Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0666777	07/28/2026
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
D0000	AMENDED 08/11/2026
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to enroll in a proficiency testing (PT) program for the moderate complexity Uricult Urine Culture Paddles (Uricult) test in the subspecialty of Bacteriology. This deficient practice had the potential to affect seven out of seven proficiency testing events reviewed from 05/09/2024 through 07/28/2026. Findings Include: 1. Surveyor review of "Criteria for Lab Performance" policy and procedure manual, approved by Laboratory Director (LD) signature and date on 12/16/2025, found the following statement: "...The policy of our facility is to participate in proficiency test for regulated analyte tested in our lab..." 2. Surveyor review of seven proficiency testing events from 05/09/2024 to 07/28/2026 failed to find evidence that the laboratory was enrolled in proficiency testing for the moderate complexity Uricult test in the subspecialty of Bacteriology. 3. An interview with TP #1, on 07/28/2026 at 3:11 PM, confirmed that the laboratory failed to enroll in a proficiency testing

	program for the moderate complexity Uricult test in the subspecialty of Bacteriology. 4. This deficient practice had the potential to affect 15 out of 15 patient Uricult test results in the subspecialty of Bacteriology from 05/09/2024 to 07/28/2026.
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 review of the laboratory's 2025 and 2026 American Proficiency Institute Proficiency Testing (PT) records and an interview with Testing Personnel (TP) #1, the laboratory failed to successfully participate in two out of three PT events for Aspartate Aminotransferase (AST) in the subspecialty of Routine Chemistry for the third testing event of 2025 and the second testing event of 2026 resulting in non-initial unsuccessful PT participation. Findings Include: 1. The laboratory failed to achieve satisfactory PT performance with a score of at least 80% (percent) for the analyte AST in the third PT event of 2025 and the second PT event of 2026 in the subspecialty of Routine Chemistry. This results in non-initial unsuccessful PT participation. (Refer to D2096) 2. An interview with TP #1 confirmed that the laboratory failed to achieve satisfactory performance PT performance with a score of at least 80% (percent) for the analyte AST in the third PT event of 2025 and the second PT event of 2026 in the subspecialty of Routine Chemistry. 3. This deficient practice had the potential to affect 217 out of 217 patient AST tests from the third PT testing event of 2025 through the second PT testing event of 2026.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two

	proficiency testing events. This STANDARD is not met as evidenced by: Based on an interview with Testing Personnel #1 and review of the laboratory's 2026 American Proficiency Institute Proficiency Testing (PT) records the laboratory failed to participate in one out of two testing events in 2026 in the specialty of Chemistry. Findings Include: 1. Review of the laboratory's PT documentation for 2026 found the following results for the second testing event of 2026: "...Chemistry Core... 2026 2nd 0% Failure to Participate..." 2. An interview with TP#1 confirmed, on 08/06/2026 at 2: 56 PM, that the laboratory failed to participate in the second testing event in 2026 for Chemistry resulting in a score of 0%. 3. This deficient practice had the potential to affect 132 out of 132 patients tested from the second PT testing event of 2026 through 08/06/2026.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (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 review of the laboratory's 2025 and 2026 American Proficiency Institute Proficiency Testing (PT) records and an interview with Testing Personnel (TP) #1, the laboratory failed to successfully participate in two out of three PT events for Aspartate Aminotransferase (AST) in the subspecialty of Routine Chemistry for the third testing event of 2025 and the second testing event of 2026 resulting in non-initial unsuccessful PT participation. Findings Include: 1. Review of the laboratory's PT documentation for the third testing event of 2025 and the second testing event of 2026 found the following results for AST: "... 2025 3rd... 2026 2nd AST 0% 0%..." 2. An interview with TP #1 confirmed that the laboratory failed to achieve satisfactory performance PT performance with a score of at least 80% (percent) for the analyte AST in the third PT event of 2025 and the second PT event of 2026 in the subspecialty of Routine Chemistry. 3. This deficient practice had the potential to affect 217 out of 217 patients tested from the second PT testing event of 2025 through 08/06/2026.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to follow the manufacturer's instructions for the moderate complexity Uricult Urine Culture Paddles (Uricult) test in the subspecialty of Bacteriology. This deficient practice had the potential to affect 15 out of 15 patient

	Uricult test results in the subspecialty of Bacteriology from 05/09/2024 to 07/28/2026. Findings Include: 1. Surveyor review of the manufacturer's instructions for the moderate complexity Uricult test found the following statement: "...Procedure Compliance with the following directions is required to achieve reliable test results... 6 Place inoculated URICULT vial upright in incubator ... for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of colony counts and possible misleading biochemical reaction..." 2. Surveyor review of incubator temperature logs failed to find evidence that Uricult test incubation times were monitored per the manufacturer's instructions. 3. The surveyor requested evidence that the lab monitored the Uricult incubation times per the manufacturer instructions. The LD confirmed, on 07/28/2026 at 3:11 PM, that the lab did not monitor Uricult incubation times per the manufacturer's instructions and could not provide the requested documentation.