

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0648560	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier Combined Physicians Lab Llc DbA Integrated Dx	Street Address, City, State 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.		

(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 Chemistry proficiency testing results from the American Proficiency Institute proficiency testing agency on 11/19/2019, the laboratory failed to successfully participate in the Cholesterol High Density Lipoprotein (HDL) certified analyte in three consecutive testing events. This is the second unsuccessful proficiency failure. See the first unsuccessful failure dated 06/28/2019. See D2087 and D2096.</p>
D2087	<p>ROUTINE CHEMISTRY 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 Institute testing agency on 11/19/2019, the laboratory failed to attain a satisfactory score of at least 80 percent on the HDL Cholesterol certified analyte. Findings include: 1. The laboratory failed to achieve a satisfactory score for the HDL Cholesterol analyte in the first testing event of 2019 with a score of 60 percent. 2. The laboratory failed to achieve a satisfactory score for the HDL Cholesterol analyte in the second testing event of 2019 with a score of 40 percent. 3. The laboratory failed to achieve a satisfactory score for the HDL Cholesterol analyte in the third testing event of 2019 with a score of 40 percent.

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 testing agency on 11/19/2019, the laboratory failed to successfully achieve satisfactory performance for the HDL Cholesterol certified analyte in three consecutive testing events. Findings include: 1. The laboratory failed to achieve a satisfactory performance for the HDL Cholesterol in the first testing event of 2019 with a score of 60 percent. 2. The laboratory failed to achieve a satisfactory performance for the HDL Cholesterol in the second testing event of 2019 with a score of 40 percent. 3. The laboratory failed to achieve a satisfactory performance for the HDL Cholesterol in the third testing event of 2019 with a score of 40 percent.

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 11/19/2019, the laboratory director failed to fulfill the responsibility of evaluating the laboratory's performance of the failed Cholesterol High Density Lipoprotein (HDL) certified analyte. Findings include: The corrective action taken for the first unsuccessful proficiency failure dated 06/28/2018, failed to correct the performance for HDL Cholesterol which is evidenced by the second unsuccessful proficiency failure occurring in the third testing event of 2019.