Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2095727	06/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Golden Toxicology Llc	2020 8th Ave Suite 218, West Linn, OR	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the package inserts for the urine validity strips and quality control (QC) material in use at time of survey, interview with the Technical Supervisor (TS) and phone conversations with the Laboratory Director (LD), the laboratory failed to establish performance verification of the urine validity test strips using FDA cleared controls to test urine specimens submitted for toxicology assays. Findings include: 1. Upon review of the package insert for the urine validity test strips used to test each urine specimen received by this lab for toxicology testing using Liquid Chromatography and Mass Spectrometry (LC/MS), it was revealed that the test strips are FDA exempt, making them a high complexity assay, requiring laboratory verification / validation of this assay. 2. Upon review of the package insert for the QC material used to QC the urine validity test strips (3 levels of controls), it was revealed that these controls were intended for forensic use only and not for clinical use. 3. During interview with the TS at approximately 1 pm on June 1, 2023 revealed that there was no verification or validation of performance for these test strips. 3. The laboratory reports testing 24,639 urine specimens since the last CLIA survey on 04/06

	/2021. 4. During a phone call received from the LD on 6/6/2023, the LD confirmed that no verification / validation studies had been performed on the urine validity tests strips currently in use by this lab.