

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2080258	<b>(X3) Date Survey Completed</b>  02/03/2023
<b>Name of Provider or Supplier</b>  Dermatology Professionals Llc	<b>Street Address, City, State</b>  153 East Washington St, North Attleboro, MA	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and confirmed through staff interview with the clinical services manager (CSM), the laboratory did not maintain a copy of all proficiency testing records in the specialty of Microbiology. Findings include: 1. Record review on 2/3/2023 of the laboratory's 2021, 2022 and 2023 to date WSLH PT records revealed: a. The attestation sheet was missing for 2021 KOH Event 2. b. The 2021 KOH Event 1 and 2022 KOH Events 1 and 2 attestation sheets were not signed by testing personnel (TP). 2. Record review on 2/3/2023 of the laboratory's 2022 KOH testing logs revealed, the laboratory did not document testing of WSLH PT KOH Event 1. 3. During staff interview with the CSM on 2/3/2023 at 10:30 AM, the CSM: a. Confirmed the attestation sheet for WSLH KOH 2021 Event 2 was missing. b. Confirmed the 2021 KOH Event 1 and 2022 KOH Events 1 and 2 attestation sheets were not signed by TP. c. Confirmed the 2022 KOH Event 1 results were not written on the laboratory log. d. Stated, "We have no way of knowing which TP performed the testing on KOH 2022 Event 1 and we do not always have TP sign the attestation</p>

sheet." 4. The laboratory performs 25 KOH tests annually in the specialty of Microbiology.

**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 of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and staff interview with the clinical services manager (CSM), the laboratory failed to verify at least twice annually the accuracy of wet mounts to identify parasites in the specialty of Microbiology. \*This is a repeat deficiency.\* Findings include: 1. Record review on 2/3/2023 of the laboratory's 2021, 2022 and 2023 to date WSLH PT records revealed the laboratory did not have any documentation to verify the accuracy of scabies wet mount testing. 2. Record review on 2/3/2023 of the laboratory's 2021, 2022 and 2023 to date quality assurance records revealed the laboratory did not have any documentation to verify the accuracy of scabies wet mount testing. 3. Record review on 2/3/2023 of the laboratory's 2021, 2022 and 2023 patient testing logs revealed the laboratory performed 6 wet mount for scabies tests from 1/1/2021 through 2/3/2023. 4. Record review on 2/3/2023 of the laboratory's 'KOH & Wet Mount Manual Policy & Procedure' quality control section revealed: a. "PT is required; All Adult & pediatric Dermatology, pc labs have been enrolled with WSLH for our PT testing which are done biannually." b. "\*Please refer to our WSLH Policy and Procedure." 5. Record review on 2/3/2023 of the laboratory's procedure manual revealed, the manual did not contain the procedure referenced in 4b above. 6. staff interview on 2/3/2023 at 10:00 AM with the CSM confirmed the laboratory did not verify the accuracy of wet mount scabies testing twice annually in 2021 and 2022 and has not performed accuracy testing in 2023 to date. 7. The laboratory has performed 6 scabies tests from 1/1/2021 through 2/3/2023 in the specialty of Microbiology.