

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0036103	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Rochester Medical Group	Street Address, City, State 633 E South Blvd #1200, Rochester Hills, 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
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 (Casper 0155D report) and review of the American Association of Bioanalysts (AAB) final proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of Hematology for 2 (3rd event 2018 and 2nd event 2019) of 3 consecutive events. Refer to D2131.</p>
D2131	<p>HEMATOLOGY CFR(s): 493.851(g)</p>

Failure to achieve an overall testing event score of satisfactory performance for 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 record review of Casper Report 0155D and graded proficiency testing results from American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance for the specialty of Hematology in 2 (3rd event 2018 and 2nd event 2019) of 3 consecutive testing events. Findings include: 1. Review of Casper Report 0155D and AAB proficiency testing results revealed the following scores for the specialty of hematology: Hematology PT Events Score 3rd event 2018 60% 2nd event 2019 0%