

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0989820	(X3) Date Survey Completed 08/28/2020
Name of Provider or Supplier Owensboro Medical Practice Laboratory	Street Address, City, State 1200 Breckenridge Street, Owensboro, KY	
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 desk review of Hematology proficiency testing results from the American Proficiency Institute (API) proficiency testing agency on 08/28/2020, the laboratory failed to successfully participate in the White Blood Cell Differential certified analyte in three of four consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 06/01/2020. See D2121 and D2130</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p>

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 desk review of Hematology proficiency testing results from American Proficiency Institute (API) proficiency testing agency on 08/28/2020, the laboratory failed to attain a score of at least 80 (eighty) percent for a satisfactory performance for the White Blood Cell Differential in three of four consecutive testing events. Findings include: 1. The laboratory failed to achieve a satisfactory score for the White Blood Cell Differential in the second testing event of 2019 with a score of 0 percent. 2. The laboratory failed to achieve a satisfactory score for the White Blood Cell Differential in the first testing event of 2020 with a score of sixty (60) percent. 3. The laboratory failed to achieve a satisfactory score for the White Blood Cell Differential in the second testing event of 2020 with a score of 0 percent.

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 desk review of Hematology proficiency test results from the American Proficiency Institute (API) proficiency testing agency on 08/28/2020, the laboratory failed to successfully achieve satisfactory performance for White Blood Cell Differential in three of four consecutive testing events. Findings include: 1. The laboratory failed to achieve a successful performance for the White Blood Cell Differential with an unsatisfactory performance in the second testing event of 2019. 2. The laboratory failed to achieve a successful performance for the White Blood Cell Differential with an unsatisfactory performance in the first testing event of 2020. 3. The laboratory failed to achieve a successful performance for the White Blood Cell Differential with an unsatisfactory performance in the second testing event of 2020.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on desk review of Hematology proficiency testing results from the American Proficiency Institute (API) proficiency testing agency on 08/28/2020, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of the failed White Blood Cell Differential certified analyte. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 06/01/2020, failed to correct the performance for White Blood Cell differential which is evidenced by the second unsuccessful proficiency failure occurring in the second testing event of 2020.