

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D1041003	<b>(X3) Date Survey Completed</b>  06/24/2025
<b>Name of Provider or Supplier</b>  Massachusetts Eye Research & Surgery	<b>Street Address, City, State</b>  1440 Main Street, Waltham, 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 Massachusetts Eye Research & Surgery Institution laboratory on 06/24/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to test Proficiency Test (PT) samples the same number of times that it routinely tests patient samples. Findings include: 1. Record review of the Laboratory Procedure Manual reviewed: a. The Laboratory "Proficiency Testing" policy states, "PT samples are tested the same number of times that patient sample are tested." b. Laboratory "MERSI Laboratory Repeat Criteria" Policy states: I. Read the print out and repeat if results are less than or greater than specified acceptable range. II. Look for the flags and repeat if there is a "L" flag. 2. Record review on 6/24/2025 of the laboratory's raw data for Wisconsin State Laboratory of Hygiene Proficiency Testing revealed: a. 2024 Event 1 PT sample AT4 was run in duplicate and the result was within acceptable range and had no flags. b. 2024 Event 3 PT sample AT12 was run in duplicate and the result was within acceptable range and had no flags. c. 2025 Event 1 AT1 and AT2 were run in duplicate and the result was within acceptable range and had no flags. 3. Staff Interview on 6/24/2025 at 10:45 AM with the Technical Consultant confirmed patient samples are not routinely run in duplicate and that these PT samples were run in duplicate. 4. The laboratory performs 28,200 tests annually in the specialty of Hematology.</p>