

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2080840	<b>(X3) Date Survey Completed</b>  11/02/2023
<b>Name of Provider or Supplier</b>  Rochester Primary Care	<b>Street Address, City, State</b>  1349 S Rochester Rd Ste 100, Rochester Hills, MI	
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 record review of the CMS database and the American Proficiency Institute proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the routine chemistry analyte total bilirubin. Findings include: The laboratory failed to attain a score of at least 80% of acceptable responses for the chemistry analyte total bilirubin, which is unsatisfactory performance. Refer to D2096.</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p>

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 review of the CMS database and the American Proficiency Institute proficiency testing reports, the laboratory failed to attain a score of at least 80% of acceptable responses for the chemistry analyte total bilirubin, which is unsatisfactory performance for 2 (1st and 3rd events of 2023) of 3 consecutive testing events. Findings include: A review of the CMS database and the American Proficiency Institute proficiency testing reports revealed the following proficiency testing results for total bilirubin: PT Event Total Bilirubin Score 1st event 2023 60% 3rd event 2023 60%