

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2043537	<b>(X3) Date Survey Completed</b> 04/10/2019
<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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: . Based on a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute proficiency testing reports, the laboratory failed to successfully participate in proficiency testing for BUN* testing under the specialty of Chemistry. Findings are as follows: D2087 - the laboratory failed to attain satisfactory BUN PT scores D2096 - the laboratory failed to achieve successful BUN PT performance *Note BUN - Blood Urea Nitrogen</p>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to attain satisfactory PT scores for BUN\* testing. Findings are as follows: 1. The laboratory failed to attain PT scores for BUN\* testing of at least 80 percent in two testing events. Scores less than 80 percent resulted in unsatisfactory performance for the analyte. 2. API PT reports listed the following unsatisfactory BUN scores. - 2018 3rd event: 0% - 2019 1st event: 60% \*Note BUN - Blood Urea Nitrogen

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

. Based on a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to achieve successful PT performance for BUN\* testing. Findings are as follows: 1. The laboratory failed to attain satisfactory BUN PT scores in two out of three consecutive PT events. Two out of three consecutive unsatisfactory PT scores for the same analyte constituted unsuccessful performance. 2. API PT reports listed the following unsatisfactory BUN scores. - 2018 3rd event: 0% - 2019 1st event: 60% \*Note BUN - Blood Urea Nitrogen