

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0962601	<b>(X3) Date Survey Completed</b>  05/06/2019
<b>Name of Provider or Supplier</b>  Primary Plus Kid Care	<b>Street Address, City, State</b>  1350 Medical Park Drive, Maysville, KY	
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 desk review of Hematology proficiency testing results from the Wisconsin State Laboratory Hygiene proficiency testing agency on 05/06/2019, the laboratory failed to successfully participate in the Red Blood Cell (RBC) certified analyte in three of five consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 05/07/2018. See D2121 and D2130</p>
<b>D2121</b>	<p><b>HEMATOLOGY</b> 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 the Wisconsin State Laboratory Hygiene on 05/06/2019, the laboratory failed to attain a satisfactory score of at least 80 percent on the Red Blood Cell analyte. Findings include: 1. The laboratory failed to achieve a satisfactory score for the Red Blood Cell analyte in the third testing event of 2017 with a score of 0 percent. 2. The laboratory failed to achieve a satisfactory score for the Red Blood Cell analyte in the first testing event of 2018 with a score of 60 percent. 3. The laboratory failed to achieve a satisfactory score for the Red Blood Cell analyte in the first testing event of 2019 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 Wisconsin State Laboratory Hygiene on 05/06/2019, the laboratory failed to successfully achieve satisfactory performance for the Red Blood Cell Count in three of five consecutive testing events. Findings include: 1. The facility failed to achieve a satisfactory score for the Red Blood Cell analyte in the third testing event of 2017 for an unsuccessful performance. 2. The facility failed to achieve a satisfactory score for the Red Blood Cell analyte in the first testing event of 2018 for an unsuccessful performance. 3. The facility failed to achieve a satisfactory score for the Red Blood Cell analyte in the first testing event of 2019 for an unsuccessful performance.

**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 Wisconsin State Laboratory Hygiene proficiency testing agency on 05/06/2019, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of the failed Red Blood Cell certified analyte. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 05/07/2018, failed to correct the performance for Red Blood Cell which is evidenced by the second unsuccessful proficiency failure occurring in the first testing event of 2019.