

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0720914	(X3) Date Survey Completed 01/26/2021
Name of Provider or Supplier Birmingham Royal Oak Medical Group	Street Address, City, State 5130 Coolidge Hwy, Royal Oak, 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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the hematology analyte: White Blood Cell Differential. Findings include: Review of the CMS database and the API proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the hematology analyte: White Blood Cell Differential. Refer to D2123 and D2130.
D2123	HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to participate in the hematology analyte, White Blood Cell Differential for 2 (1st and 3rd events 2020) of 3 testing events. Findings include: 1. A review of the CMS database and review of the API final proficiency testing reports revealed the laboratory attained the following scores for the hematology analyte: White Blood Cell Differential: PT Event Score 1st event of 2020 0% 3rd event of 2020 0% 2. A review of API proficiency testing reports revealed the laboratory failed to participate in proficiency testing for the hematology analyte: White Blood Cell Differential.

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 the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to participate and achieve satisfactory performance for 2 (1st and 3rd events 2020) of 3 testing events for the hematology analyte: White Blood Cell Differential. Findings include: For the hematology analyte: White Blood Cell Differential the following scores were attained: Hematology PT Event Score 1st event 2020 0% 3rd event 2020 0%