Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2075628	05/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Global Laboratories	8031 Ritchie Highway #202, Pasadena, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of quality control records and email responses to finalize the survey, the laboratory did not have written procedures to document interpretations of toxicology quality control test results. Findings: 1. The laboratory performs toxicology testing on patient specimens. The analyzer prints out the quality control results as a quantitative value in nanograms per deciliter, but does not provide a qualitative interpretation for the quality control test results, and the testing person is responsible for determining if the quantitative results for the positive and negative control reagents provide both a negative result for the designated negative control and

	a positive result for the designated positive control. 2. Patient test results are reported to the health care provider as (+) detected or (-) not detected 3. The laboratory did not have documentation showing the qualitative interpretation of the quality control test results for both the negative and positive controls. 4. The findings were confirmed through email dated May 9 and 17, 2024 from the technical consultant.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of written procedures and email responses from the laboratory, the laboratory did not have written procedures to require the laboratory to followup and provide written responses or corrective actions for problems identified by the technical consultant during the monthly review of quality assurance reports and test records. Findings: 1. The technical consultant reviews testing records, preventative maintenance records, temperature and humidity records, calibrations and other records monthly. 2. The written quality assurance procedure did not state that the technical consultant or the laboratory director must provide a written response to any problems that were identified during the monthly review and describe how any problems that were identified, were corrected and who is responsible for monitoring the corrective action to ensure the problem does not reoccur 3. These findings were confirmed with the technical consultant through email dated May 9 and 17, 2024
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of corrective action logs and email responses from the laboratory, the laboratory did not document corrective actions or the reason for failed quality control testing that occurred on December 15 and 19, 2023 for the cocaine metabolite and repeated quality control testing on June 27, 2023 for PCP testing. Findings: 1. On December 15 and 19, 2023 the cocaine metabolite quality control reagent failed to meet the laboratory's criteria for acceptability. The laboratory decided not to perform patient testing. The laboratory did not document that quality control testing was unacceptable, that patient samples were not tested and troubleshooting performed, if indicated on both days on the corrective action log. 2. On June 27, 2023, the PCP quality control reagents, both negative and positive were retested three times. The

	laboratory did not document the reason for performing the quality control in triplicate on the corrective action report. 3. This was confirmed through email responses provided by the technical supervisor that was dated May 9 and 17, 2024.