

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D1015174	<b>(X3) Date Survey Completed</b>  03/19/2024
<b>Name of Provider or Supplier</b>  Mystic Valley Dermatology Associates	<b>Street Address, City, State</b>  92 Montvale Ave, Stoneham, 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>D0000</b>	A CLIA recertification survey was conducted for the Mystic Valley Dermatology Associates laboratory on 3/19/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 Practice Manager on 3 /19/2024, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: The surveyors reviewed the Wisconsin State Laboratory of Hygiene (WSLH) PT records for calendar years 2022 and 2023. The review revealed: 1. The coding reports were not available for WSLH Module 3170 PPM (KOH) 2023 Events POC 1 and POC 2. 2. The final reports were present but not reviewed and signed by the laboratory director/designee for WSLH Module 3170 PPM (KOH) for 2022 Events POC 1 and POC 2 and for 2023 Events POC 1 and POC 2. 2. The Practice Manager confirmed in an interview on 3/19/2024 at 4:30 P.M. that the</p>

coding reports were not present and the final reports were not reviewed and signed by the laboratory director/designee. The laboratory performs 5 Mycobacteriology and Mycology (KOH) tests annually.