

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0666777	(X3) Date Survey Completed 04/08/2020
Name of Provider or Supplier Delphos Family Physicians Inc	Street Address, City, State 1775 E Fifth St, Delphos, OH	
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 record review and interviews with the Laboratory Director and an American Proficiency Institute (API) proficiency testing (PT) representative, the laboratory failed to successfully participate in a PT program for the non-waived red blood cell count (RBC) testing performed under the subspecialty of Hematology. All patients who had RBC testing in this laboratory from the third API PT event of 2018 to the third API PT event of 2019 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to achieve satisfactory PT performance for the analyte red blood cell count (RBC) in three out of three consecutive PT testing events in 2019 which resulted in subsequent unsuccessful analyte performance. All</p>

patient RBC specimens tested from the third API PT event of 2018 to the third API PT event of 2019 had the potential to be affected by this deficient practice. (Refer to D2130)

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 record review and interviews with the Laboratory Director and an American Proficiency Institute (API) proficiency testing (PT) representative, the laboratory failed to achieve satisfactory performance for the analyte red blood cell count (RBC) in three out of three consecutive PT events in 2019 and is unsuccessful PT performance. All patients who had RBC testing in this laboratory from the third API PT event of 2018 to the third API PT event of 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2019 API PT documentation revealed a RBC analyte score of 0% for the first, second and third PT events of 2019. %; percent 2. The Laboratory Director confirmed, 04/01/2020 at 4:14 PM, that the laboratory did not achieve successful PT performance for the analyte RBC in three out of three consecutive PT testing events in 2019. 3. The API PT representative confirmed the laboratory's RBC PT analyte score to be 0% for the first, second and third PT events of 2019. The telephone interview occurred on 04/02/2020 at 10:00 AM.