

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0648560	<b>(X3) Date Survey Completed</b>  03/29/2019
<b>Name of Provider or Supplier</b>  Combined Physicians Lab Llc DbA Integrated Dx	<b>Street Address, City, State</b>  3945 Simpson Lane, Richmond, 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 Chemistry proficiency testing results from the American Proficiency Institute proficiency testing agency on 03/29/2019, the laboratory failed to successfully participate in the Creatinine certified analyte in three of four consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 10/08/2018. See D2087 and D2096</p>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(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 Chemistry proficiency testing results from the American Proficiency testing agency on 03/29/2019, the laboratory failed to attain a satisfactory score of at least 80 percent on the Creatinine certified analyte. Findings include: The laboratory scored 40 percent in the first testing event of 2018, scored 20 percent in the third testing event of 2018, and scored 60 percent in the first testing event of 2019.

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 Chemistry proficiency testing results from the American Proficiency Institute proficiency testing agency on 03/29/2019, the laboratory failed to successfully achieve satisfactory performance for the Creatinine certified analyte in three of four consecutive testing events. Findings include: The laboratory had an unsatisfactory performance in the first testing event of 2018 with a score of 40 percent, had an unsatisfactory performance in the third testing event with a score of 20 percent, and had an unsatisfactory performance in the first testing events of 2019 with a score of 60 percent for a second 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 Chemistry proficiency testing results from the American Proficiency Institute proficiency testing agency on 03/29/2019, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of the failed Creatinine certified analyte. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 10/08/2018, failed to correct the performance for creatinines which is evidenced by the second unsuccessful proficiency failure occurring in the first testing event of 2019.