Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2023100	03/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Office Of Forensic Toxicology Services	500 Indiana Ave, Nw, Level C, Room 225, Washington, DC	

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
D0000	The Office of Forensic Toxicology Services was surveyed under 42 CFR part 493 CLIA regulations. The following standard deficiencies were found during the announced routine CLIA recertification survey performed on March 23, 2023:
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 observation, review of the Beckman Coulter User's Guide, and interview with the laboratory technical supervisor, the laboratory failed to follow the manufacturer's instructions for documenting weekly maintenance procedures for 3 of 104 weeks reviewed. Findings include: 1. A tour of the Toxicology laboratory on March 23, 2023, at 9:45 am, revealed it was one Beckman Coulter AU5800 (Device #1) in the laboratory for performing Urine Immunoassay Screening tests. 2. On 03/23 /2023 at 10:30 am, a review of the manufacturer's User's Guide, section 8.4 Weekly Maintenance required the following weekly procedures: Clean the sample probes and mix bars, perform a W2 and a photocal, and clean the pre-dilution bottles. 3. On 03/23 /2023 at 10:45 am, a review of the AU5800 preventive maintenance log, showed that weekly maintenance had not been documented for the third week of April 2021, and the first and second weeks of June 2022. 4. On 03/23/2023 at 11:10 am, the laboratory technical supervisor confirmed the above findings.
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 observation, the review of the final test report, and an interview with the laboratory director, the laboratory's final test report failed to include the correct address where the laboratory testing is performed. Findings include: 1. A tour of the Toxicology laboratory on March 23, 2023, at 9:45 am, revealed it was one Beckman Coulter AU5800 (Device #1) in the laboratory for performing Urine Immunoassay Screening tests. 2. Device #1, Beckman Coulter's printout (Specimen number: XXXX7076) listed the raw data for the donor's tests performed in this lab. 3. The laboratory's final test report (Specimen number: XXXX7076) listed the testing laboratory's address as "90 K Street NE, Washington, DC 20002" The CLIA Certificate of Compliance listed the laboratory's address as "500 Indiana Ave NW, Level C, Room 225, Washington, DC 2001." 4. Interview with the lab director on 03 /23/2023 at 11:00 AM confirmed that the final test report had an incorrect address listed.