

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2064071	<b>(X3) Date Survey Completed</b>  08/20/2025
<b>Name of Provider or Supplier</b>  M I Lab	<b>Street Address, City, State</b>  246 E Janata Blvd, Ste 260, Lombard, IL	
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>D6092</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of documentation, and interview with testing personnel (TP) #1; the laboratory director failed to perform corrective actions for 13 of 13 unacceptable sample results received from bi-annual method accuracy/proficiency testing (PT) events from 2023 to the date of survey, 08/20/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Laboratory Director responsibilities and Duties", which stated, "Ensure that the laboratory is enrolled in a proficiency testing program for the testing performed and a corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory." 2. Review of laboratory records revealed a lack of documented corrective actions plans followed for 13 of 13 unacceptable proficiency testing sample results upon receipt of peer reviewed alternative PT assessments for Antiphospholipid Antibody Assay (APA), Natural Killer Cell Activation Assay (NKa), and Reproductive Immunophenotype (RI). Analyte/ MI Lab accession number Date IgG Choline/59524 06/09/25 IgM Annexin/59524 06/09/25 IgM Ethanolamine/59524 06/09/25 IgM Annexin/59504 04/28/25 IgM Prothrombin/59504 04/28/25 IgM Ethanolamine/59504 04/28/25 IgG Cardiolipin/59434 11/25/24 IgM Annexin/59261 12/29/23 IgM Ethanolamine/59261 12/29/23 NKa IVI G/59504 06/09/25 NKa Intralipid/59504 06/09/25 NKa IVIG /59255 12/29/23 RI CD19 /59366 07/11/24 3. Interview with TP #1 on 08/20/2025, at 09:24 am, confirmed the laboratory director failed to ensure that corrective actions were taken for 13 of 13 unacceptable results received from bi-annual method accuracy (proficiency testing) events from the beginning of 2023 to the date of survey, 08/20/2025.</p>