

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2276856	(X3) Date Survey Completed 09/22/2026
Name of Provider or Supplier Platinum Diagnostics Llc	Street Address, City, State 3 Cornwall Drive, East Brunswick, NJ	
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with General Supervisor (GS), the laboratory failed to verify the accuracy of Cytochrome P450 4F2 (GYP4F2) in the calendar year 2025. The findings include: 1. PT results obtained from College of American Pathologists (CAP) where as follows: a) Samples PGX-01, PGX-02, PGX-03 received an exception code of 11 (unable to analyze) for GYP4F2 in event A-2025. b) No corrective action (CA) was documented when PGX-01, PGX-02, PGX-03 received an exception code of 11 (unable to analyze) for GYP4F2 in event A-2025. c) GYP4F2 PT challenge was not offered by CAP in event B-2025 2. The GS confirmed on 09/22/2026 at 1:00 PM the laboratory failed to verify the accuracy of GYP4F2 in the calendar year 2025
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information

regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Test Reports (TR), Requisition Report (REQ), and interview with General Supervisor (GS), the laboratory failed to ensure that the patient TR and REQ had all the required information from 09/03/2026 to the 9/22/26. The finding includes: 1. Ten out of ten FR and REQ reviewed did not have the correct address of the laboratory where tests were performed. 2. The GS confirmed on 09/22/2026 at 1:30 PM that laboratory failed to have the correct the address where laboratory test where performed.