

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0962469	(X3) Date Survey Completed 08/20/2025
Name of Provider or Supplier Macomb Physicians Group PLLC	Street Address, City, State 8244 Metro Parkway Suite C, Sterling Heights, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A proficiency testing desk review survey was performed on August 20, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following Conditions: 493.803 Condition: Successful participation. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D2016	<p>SUCCESSFUL PARTICIPATION 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 review of the CMS database, American Association of Bioanalysis-Medical Laboratory Evaluation (AAB-MLE) proficiency testing reports, and</p>

	<p>interview with the technical consultant, the laboratory failed to achieve satisfactory performance for the chemistry analyte, High-Density Lipoprotein (HDL) Cholesterol. Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the CMS database, American Association of Bioanalysis-Medical Laboratory Evaluation (AAB-MLE) proficiency testing reports, and interview with the technical consultant, the laboratory failed to achieve satisfactory performance for the chemistry analyte, High-Density Lipoprotein (HDL) Cholesterol, for two (2025 1st and 2nd events) of two consecutive testing events in 2025. Findings include: 1. A review of the CMS database and American Association of Bioanalysis-Medical Laboratory Evaluation (AAB-MLE) proficiency testing reports revealed the laboratory obtained the following proficiency testing scores for High-Density Lipoprotein (HDL) Cholesterol: PT Event HDL Score 1st event 2025 60% 2nd event 2025 0% 2. A phone interview on 8/20/25 at 1:40 pm with the technical consultant confirmed the scores listed above.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on review of the CMS database, American Association of Bioanalysis-Medical Laboratory Evaluation (AAB-MLE) proficiency testing reports, and interview with the technical consultant, the laboratory director failed to achieve satisfactory performance for the chemistry analyte, High-Density Lipoprotein (HDL) Cholesterol. Refer to D6089.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: . Based on review of the CMS database, American Association of Bioanalysis-Medical Laboratory Evaluation (AAB-MLE) proficiency testing reports, and interview with the technical consultant, the laboratory director failed to ensure the laboratory achieved satisfactory performance for the chemistry analyte, High-Density Lipoprotein (HDL) Cholesterol. Refer to D2096.</p>