

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2276856	(X3) Date Survey Completed 01/11/2024
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories NJ State License, Proficiency Testing (PT) and interview with the State of New Jersey Proficiency Provider Program lead, the Laboratory Director (LD) failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. The finding includes: 1. N.J.A.C. 8:44-2.5 (b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The LD failed to make PT Pharmacogenetics data routinely available to the Department of Health and Senior Services and Centers for Medicare & Medicaid Services.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisors (GS) the laboratory failed to review coded and unacceptable results for Pharmacogenetics Testing performed with the College of American Pathologists (CAP) in the calendar year 2022. The findings include: 1. The laboratory received coded results (Code 26 -Educational Challenge) for event PGX-B 2022</p>

Pharmacogenetics. a) CYP2C19 Interpretation samples PGX- 04, 05, 06 received code 26. b) CYP2C19 Clinical Manage samples PGX- 04, 05, 06 received code 26. c) CYP2D6 Interpretation samples PGX- 04, 05, 06 received code 26. d) CYP2D6 Clinical Manage samples PGX- 04, 05, 06 received code 26. e) CYP2C9 Interpretation samples PGX- 04, 05, 06 received code 26. f) CYP2C9 Clinical Manage samples PGX- 04, 05, 06 received code 26. g) VKORC1 Interpretation samples PGX- 04, 05, 06 received code 26. h) CYP2C9/VKORC1 Clinical PGX- 04, 05, 06 received code 26. i) CYP3A4 Interpretation samples PGX- 04, 05, 06 received code 26. j) CYP3A5 Interpretation samples PGX- 04, 05, 06 received code 26. 2. The laboratory received coded results (Code 11 - Unable to analyze documentation to be provided by laboratory) for event PGX-B 2022 Pharmacogenetics. a) CYP2C9 Genotype sample PGX-045 recived code 11. b) CYP4F2 Genotype samples PGX- 04, 05, 06 received code 11. c)SLCO1B1 Clinical Manage samples PGX- 04, 05, 06 received code 11. 3. The laboratory received unascertainable results for event PGX-B 2022 Pharmacogenetics. a) CYP2D6 Genotype sample PGX-05 received unacceptable results. b) CYP2C9 Genotype sample PGX-05 and 06 received unacceptable results. c) VKORC1 Genotype sample PGX-05 and 06 received unacceptable results. d) SLCO1B1 Genotype sample PGX-04, 05 and 06 received unacceptable results. e) SLCO1B1 Interpretation sample PGX-04, 05 and 06 received unacceptable results. 4. There was no documented evidence that aforementioned coded PT and unacceptable results were reviewed. 5. The GS confirmed on 1/11/23 at 11:14 am that the laboratory did not review coded and unacceptable PT results.

D5805

TEST REPORT
CFR(s): 493.1291(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) for Clinical Cytogenetics tests performed on the Quantstudio 7 Flex System and interview with the Technical Supervisor (TS) the laboratory failed to ensure the TR included all the required information from 3/7/23 to the date of survey. The findings include: 1. TR did not include the required statement for tests that have not been FDA-cleared or approved which is "The performance characteristics of this test were determined by Platinum Diagnostics LLC. It has not been cleared or approved by the U.S. Food and Drug Administration". 2. The TS confirmed on 1/11/24 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.