Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0666777	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Delphos Family Physicians Inc	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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to successfully participate in a Proficiency Testing (PT) program for the non-waived LDL (low-density lipoprotein) and sodium (Na) testing performed under the specialty of Chemistry. This deficient practice had the potential to affect 2,616 out of 2,616 LDL tests performed in this laboratory during the second and third PT testing events of 2023 and the first PT testing event of 2024. This deficient practice had the potential to affect 167 out of 167 Na tests performed during the second PT testing event of 2023. Findings Include: 1. The laboratory failed to achieve a PT score of 80% (percent) for LDL testing in the second and third PT events in

	2023, and the first PT event in 2024 in the specialty of Chemistry. (Refer to D2087, Item I) 2. The laboratory failed to achieve a PT score of 80% (percent) for Na testing in the second PT event in 2023 in the specialty of Chemistry. (Refer to D2087, Item II) 3. The laboratory failed to achieve satisfactory performance for the same analyte, LDL, in consecutive events, including the third PT event in 2023, and the first PT event in 2024 in the specialty of Chemistry. (Refer to D2096)
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) 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: Item I: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte low-density lipoprotein (LDL) for the second and third PT events in 2023, and the first PT event in 2024 in the specialty of Chemistry. This deficient practice had the potential to affect 2,616 out of 2,616 patient LDL test results during the second PT event in 2023 in the speciality of Chemistry. Findings Include: 1. Review of the laboratory's API Chemistry PT documentation from the second and third testing events of 2023, and the first event of 2024, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: Second PT Event 2023 LDL; 20% Third PT Event of 2023 LDL; 60% First Event of 2024 LDL: 0% 2. TP #1 confirmed the unsatisfactory LDL PT score for the second and third PT testing events of 2023, and the first PT testing event of 2024. The interview occurred on 05/08/2024 at 2:09 PM. Item II: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte sodium (Na) for the second PT event in 2023 in the specialty of Chemistry. This deficient practice had the potential to affect 167 out of 167 patient Na test results during the second PT event in 2023 in the speciality of Chemistry. Findings Include: 1. Review of the laboratory's API Chemistry PT documentation from the second testing event of 2023, provided on the date of the inspection, revealed the following unsatisfactory analyte testing score: Second PT Event 2023 Na; 60% 2. TP #1 confirmed the unsatisfactory Na PT score for the second testing event of 2023. The interview occurred on 05/08/2024 at 2:09 PM.
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 record review and an interview with Testing Personnel (TP) #1, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte low-density lipoprotein (LDL), in two consecutive testing events, including the second and third PT events in 2023, and the first PT event in 2024 in the specialty of Chemistry. This deficient practice had the potential to affect 2,616 out of 2,616 patient LDL test results during the third PT event in 2023, and the first PT event in

	2024 in the speciality of Chemistry. Findings Include: 1. Review of the laboratory's API Chemistry PT documentation from consecutive events, including the second and third testing events of 2023, and the first event of 2024, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: Second PT Event 2023 LDL; 20% Third PT Event 2023 LDL; 60% First PT Event 2024 LDL; 0% 2. TP #1 confirmed the unsatisfactory LDL PT score in two consecutive events, including the second and third testing events of 2023 and the first testing event of 2024. The interview occurred on 05/08/2024 at 2:09 PM.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record reviews and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure the individuals who performed moderate complexity testing met the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the testing procedures performed. This deficient practice affected three out of four TP. Findings Include: 1. The laboratory failed to ensure TP #2, TP #3 and TP #4 met the education requirements, as specified in subpart M for moderate complexity testing procedures performed. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on document reviews and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure TP #2, TP #3 and TP #4 had the appropriate education documentation to perform all test operations reliably to provide and report accurate results. This deficient practice affected three out of four TP. Findings Include: 1. Review of the laboratory's Form CMS 209, approved, signed and dated on 04/28/2024 by the Laboratory Director found four individuals listed and credentialed to perform moderately complex testing procedures. 2. Review of the laboratory's documents provided on the date of inspectoin did not find education records for TP #2, TP #3 and TP #4. 3. The inspector requested education documentation from TP #1 for TP #2, TP #3 and TP #4. 4. An interview with TP #1, on 05/08/2024 at 12:30 PM,

	confirmed the laboratory failed to ensure TP #2, TP #3 and TP #4 had the appropriate education documentation to perform all test operations reliably to provide and report accurate results and was unable to provide the requested documentation for the inspection.