

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D0979344	<b>(X3) Date Survey Completed</b>  03/16/2023
<b>Name of Provider or Supplier</b>  Office Of Forensic Toxicology Services	<b>Street Address, City, State</b>  90 K Street Ne Suite 102, Washington, DC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Office of Forensic Toxicology Services was surveyed under 42 CFR part 493 CLIA regulations. The following standard deficiency was found during the announced routine CLIA recertification survey performed on March 16, 2023:
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory Standard Operating Procedures (SOP) and an interview with the Laboratory Director, the laboratory failed to follow its policy to review 1 of 2 SOPs at least on an annual basis, and every change to the SOP from the last survey. Findings Include: 1. Review of the Quality Assurance Confirmation Unit (QA-1, QA Program), section B.6.1 stated, "The director is ultimately responsible for the SOPs. He/ She must review, approve and sign each SOP pertaining on an annual basis and must review, approve, and sign every change to an SOP." 2. On the day of the survey, 3/16/2023 at 1 pm, a review of the Immunoassay/Screening Urine Section SOP, revealed that the SOP was not reviewed at least on an annual basis, and every change to the SOP from the last survey. 3. Interview with the Laboratory Director on 3 /16/2023 at 1:40 pm confirmed the laboratory did not follow the established written policy QA-1, QA Program SOP regarding SOP review, approval, and signature.</p>