

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2136302	(X3) Date Survey Completed 09/25/2025
Name of Provider or Supplier Regional Dermatology	Street Address, City, State 989 Governors Ln, Lexington, KY	
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
D0000	A Recertification Survey was initiated on 09/25/2025 and concluded on 09/25/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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 document review and interview, the laboratory failed to ensure the Laboratory Director (LD) and testing personnel signed a proficiency testing (PT) attestation statement for 5 of 6 PT events reviewed. Findings included: A review of an American Proficiency Testing Institute (API) document titled "2023 Microbiology 2nd Event Attestation Statement" indicated, "An attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." A review of the following API Attestation Statements revealed they were not signed by the LD or the person(s) who performed the test: -API 2024 Microbiology 1st Event -API 2024 Microbiology 2nd Event -API 2024 Microbiology 3rd Event - API 2025 Microbiology 1st Event -API 2025 Microbiology 2nd Event During an interview on 09/25/2025 at 1:30 PM, the LD confirmed the above findings.</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>

This STANDARD is not met as evidenced by:
 Based on document review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) results for potassium hydroxide (KOH) preparation (glass slide) for 6 of 6 PT events reviewed. Findings included: A review of an American Proficiency Testing Institute (API) document titled "2023 Microbiology 2nd Event Proficiency Testing Performance Evaluation" indicated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." A review of the following API Performance Summary and Comparative Evaluations revealed that the statements were not signed and dated by the Laboratory Director (LD): -API 2024 Microbiology 3rd Event -API 2024 Microbiology 1st Event -API 2024 Microbiology 2nd Event -API 2024 Microbiology 3rd Event -API 2025 Microbiology 1st Event -API 2025 Microbiology 2nd Event A review of the signed "Quarterly Quality Assurance Checklist" documents dated 12/28/2023, 04/12/2024, 08/12/2024, 12/12/2024, 04/12/2025, and 08/12/2025, found in the binder titled "Laboratory Policy and Procedure Manual, Skin MD, PLLC," failed to include documented evidence of the review and evaluation of PT for the PT events listed above. During an interview on 09/25/2025 at 1:30 PM, the LD confirmed the above findings.

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 document review and interview, the facility failed to achieve successful performance for potassium hydroxide (KOH) preparation (glass slide) on 2 of 6 proficiency test (PT) events reviewed. Findings included: A review of the following American Proficiency Testing Institute (API) Comparative Evaluations revealed unsuccessful performance for the following PT events and tests: -API 2024 Microbiology 3rd Event / KOH Preparation (glass slide) / Score = 50% -API 2025 Microbiology 2nd Event / KOH Preparation (glass slide) / Score = 50% During an interview on 09/25/2025 at 1:30 PM, the Laboratory Director (LD) confirmed the above findings.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
 Based on document review and interview, the facility failed to document corrective action for unacceptable proficiency test (PT) results on 2 of 2 failed PT events reviewed. Findings included: A review of a signed, undated document from the "Laboratory Policy and Procedure Manual, Skin MD, PLLC [Professional Limited Liability Company]" indicated, "Ongoing Assessment: Each of the laboratory's quality

systems will undergo assessment on a regular basis to maintain and improve laboratory performance and services. This assessment includes the following practices: A review of every Request for Corrective Action will be performed by the Laboratory Director as soon as practical after the event with special attention given to investigation of complaints, Proficiency Testing failures, or deficiencies noted during a CLIA inspection." A review of the following American Proficiency Testing Institute (API) Comparative Evaluations revealed unsuccessful performance for the following PTs: -API 2024 Microbiology 3rd Event / Specimen KOH-05: Unacceptable result - API 2025 Microbiology 2nd Event / Specimen KOH-03: Unacceptable result A review of the corresponding API Performance Summary and Comparative Evaluations failed to reveal documentation of corrective actions for the unacceptable results. A review of the signed "Quarterly Quality Assurance Checklist" documents dated 04/12/2024 and 08/12/2025, found in the binder titled "Laboratory Policy and Procedure Manual, Skin MD [Medical Doctor], PLLC," failed to reveal corrective actions for the PT events and testing listed above. During an interview on 09/25/2025 at 1:30 PM, the Laboratory Director (LD) 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 document review and interview, the laboratory failed to establish a written proficiency testing (PT) policy or procedure to define the performance, evaluation, and documentation of PT activities for 2 of 2 years reviewed (2024 and 2025). Findings included: A review of a signed, undated document from the "Laboratory Policy and Procedure Manual, Skin MD [Medical Doctor], PLLC [Professional Limited Liability Company]" failed to include specific procedures for the performance, evaluation, and documentation of PT activities. A review of an unsigned, undated document from the "Laboratory Policy and Procedure Manual, Skin MD, PLLC," titled "EctoParasites & Potassium Hydroxide (KOH) Examination of Skin, Hair & Nails," failed to indicate specific procedures for the performance, evaluation, and documentation of PT activities. During an interview on 09/25/2025 at 1:30 PM, the Laboratory Director (LD) confirmed the above findings.