

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0364318	(X3) Date Survey Completed 07/01/2019
Name of Provider or Supplier Rochester Diagnostic & Specialty Ctr	Street Address, City, State 543 N Main St, Rochester, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: . Based on review of the CMS database and review of the American Proficiency Institute (API) final graded proficiency testing reports, it was determined that the laboratory failed to successfully participate in a CMS approved proficiency testing program for the hematology white blood cell differential. Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for two of three proficiency testing events for the hematology white blood cell differential. Refer to D2130. .
D2130	HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive 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 review of the American Proficiency Institute (API) final graded proficiency testing reports, the laboratory failed to achieve satisfactory performance for the hematology white blood cell differential two out of three consecutive testing events. Findings include: Unsatisfactory performance for two out of three consecutive PT events constituting unsuccessful performance for white blood cell differential: White Blood Cell Differential PT Event Score 2nd event 2018 60% 1st event 2019 40%