

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0955875	<b>(X3) Date Survey Completed</b>  06/05/2023
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology Grand Blanc	<b>Street Address, City, State</b>  8245 N Holly Road, Suite 101, Grand Blanc, MI	
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>D5217</b>	<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 Mohs Technician, the laboratory failed to verify the accuracy of its Mohs surgery histopathology testing at least twice annually for 1 (2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's twice annual verification of accuracy documentation revealed one event was performed reviewing the accuracy of its Mohs surgery histopathology testing from June 2022 to December 2022. 2. A review of the laboratory's "Quality Assurance- Proficiency Testing" policy revealed a section stating, "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. These slides will be checked for accuracy." 3. An interview on 6/5/23 at 3:20 pm with the Mohs Technician revealed the laboratory did not have documentation of the January to June 2022 verification of accuracy testing for its Mohs surgery histopathology testing.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other</p>

materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the laboratory failed to include the reportable range for test results for its Potassium Hydroxide (KOH) preparation testing for 10 (August 2022 to June 2023) of 10 months since the laboratory started performing KOH preparation testing. Findings include: 1. A review of the laboratory's "Potassium Hydroxide (KOH)" procedure revealed a lack of reportable range for test results. 2. A review of the test records for Patient #5, with testing performed on 05/21 /2023 revealed the patient was given the result of "+/-" for the qualitative test. 3. An interview on 6/5/23 at 3:20 pm with Testing Personnel #2, the personnel performing testing, revealed the test result could not be obtained and "+/-" was meant to signify that the result was inconclusive. 4. An interview on 6/5/23 at 3:20 pm with the Mohs Technician confirmed the laboratory had not included the reportable range for its KOH preparation testing in its test procedure.

**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 on observation, record review, and interview with the Lead Medical Assistant, the laboratory failed to ensure its Chlorazol Black E Potassium Hydroxide reagent had not exceeded its expiration date since the reagent expired on 4/30/23. Findings include: 1. The surveyor observed the laboratory's Chlorazol Black E Potassium Hydroxide reagent used in Potassium Hydroxide (KOH) preparation testing on 6/5/23 at 12:54 pm. The bottle indicated it had expired on 4/30/23. 2. An interview on 6/5/23 at 1:10 pm with the Lead Medical Assistant revealed the Chlorazol Black E Potassium Hydroxide that had expired was the bottle currently in use. 3. A review of the KOH preparation testing records revealed a total of 6 patients had received testing with this reagent since it had expired on 4/30/23.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Mohs Technician, the Laboratory Director failed to ensure testing personnel performing Potassium Hydroxide (KOH) preparation testing received the appropriate training and could reliably provide accurate results for 1 (Testing Personnel #2) of 1 testing personnel performing KOH preparation testing. Findings include: 1. A review of testing records revealed Testing Personnel #2 started performing KOH preparation testing in April 2023 and had given Patient #5 a result of "+/-" on 5/21/23 for the qualitative test. 2. A review of the laboratory's "Policy for Personnel Competency" revealed a section stating, "Personnel must not report test results for patient specimens until training is complete and competency verified for each test procedure they perform." 3. The surveyor requested documentation of training and competency assessments performed for Testing Personnel #2 on 6/5/23 at 1:42 pm and the documents were not made available. 4. An interview on 6/5/23 at 3:20 pm with the Mohs Technician confirmed the laboratory had not ensured Testing Personnel #2 was trained and verified their competency prior to performing patient testing according to its policy.