, including Mohs map, will be pulled. Slides for the case chosen will also be pulled. The approved quality assurance checklist will be

filled out for this case. Any discrepancies found in any area of the checklist will be documented and a corrective action form will be completed. These corrective action forms do not need to go in the patient's chart. These forms will be kept in the Mohs manual for two years." 2. Review of the Mohs manual found no documented quarterly quality assurance checklists as described in the "Policy on Quality Assurance-Quarterly Checklist". 3. On survey date 8-24-2023, at 1:35 pm, the laboratory representative confirmed the laboratory failed to complete the new quarterly checklist form associated with the updated quality assurance policy implemented by the laboratory in September of 2022.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on review of laboratory competency assessment records, lack of documentation, and interview with a laboratory representative; the laboratory director failed to ensure the competency assessments were performed as described for the laboratory director and the two additional Mohs surgeons identified on the CMS-209 (Laboratory Personnel Report) that perform Mohs histopathology testing. Findings Include: 1. Review of the document, "Annual Personnel Assessment: Mohs Surgeon (Non-Director)", stated the following: "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High complexity testing. Thereafter, evaluation must be performed at least annually." 2. A separate competency assessment form for the laboratory director was also identified in the laboratory procedure manual, "Competency Assessment for Laboratory Director". 3. The CMS-209 (Laboratory Personnel Report) identified three testing personnel (TP) performing Mohs histopathology testing. a. TP#1 (Laboratory Director) b. TP#2 c. TP#3 4. Review of competency assessment records found no documentation of competency assessments for the Mohs surgeons or laboratory director in 2021 through the date of survey 8-24-2023. 5. On survey date 8-24--2023, at 12:45 pm, the laboratory representative confirmed no competency assessments had been performed in 2021 through 2023 for the laboratory director or two additional Mohs surgeons listed on the CMS-209.