

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0698986	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier Emw Womens Surgical Center	Street Address, City, State 136 W Market St, Louisville, 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 on 10/02/2018, the laboratory failed to successfully participate in the Red Blood Cell certified analyte in two consecutive testing events. See D2121 and D2130</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte</p>

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 the American Proficiency Institute 10/02/2018, the laboratory failed to attain a satisfactory score of at least 80 percent on the Red Blood Cell analyte. Findings include: The laboratory scored an unsatisfactory 60 percent in the first testing event of 2018 and scored an unsatisfactory 40 percent in the second testing event of 2018.

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 on 10/02/2018, the laboratory failed to successfully achieve satisfactory performance for the Red Blood Cell certified analyte in two consecutive testing events. Findings include: The facility scored 60 percent in the first testing event of 2018 and scored 40 percent in the second testing event of 2018 for an unsuccessful performance.