Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2075628	06/04/2026
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and interview with the testing person (TP), the laboratory failed to document the lot numbers, dates of expiration, and dates of usage for the reagents and quality control (QC) materials used for urine toxicology testing to ensure they were all used before their expiration date. Findings: 1. The laboratory performed urine toxicology testing using an Indiko Plus analyzer. 2. During the recertification survey on 06/04/2026 at 11:57 AM, the TP confirmed that the lot numbers, expiration dates, and dates of usage for the reagents and QC materials used for urine toxicology testing were not stored in the analyzer and were not documented anywhere else.
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 final test reports, review of proficiency testing (PT) records, and interview with the technical consultant (TC), the laboratory failed to verify the accuracy of the analyte pH which was included in the final patient test report. Findings: 1. The laboratory performed urine toxicology testing. 2. The final patient

	test reports included results for the analyte pH. 3. The laboratory was enrolled in PT for urine drug screening which did not include the analyte pH. 4. During the recertification survey on 06/04/2026 at 10:10 AM, the TC confirmed that pH was used for sample validity and should not be on the final test report and that the laboratory did not verify accuracy of pH at least twice annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, review of the procedure manual, and interview with the technical consultant (TC), the laboratory failed to establish acceptability criteria for the low and high QC levels for the analyte pH. Findings: 1. The laboratory tested a low and high level of QC reagent for the analyte pH each day of patient testing. 2. There were no acceptable pH QC ranges defined in the analyzer or in the procedure manual to be able to evaluate whether the QC results for pH were acceptable. 3. During the recertification survey on 06/04/2026 at 12:40 PM, the TC confirmed that the acceptable ranges for both levels of the pH QC were not specified by the manufacturer and not established by the laboratory.