

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1102971	(X3) Date Survey Completed 06/20/2024
Name of Provider or Supplier Dermcare Physicians And Surgeons	Street Address, City, State 22 Mill Street, Arlington, 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 the Dermcare Physicians and Surgeons laboratory on 06/20/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	<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 proficiency testing (PT) review and interview with Histotechnologist the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed Wisconsin State Laboratory of Hygiene (WSLH) KOH module 3170 proficiency testing (PT) records for 2022 Event POC 2 and 2023 Event POC 1 and POC 2. The review revealed that PT results were not present and the final evaluation reports were no reviewed/signed by the Laboratory Director/designee for all events. The Histotechnologist confirmed in an interview on 06/20/24 at 12:00 PM that the PT results and final evaluation reports for WSLH Event POC 2 of 2022 and Events POC 1 and POC 2 of 2023 were not present and signed by Laboratory Director. The laboratory performs 2 KOH patient tests annually. .</p>

D5211**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) review and interview with the Histotechnologist, the laboratory director failed to effectively review and evaluate PT results obtained on proficiency testing performed as specified in subpart H of this part as evidenced by the following: The surveyor reviewed Wisconsin State Laboratory of Hygiene (WSLH) PT records for the 2022 Event POC2 and 2023 Events POC1 and POC2. The review revealed: The Laboratory received 0% for Module 3170 KOH for event POC2 of 2023. There was no documented corrective actions. The Histotechnologist confirmed in an interview on 06/20/24 at 12:00PM. that the laboratory director failed to review and evaluate the WSLH PT for the second event of 2022 and first and second events of 2023. The laboratory performs 2 KOH tests annually. .