

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2043537	<b>(X3) Date Survey Completed</b> 06/19/2018
<b>Name of Provider or Supplier</b> Mlm Medical Labs, Mn	<b>Street Address, City, State</b> 3510 Hopkins Pl N, Oakdale, MN	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review and interview with laboratory personnel, the laboratory failed to retain quality control records for testing performed on a Hematology (Coagulation) analyzer. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory on 06/19/18 at 9:45 a.m. 2. An Instrument Labs ACL Elite analyzer was observed as present and available for use during the tour of the laboratory. The MDB Test and Instrument Menu provided by the laboratory indicated Coagulation tests Prothrombin Time, INR, Activated Partial Thromboplastin Time and Fibrinogen were performed on this analyzer. 3. Quality control (QC) records from the analyzer for the time period of 04/01/17 - 06/30/17 were not available on date of survey. The laboratory was unable to retrieve the records from electronic storage upon request. 4. In an interview on 06/19/18 at 3:50 p.m., General Supervisor 2 (GS2) confirmed the above finding. GS2 indicated the electronic file containing the QC records would not open.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Hematology and Chemistry testing as confirmed by General Supervisor 1 during a tour of the laboratory on 06/19/18 at 9:45 p.m. 2. The laboratory performed PT using the Wisconsin State Laboratory of Hygiene (WSLH) PT provider. 3. The laboratory received unacceptable PT results in 2017 from WSLH for the analytes and samples listed below. Microalbumin Sample Lab Result WSLH expected CU-2 8.7 58.8-81.1 Blood Cell Identification Sample Lab Result WSLH expected XI-12 Lymph atypical Lymph normal XI-15 Echinocyte Acanthocyte XI-17 H-J\* bodies Pappenheimer bodies Magnesium Sample Lab Result WSLH expected CET-13 3.0 1.6-2.6 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 06/19/18 at 5:05 p.m., the Technical Consultant (TC) confirmed a documented evaluation of the unacceptable results was not performed. The TC stated she was not aware individual unacceptable results must be evaluated if the overall score for the analyte was satisfactory. \*Note - Howell-Jolly

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of General Immunology proficiency testing scores when the proficiency testing (PT) program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory on 06/19/18 at 9:45 a.m. 2. The laboratory performed PT using the Wisconsin State Laboratory of Hygiene (WSLH) PT provider. 3. PT results from two HIV/HP/SS events in 2017 were not graded due to insufficient peer group or lack of consensus. See below. 2017 HIV/HP/SS1 Sample ID Analyte YB-1 Anti-HBc (total Antibody) YB-2 Anti-HBc (total Antibody) YB-3 Anti-HBc (total Antibody) YB-4 Anti-HBc (total Antibody) YB-5 Anti-HBc (total Antibody) YB-1 Anti-HBc IgM 2017 HIV/HP /SS2 Sample ID Analyte YB-6 Anti-HBc (total Antibody) YB-7 Anti-HBc (total Antibody) YB-8 Anti-HBc (total Antibody) YB-9 Anti-HBc (total Antibody) YB-10 Anti-HBc (total Antibody) YB-7 Anti-HBs YB-6 HBsAg 4. The WSLH expected results data summary was not present in laboratory records. An evaluation for accuracy of the non-graded results was not found during review of laboratory documents. The laboratory was unable to provide an evaluation of non-graded results upon request. 5. In an interview on 06/19/18 at 5:05 p.m., the Technical Consultant confirmed these results had not been evaluated for accuracy.