

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2261768	(X3) Date Survey Completed 03/06/2025
Name of Provider or Supplier Optima Dermatology	Street Address, City, State 31 Stiles Rd, Ste 2100, Salem, NH	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory (lab) personnel performing proficiency testing (PT) and the Laboratory Director (LD) failed to sign the PT attestation form for 6 out of 6 PT events in 2023 and 2024. Findings include: 1. Review on 3/6/2025 of the lab's PT records revealed 3 PT events in 2023 and 3 PT events in 2024 and the attestation forms for the 6 of 6 PT events were not signed by the testing personnel and LD. 2. Interview on 3/6/2025 at 10:30 a.m. with the Practice Manager confirmed the above finding.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to review and evaluate potassium hydroxide slide examination (KOH) proficiency testing (PT) results for 3 of 5 PT events with unacceptable scores in 2023 and 2024. Findings include: 1. Review on 3/6/2025 of the lab's PT records revealed the lab obtained unacceptable results for KOH testing in 5 of 6 PT events from 2023 through 2024. PT scores for KOH are as follows: 2023 Event 1 - 100% 2023 Event 2 - 50% 2023 Event</p>

3 - 0% 2024 Event 1 - 0% 2024 Event 2 - 0% 2024 Event 3 - 50% Further review of the 5 events with unacceptable results revealed the lab documented review and evaluation for 2 of the 5 events. The evaluation form for 2024 Event 3 documented the slides were reevaluated and obtained acceptable results and the KOH protocol was reviewed by the Laboratory Director; this evaluation form was not signed by the Laboratory Director and did not include documentation of the results obtained during reevaluation. A PT "Corrective Action Checklist" was filled out for 2024 Event 1 but failed to identify the expired reagent and the checklist noted that an additional kit was obtained but no records of results were available at the time of survey for the additional slides reviewed; this document was not signed by the Laboratory Director. 2. Interview on 3/6/2025 at 9:50 a.m. with the Practice Manager confirmed the above finding.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory (lab) failed to verify the accuracy of potassium hydroxide slide examinations (KOH) twice in 2023 and twice in 2024. Findings include: 1. Review on 3/6/2025 of the lab's proficiency testing (PT) records revealed the lab obtained unacceptable results for KOH testing in 5 of 6 PT events from 2023 through 2024. PT scores for KOH are as follows: 2023 Event 1 - 100% 2023 Event 2 - 50% 2023 Event 3 - 0% 2024 Event 1 - 0% 2024 Event 2 - 0% 2024 Event 3 - 50% The lab was not able to provide any other records demonstrating verification of accuracy had been performed for KOH in 2023 and 2024. 2. Interview on 3/6/2025 at 10:45 a.m. with the Practice Manager and with Compliance/Training Personnel confirmed the above findings.

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:
Based on record review and staff interview, the laboratory (lab) failed to follow its policy for proficiency testing (PT) in 2023 and 2024. Findings include: 1. Review on 3/6/2025 of the lab's policy titled "Proficiency Testing Policy" effective 5/16/2021 revealed, on page 1 at #6, instruction for testing personnel to sign the PT attestation form for each event; and, #10 to #13, instructions for review and evaluation of PT scores and instruction to complete the PT "Corrective Action Checklist" and develop a plan for corrective action when PT scores are unsatisfactory. 2. Review on 3/6/25 of the lab's PT records from 2023 and 2024 revealed attestation forms for 6 of 6 events were not signed and 2 out of 6 PT events had documentation of review and evaluation of PT scores. Further reviewed revealed 5 out of 6 event scores were unsatisfactory and the lab completed the "Corrective Action Checklist" for 1 of the 5 events. 3.

	<p>Interview on 3/6/2025 at 10:30 a.m. with the Practice Manager confirmed the above findings.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to sign and date for approval the policies and procedures. Findings include: 1. Review on 3/6/2025 of the laboratory's (lab) policy titled "Proficiency Testing Policy" effective 5/16/2021 and the lab's policy titled "Lab Quality Assurance Policy" effective 6/1/2021 revealed no dated signature by the LD for approval. 2. Interview on 3/6/2025 at 10:30 a.m. with the Practice Manager confirmed the above findings.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory (lab) failed to ensure expired potassium hydroxide (KOH) reagent is not used for slide examinations in 2023 and 2024. Findings include: 1. During a tour of the lab area on 3/6/2025 at 9:50 a.m. the surveyor observed 1 of 1 KOH reagent bottle stored in the cabinet with the glass slides used for KOH slide examinations. 2. Review on 3/6/2025 of the KOH reagent bottle label revealed the lot # was 513028 and the expiration was 5/30/2023. 3. Interview on 3/6/2025 at 9:50 a.m. with the Practice Manager confirmed the above findings and revealed the expired bottle of KOH reagent was the only KOH reagent available for use.</p>
D5980	<p>PPM LABORATORY DIRECTOR CFR(s): 493.1355</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to provide overall management and direction in 2023 and 2024. Findings include: 1. The LD failed ensure policies and procedures were followed and potassium hydroxide slide examination (KOH) was performed in accordance with Subparts H and K. Refer to D5987. 2. The LD failed to evaluate competency of testing personnel with assessment of test performance in 2023 and 2024. Refer to D5988.</p>
D5987	<p>PPM LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1359(b)

The laboratory director must-- (b) Ensure that any procedure listed under 493.19(c)-- (b)(1) is personally performed by an individual who meets the qualification requirements in 493.1363; and (b)(2) Is performed in accordance with applicable requirements in subparts H, J, and K of this part.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure procedures were performed in accordance with subparts H and K in 2023 and 2024. Findings include: 1. The LD failed to ensure proficiency testing (PT) attestation forms were signed in accordance with Subpart H. Cross reference D2009. 2. The LD failed to ensure procedures performed for Quality Systems were performed in accordance with subpart K. The LD failed to ensure: PT scores were reviewed and evaluated, cross reference D5211; the laboratory verified accuracy of potassium hydroxide slide examinations twice a year in 2023 and 2024, cross reference D5217; policies and procedures were followed to identify and correct PT failures, cross reference D5291; policies and procedures in use were signed, dated, and approved by the LD, cross reference D5407; and expired KOH reagent was not used for testing, cross reference D5417.

D5988

PPM LABORATORY DIRECTOR RESPONSIBILITIES

(c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to- (c)(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing; (c)(2) Monitoring the recording and reporting of test results; (c)(3) Review of test results or worksheets; (c)(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and (c)(5) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to evaluate competency through assessment of test performance for personnel performing potassium hydroxide slide examination (KOH) in 2023 and 2024. Findings include: 1. Review on 3/6/2025 of proficiency testing (PT) records from 2023 and 2024 revealed the lab failed to obtain satisfactory scores in 6 of 6 PT events. Further review of the PT results evaluations for these 6 events revealed the lab failed to correctly identify the presence of fungal elements 2 out of 10 times in 2023 and 2024 when the PT KOH specimens were positive for fungal elements. All KOH PT was performed by the same individual (TP1). The lab was not able to provide any additional documentation during the survey that TP1 was assessed for competency of KOH test performance using other methods. 2. Interview on 3/6/2025 at 10:45 a.m. with the Practice Manager and with Compliance/Training Personnel confirmed PT was used for assessment of test performance and no other assessments were performed for TP1.