

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0243280	(X3) Date Survey Completed 02/16/2024
Name of Provider or Supplier Pinnacle Dermatology DbA Qualderm Partners	Street Address, City, State 10512 Park Road, Suite 113, Charlotte, NC	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based upon review of 2023 competency records and interview with the Practice Administrator on 2/16/24, the laboratory failed to assess the competency of their Clinical Consultant, Technical Supervisor and General Supervisor. Findings: Review of 2022 and 2023 competency records did not reveal the documentation of a competency for the individual filling the following roles: 1. Clinical Consultant 2. Technical Supervisor 3. General Supervisor In interview at approximately 9:45 a.m., the Practice Administrator confirmed the following: 1. The individual filling these roles is also Testing Personnel #2. 2. The Laboratory Director has not performed a competency on this individual for the additional roles he fills as Clinical Consultant, Technical Supervisor and General Supervisor.</p>
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 up review of 2023 and 2024 records, review of the laboratory's policies and interview with TP#3 (Testing Personnel), the laboratory failed to verify the accuracy of Mohs slides interpreted in the office twice annually. Findings: Review of 2023 and</p>

2024 records revealed the 2/16/24 performance of one event to verify the accuracy of Mohs slides interpreted in the office. Review of the laboratory's "Protocol for Proficiency Testing" policy states "... #5. Proficiency testing will be performed biannually." In interview at approximately 10:45 a.m., TP#3 confirmed the following: 1. An activity to verify the accuracy of Mohs slides interpreted in the office was performed on the day of the survey, 2/16/24. 2. No previous verifications of accuracy have been performed by the laboratory.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based upon review of 2023 patient KOH (potassium hydroxide) logs and interview with the Practice Administrator on 2/16/24, the laboratory failed to discard KOH reagent when it exceeded its expiration date. Review of 2023 patient KOH logs revealed the following: 1. KOH reagent with an expiration date of 7/31/21 was in use from 2/16/23 through 7/31/23. 2. Eighteen patients were tested using the expired reagent. In interview at approximately 11:00 a.m., the Practice Administrator reviewed the patient KOH log and confirmed the findings.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based upon review of the laboratory's policies and review of 2022 and 2023 patient KOH (potassium hydroxide) logs, TP#1 (Testing Personnel) and TP#4 failed to follow the laboratory's procedure for KOH microscopy test performance. Findings: Review of the laboratory's "KOH Procedure Protocol" states "...8. Following examination by the provider, another provider is asked to blindly read the KOH specimen and verify the appropriate presence or absence of spores or hyphae. The results are documented on the KOH log form, as well as entered in the patient's electronic medical record." Review of 2022 and 2023 patient KOH logs revealed the following: 1. KOH logs have a designated column titled "Blinded/Duplicate verification" to document the results of the second provider who blindly reads KOH specimens and verifies the first provider's results. 2. There was no documentation of the performance of a second provider blindly reading a KOH specimen and verifying the first provider's results.