

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0984811	<b>(X3) Date Survey Completed</b>  08/11/2020
<b>Name of Provider or Supplier</b>  John R Medical Clinic	<b>Street Address, City, State</b>  26505 John R Street, Madison Heights, 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 Association of Bioanalysts (AAB) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the specialty of hematology analyte hematocrit. Findings include: Review of the CMS database and the AAB proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the specialty of hematology analyte hematocrit. Refer to D2121 and D2130.</p>
<b>D2121</b>	<b>HEMATOLOGY</b>

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on record review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to achieve at least 80 percent for the analyte hematocrit for 2 (1st and 2nd events in 2020) out of 2 consecutive testing events. Findings include: 1. A record review of the CMS database and AAB proficiency testing reports revealed the following scores for 2 out of 2 consecutive testing events: Hematocrit PT Event Score 1st event 2020 40% 2nd event 2020 0%

**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 record review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the analyte hematocrit for 2 (1st and 2nd events in 2020) out of 2 consecutive testing events. Findings include: 1. A record review of the CMS database and AAB proficiency testing reports revealed unsatisfactory performance for 2 out of 2 consecutive testing events: Hematocrit PT Event Score 1st event 2019 40% 2nd event 2019 0%