

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0072589	<b>(X3) Date Survey Completed</b>  06/04/2025
<b>Name of Provider or Supplier</b>  Howard S Goldberg, Md Inc	<b>Street Address, City, State</b>  990 Paradise Rd, Swampscott, 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 on 06/04/2025 for the Howard S Goldberg, MD, Inc laboratory pursuant to the Clinical Laboratory Improvement Act (CLIA) of 1988 and CLIA regulations at 42 CFR CFR 493.
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(b)(7) 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 Administrator (PA) 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 6230 proficiency testing (PT) records for 2023 Event POC 2; 2024 Event POC 1 and POC 2; and 2025 Event POC1. The review revealed that the PT final evaluation reports were not reviewed/signed by the Laboratory Director (LD) or designee for all events. The Practice Administrator confirmed in an interview on 06/04/2025 at 10:30 AM that the PT final evaluation reports for WSLH Event POC 2 of 2023; Events POC 1 and POC 2 of 2024; and Event POC 1 of 2025 were not reviewed and signed by LD. The laboratory performs 420 KOH patient tests annually.</p>
<b>D5211</b>	<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 proficiency testing (PT) review and interview with the Practice Administrator (PA) the Laboratory Director (LD) 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: 1. The surveyor reviewed Wisconsin State Laboratory of Hygiene (WSLH) PT records for the 2023 Event POC2; 2024 Events POC1 and POC2; and 2025 POC1. The review revealed: a. The Laboratory failed one of three challenges for Module 6230 KOH for Event POC1 of 2024. b. There was no documented corrective actions for the failed PT result. 2. The Practice Administrator confirmed in an interview on 06/04/2025 at 10:30 AM that the LD failed to review and evaluate the WSLH PT for the second event of 2023; first and second events of 2024; and first event of 2025. The laboratory performs 420 KOH tests annually.