Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2075628	11/14/2022
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the procedure and eyewash station log and interview with the technical consultant (TC), the laboratory failed to perform weekly preventative maintenance on the eyewash station. Findings: 1. The procedure titled "Eyewash Preventative Maintenance (P.M.)" gave instructions on flushing out the eyewash station and stated to "Document checks and/or concerns with action taken on the Office or Outpatient Log" and that the "Eyewash MUST be checked every 7 days +/- 1 day." 2. The laboratory documented the eyewash checks on the "Eye Wash Station Log." 3. The last entry on the log was dated 08/05/2020. 4. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that the weekly flushing of the eyewash station was not documented as performed.
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 proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to verify the accuracy of buprenorphine and tricyclic antidepressants (TCA) at least twice annually in 2019. Findings: 1. The

	laboratory was enrolled in the College of American Pathologists (CAP) urine drug screen (UDS) PT program which shipped three challenges per year (A-C). 2. The 2019 PT records only contained documentation from the UDS-C PT event. The TC confirmed at 10:15 AM that the laboratory only participated in the UDS-C PT event in 2019. 3. The UDS-C PT event did not include an evaluation of results for buprenorphine and TCA. 4. The laboratory performed split sample testing with another laboratory which included results for buprenorphine and TCA 5. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that the accuracy of buprenorphine and TCA was not verified at least twice in 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's operator's manual and the monthly preventive maintenance forms and interview with the technical consultant (TC), the laboratory failed to perform all weekly maintenance tasks as defined by the manufacturer for the Indiko Plus toxicology analyzer. Findings: 1. The manufacturer's manual for the Indiko Plus analyzer stated that weekly maintenance included cleaning and checking the probes and mixer paddle and cleaning the wash wells. 2. The monthly "Indiko Plus Analyzer Maintenance Log" template used by the laboratory had these two items crossed off. 3. The laboratory did not perform these two maintenance tasks from 01/2021-10/2022. 4. The completed maintenance log from 03/2022 was missing. 5. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that the testing personnel were not performing two of the weekly preventive maintenance tasks for the Indiko Plus toxicology analyzer.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the procedure manual, monthly temperature logs, and thermometer validation records and interview with the technical consultant (TC), the laboratory failed to ensure refrigerator temperatures remained within acceptable limits for reagent storage. Findings: 1. The procedure titled "III. Environmental Controls" stated that if the "temperature is not within specified ranges, corrective action must be taken and noted on temperature recording chart" and that the TC will "check all temperature charts on a regular basis" and if a "consistent problem is observed, laboratory director must take steps to eliminate the problem." 2. The laboratory recorded refrigerator and room temperatures on the forms titled "Monthly Temperature Chart Refrigerator" and "Monthly Temperature Chart Room Temp", respectively. The refrigerator log listed an acceptable range of 2-8 C and the room temp log listed an acceptable range of 22-30 C. Both forms included a grid that listed

	days of the month horizontally in the columns and the acceptable temperatures vertically in the rows so that on each day temperature was taken, a check mark was placed in the cell that matched the day of the month and the measured temperature. 3. Temperature charts were reviewed from 01/2022 through 10/2022 for a total of 10 months. 4. Records from 03/2022 were missing. 5. Refrigerator temperatures were documented as out of range (OOR) in seven of the nine months of available 2022 temperature logs. 6. Refrigerator temperatures were recorded on the room temperature logs in 04/2022 and 06/2022-10/2022. The acceptable temperatures for room temperature were crossed out in the rows and refrigerator temperatures were handwritten in the chart. The handwritten temperatures did not match the acceptable range listed on the refrigerator log. 7. The refrigerator temperatures were OOR in eight of eight days recorded in 04/2022, eight of eight days recorded in 05/2022, six of ten days recorded in 06/2022, three of eight days recorded in 07/2022, seven of seven days recorded in 08/2022, one of eight days recorded in 09/2022, and seven of ten days recorded in 10/2022. 8. The TC reviewed the monthly temperature charts as part of the quality assurance activities and noted on the 05/2022 review that "refrigerator temperature is too high" and "if a temp is out of range, you must take corrective action. All reagents stored in this refrigerator in May are no good. Write corrective action steps taken on lower left of temp chart." The review then noted "reagents must be discarded as not stored at proper temp." 9. There was no additional documentation or follow-up stating whether the reagents were discarded and if patient results may have been affected by the improperly stored reagents. 10. Corrective actions were not recorded on any of the monthly refrigerator temperature logs before or after 05/2022. 11. The "Annual Thermometer Temperature Validation" showed that the refrigerator thermometer was last calibrated on 07/01/2020 and was overdue for accuracy verification. 12. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that the refrigerator temperatures were OOR on multiple days from 04 /2022-10/2022, that corrective actions were not performed or documented, and that the thermometers were overdue for accuracy verification.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on review of records and interview with the technical consultant (TC), the laboratory failed to ensure that all quality assessment (QA) records were reviewed and that monthly reviews were performed in a timely manner to ensure that potential problems could be promptly identified and corrective actions implemented for urine drug screen testing. Findings: 1. The TC stated that the testing personnel would scan and email laboratory records to the TC for QA review at the end of every month. The records were printed by the TC and attached to a cover sheet that contained a checklist of documents to be received and reviewed and a section for notes and corrective actions to be taken. The documents listed on the cover sheet were "Complaint /Problem Log", "Temp charts", "Bench Cleaning", "Corrective Action", "Monthly QA req[uisition] review", "Maintenance", and "Eye Wash" and the TC would also receive the monthly quality control (QC) results summary. 2. Monthly QA packets from 12 /2021 - 10/2022 were reviewed. 3. Refrigerator temperature charts and maintenance

	forms were missing in 03/2022. 4. Bench cleaning charts were missing after 01/2022. 5. Corrective action logs for QC outliers were missing after 12/14/2021. 6. All weekly analyzer maintenance activities were not routinely performed. Cross-refer to D5429 for more details. 7. The eyewash check log was last completed on 08/05/2020. Cross refer to tag D3011 for more details. 8. The document checklist on the cover sheet was filled out each month stating which documents had been received, but there was no indication that missing documents were requested and reviewed for QA. 9. The QA packets for the months of 01/2021 - 08/2021 were all reviewed on 09/13/2022 (up to eight months after documented events), 09/2022 was reviewed on 01/24/2022 (five months after documented events), 10/2019 - 01/2022 were reviewed on 02/10/2022 (up to four months after documented events), 02/2022 - 06/2022 were reviewed on 08 /03/2022 (up to four months after documented events), 07/2022 - 10/2022 were reviewed on 11/08/2022 (up to four months after documented events). 10. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that the monthly QA packets that were reviewed did not always contain all QA documents and the monthly QA packets were not always reviewed in a timely manner to ensure that any potential problems were promptly identified and corrective actions implemented. II. Based on review of monthly quality control (QC) instrument printout summaries and monthly maintenance forms and interview with the technical consultant (TC), the laboratory failed to ensure that QC and maintenance activities were performed on each day patient specimens were tested. Findings: 1. Daily maintenance activities and QC testing are required to be performed each day of patient testing. 2. At 1:00 PM on 10 /14/2022, the TC confirmed that dates the instrument maintenance was performed and documented should match the dates that QC was tested. 3. Monthly maintenance and QC logs were reviewed from 04/2022 - 10/2022. 4. The following dates in 2022 showed that QC was performed but daily maintenance was not recorded: 04/29, 07/01, 08/12, 09/23, 10/05, 10/13, and 10/28. 5. On 10/03/2022 maintenance was performed, but no QC was performed. 6. During the survey on 11/14/2022 at 2:30 PM, the TC confirmed that both maintenance and QC should be performed on dates patient testing is performed and there were dates when QC was performed and maintenance was not and vice versa.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD) failed to date the review of PT results evaluations to ensure timely resolution of potential problems. Findings: 1. The laboratory was enrolled in the College of American Pathologists (CAP) urine drug screen PT program which shipped three challenges per year. 2. Records from three PT events in 2022 and one PT event in 2019 were reviewed. 3. The results evaluations forms were signed as reviewed by the LD but not dated to ensure that results were reviewed in a timely manner to address any potential testing issues. 4. During the

	survey on 11/14/2022 at 2:30 PM, the TC confirmed that the LD signed but didn't date the review of PT results evaluations.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the quality assessment (QA) program was maintained by ensuring that all weekly analyzer maintenance activities were performed, the refrigerator temperature consistently remained within acceptable range, and all QA forms were reviewed in a timely manner. Cross-refer to tags D5429, D5785, and D5791 for more information.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that recommended corrective actions were implemented and successful in preventing recurrences when the refrigerator that stored testing reagents was out of acceptable range. Cross-refer to tag D5785 for more details.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: The testing personnel failed to perform and document corrective actions when refrigerator temperatures were out of acceptable range for reagent storage. Cross-refer to tag D5785 for more details.