

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0979344	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Office Of Forensic Toxicology Services	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Federal surveyors from the Division of Clinical Laboratory Improvement & Quality CLIA Operations, Centers for Medicare and Medicaid Services (CMS) - Philadelphia CMS Office conducted an announced CLIA Recertification survey at the Office of Forensic Toxicology Services- 90K laboratory on March 16, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. Specific deficiencies cited are as follows:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, inventory records review and staff interview the laboratory failed to discard current in use lot of expired Dimethyl Sulfoxide (DMSO) reagents . Findings include: 1. During a tour of the Pretrial Services Agency (PSA) laboratory testing area on March 16, 2021 at approximately 9:55am, the tour revealed 3 of 3 current lot at the time of the survey of expired bottles of Dimethyl Sulfoxide (DMSO). a. Lot # : SHBJ45963 2. An inventory document on the outside of the reagent storage cabinet detailed: a. Type of Reagent: (DSMO) Quantity: 3 Expiration date : February-2021. 3. During the exit interview on March 17, 2021 at approximately 1:00 PM, the laboratory director confirmed the above finding.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient</p>

preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of competency records, policy and procedures, and staff interview the laboratory technical supervisor#1 failed to follow competency assessment policy to directly observe staff during the 2020 competency assessments for 90K laboratory testing personnel. Findings include 1. On March 17, 2021, during a review of 2020 competency records of 90K laboratory evaluation period of July 2020- December 2020, the records revealed, in the section titled " Directly Observing Performance of Routine Drug of Abuse Tests", a diagonal line crossing out the entire section with no information of dates or initials of the reviewer. a.5 out of 5 testing personnel had no information completed 2. Review of staff competency Assessment Section procedures states " all competency assessment shall be recorded showing date and results and shall be kept confidential" 3. CMS surveyor #2 asked Technical Supervisor (TS#1) of the section why were the other sections completed in the assessment and not direct observation? TS#1 stated " I couldn't do it due to distancing issue with COVID-19". 4. During the exit interview on March 17, 2021 at approximately 1:00 PM, the laboratory director confirmed the above finding.