

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0070557	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Dermatology Associates Of Concord Inc	Street Address, City, State 290 Baker Avenue Ext, Concord, MA	
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 CLIA recertification survey was conducted for at Dermatology Associates of Concord, Inc. on May 13, 2026, pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 found at 42 CFR 493.
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 conducted on 5/13/2026 of 2025 and 2026 Proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory failed review and provide corrective actions for unsatisfactory KOH PT performance. Findings include: 1. Record review of 2025 PT events 1, 2, and 3, and 2026 PT event 1 Microbiology KOH revealed a score of 50% for the 2025 PT 3rd event for KOH Prep; Sample KOH-06: Submitted result- Fungal elements/yeast observed Expected results- NO fungal elements/yeast observed 2. Interview conducted on 5/13/2026 at 11:00 AM with TP1 confirmed that no investigation or corrective actions were performed in response to the laboratory's unsatisfactory 2025 3rd event KOH PT performance.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) 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; and</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of proficiency testing (PT) records and interview with the testing personnel 1 (TP1) conducted on 5/13/2026, the laboratory director failed to ensure all proficiency testing (PT) records are reviewed to assess the laboratory's performance. Findings include: 1. Record review conducted on 5/13/2026 of 2025 and 2026 PT records revealed a lack of review of the laboratory's performance for the following PT events: a. 2025 API Chem Core PT events 1, 2, and 3, and 2026 API Chem Core PT event 1 ALL lacked review and evaluation of the laboratory's performance. b. 2025 API KOH Microbiology PT events 1, 2, and 3 and 2026 API KOH Microbiology PT event 1 ALL lacked review and evaluation of the laboratory's performance. 2. On 5/13/2026 at 11:15 AM, TP1 confirmed the findings identified above.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:
Based on 2025 and 2026 Proficiency testing (PT) record review conducted on 5/13/2026 and interview with the testing personnel (TP), the laboratory director failed to review and provide corrective actions for their unsatisfactory KOH PT performance. Refer to D5211