

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0887857	<b>(X3) Date Survey Completed</b>  04/10/2026
<b>Name of Provider or Supplier</b>  Physicians Immunodiagnostic	<b>Street Address, City, State</b>  512 S Verdugo Dr, Burbank, CA	
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>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) records and interviews with the laboratory director (LD), technical consultant (TC), and testing personnel (TP), the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Urea Nitrogen (UN) analyte. The findings include: 1. The surveyor reviewed the PT records reported by CAP for the second event of 2024 (Q2-2024) as an unsatisfactory score for UN analyte of 20%. 2. The LD, TC, and TP affirmed by interviews on April 10, 2026, at approximately 11:30 a.m. that the laboratory obtained the unsatisfactory PT scores for UN as mentioned in statement #1. 3. According to the laboratory's testing declaration form (Lab-144) signed by the LD and submitted on the day of the survey 04/10/2026, the laboratory performed approximately 29,716 UN patient test samples annually including at the time when the laboratory received the unsatisfactory proficiency for UN analyte testing score.</p>
<b>D2099</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) reports and interviews with the laboratory director (LD), technical consultant (TC), and testing personnel (TP), the laboratory failed to attain a score of at least 80 percent in Endocrinology for Triiodothyronine (T3) for the second event of 2025 (Q2-2025). The findings include: 1. The laboratory obtained a score of 60% for the T3 analyte as reported by CAP-PT for the Q2-2025 event. 2. The LD, TC, and TP affirmed on the day of the survey April 10, 2026, at approximately 11:40 a. m. that the laboratory obtained the unsatisfactory proficiency score as mentioned on statement#1 for the T3 analyte. 3. Based on the laboratory's annual test volume declaration signed by the laboratory director on 04/09/2026, the laboratory analyzed and reported approximately 1,079 T3 patient tests. The reliability and quality of patient tests reported during the period the laboratory received an unacceptable T3 - PT report cannot be assured.

**D2121**

**HEMATOLOGY**

CFR(s): 493.851(a)

(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:  
Based on the surveyor's review of College of American Pathologists (CAP) proficiency testing (PFT), the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, nine (9) randomly selected patient test records, and interviews with the laboratory's laboratory director (LD), technical supervisor (TS) and testing personnel (TP); the laboratory failed to attain at least 80 percent of the acceptable response resulting to an unsatisfactory performance for the Prothrombin Time (PT) analyte third event for 2025 (Q3-2025). The findings include: 1. The laboratory was enrolled in the CAP - PT program and received an unsatisfactory score of 60% for PT for Q3-2025 event. 2. The LD, TC, and TP affirmed by interviews on April 10, 2026, at approximately 12:00 a.m. that the laboratory obtained for the PT analyte PFT unsatisfactory scores as mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 2,623 samples annually for PT analytes. Thus, the reliability and quality of PT patient results reported could not be assured at the time when the laboratory obtained unsatisfactory CAP-PT scores.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on review of laboratory's proficiency testing (PT) records (peer review), and interview with the Laboratory Director (LD) and technical supervisors (TS) on April 10., 2026, the laboratory failed to verify the accuracy of histopathology testing at least twice annually. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for the laboratory testing performed in the laboratory. However, Histopathology did not have a competency

evaluation or peer review performed for the years 2023, 2024, and 2025. 2. The laboratory performed Histopathology, which is not listed in subpart I of 42 CFR part 493. For the test procedure not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually. The laboratory did not have any record for Histopathology accuracy verification for the years 2023, 2024, 2025. 3. The laboratory director confirmed by interview that the laboratory did not verify the accuracy of histopathology at least twice annually for the years 2023, 2024, and 2025. 4. The laboratory's testing declaration form, signed by the laboratory director on April 9, 2026 2026, stated that the laboratory performed approximately 1,104 Histopathology testing annually for which no verification of accuracy was performed for 2023, 2024, and 2025.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of the proficiency testing results documentation, randomly selected patient test records, and interviews with the laboratory personnel on April 10, 2026; the laboratory director is herein cited due to failure to ensure that several aspects of the analytic and postanalytic phases of the laboratory testing were monitored. The findings include See D2087, D2099, D2121, and D5217.