Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2023100	08/28/2024
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	An onsite recertification survey was conducted on 08/28/2024 and standard level deficiencies were cited.
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 the laboratory's test menu, proficiency testing documents, and in interview with staff, the laboratory failed to ensure 1 of 12 analytes (ethyl glucuronide [EtG]) tested on the Beckman Coulter AU5800 was verified for accuracy at least twice annually in 2023. Findings included: 1. Review of the laboratory's test menu included EtG, a non-subpart I analyte, as part of the urine screen panel on the Beckman Coulter AU5800 analyzer. 2. Review of College of American Pathology (CAP) and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing documents for 2023 did not include EtG drug analyte. 3. During an interview on 08/28/2024 at 3:04 pm, technical supervisor 1 and testing person 8 was asked whether the laboratory does alternative assessments or blind sample testing to verify accuracy of EtG, they confirmed no.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, reagent lot worksheets, analyzer data, and interview with testing person 8, the laboratory failed to follow their written procedure for verifying 6 of 6 new reagent lot numbers on the Beckman Coulter AU5800 analyzer (Instrument #1) in 2023. Findings included: 1. Review of the laboratory's procedure "Reagent Lot Validation" stated, "New reagent lots must be validated in the laboratory on the instrumentation before they go into use for testing. Reagent lots that do not pass validation requirements are not to be used for specimen testing." Further review of the procedure stated, "11. Input the data into spreadsheet. S: /Quality Control/Reagent Precision Worksheet ...b. %RSD should be within 10%. If it is not within 10% the validation needs to be repeated. Values obtained should also be within range of the target value for the corresponding drug." 2. During a tour of the laboratory on 08/28/2024 at 4:14 pm, there was one Beckman Coulter AU5800 analyzer observed identified as "Instrument #1" with System ID #67472852 that tested urine drug screens. 3. Review of "REAGENT VALIDATION Precision Worksheet Lot #23055237 23055238 Inst #3" completed 06/07/2023 included new lot reagents of cocaine, opiates, methadone, amphetamines, phencyclidine (PCP), and creatinine. The %RSD for opiates was 47% and for PCP was 14.1% (acceptable criteria 10% or less). The %RSD was outside of the acceptable criteria and signed for approval and use 06 /07/2023 by the general supervisor. In addition, the reagent lot validation was not performed on Beckman Coulter AU5800 "Instrument #1, it was performed on "Instrument #3" at their sister laboratory on 90 K Street. 4. Review of "Frozen Control Precision Worksheet validation lot 23055237-5238 6-6-23" completed 06/07/2023 included new lot for quality control on the new lot reagents of cocaine, opiates, methadone, amphetamines, PCP, and creatinine. The %RSD for opiates was 36.6% and for PCP was 11.8% (acceptable criteria 10% or less). The %RSD was outside of the acceptable criteria and signed for approval and use 06/07/2023 by the general supervisor. 5. Review of "REAGENT VALIDATION Frozen Control Precision Worksheet Lot# 23055237 23055238 Inst #2" completed 06/07/2023 new lot for quality control on the new lot reagents of cocaine, opiates, methadone, amphetamines, PCP, and creatinine. The %RSD for opiates was 43.3% (acceptable criteria 10% or less). The %RSD was outside of the acceptable criteria and signed for approval and use 06/07/2023 by the general supervisor. In addition, the reagent lot validation was not performed on Beckman Coulter AU5800 "Instrument #1", it was performed on "Instrument #2" at their sister laboratory on 90 K Street. 6. During an interview on 08 /28/2024 at 3:24 pm, testing person 8 was asked whether the above new reagent and quality control validations were repeated, she confirmed no. The laboratory failed to perform reagent and quality control validation on their Beckman Coulter AU5800 instrument #1 and ensure data was within their defined acceptable criteria of 10% or less.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on review of manufacturer's instructions, Centers for Medicare & Medicaid Services (CMS) -116 application form, direct observation, and interview with staff, the laboratory failed to follow manufacturer's instructions when storing 12 of 12 reagents that are not in-use on the Beckman Coulter AU5800 analyzer. Findings included: 1. Review of Siemens Syva Emit II Plus Amphetamines, Ethyl Alcohol, Methadone, Opiate, Creatinine, Cocaine, Cannabinoid, Phencyclidine (PCP), 6-Acetylmorpine (6-AM) Assays and ARK Diagnostics Fentanyl II, Ethyl Glucuronide (EtG), AB-PINACA (K2) Assays stated, "When not in use, reagents must be stored at 2-8C (36-46F), upright, and with screw caps tightly closed." 2. Review of the laboratory's completed CMS-116 application form page 2 included hours of testing Monday through Saturday, 9 am to 6 pm. During an interview on 08/28/2024 at 2:45 pm, testing person 3 was asked how on-board reagents were handled at the end of the day (6 pm). She stated the reagents were left uncapped on the Beckman Coulter AU5800 analyzer. She was asked whether the uncapped reagents were left on the analyzer Saturday night through Monday morning, she stated yes. 3. During a tour of the laboratory on 08/28/2024 at 4:40 pm, reagents were observed stored in two compartments (Reagent 1 and Reagent 2) on the Beckman Coulter AU5800 analyzer: Amphetamines (Lot #9C958UL-S5, expiration 11/28/2024) Ethyl Alcohol (Lot #9K418UL-S5, expiration 05/28/2025) Methadone (Lot #9E418UL-S3, expiration date 10/06/2025) Opiate (Lot #9B418UL-T2, expiration 11/17/2025) Creatinine (Lot #3T018UL-S2, expiration 07/26/2025) Cocaine (Lot #9H428UL-S9, expiration 12/15 /2024) Cannabinoid (Lot #9N448UL-S5, expiration 04/24/2025) PCP (Lot #75061155, expiration 10/31/2026) 6-AM (Lot #9R318UL-S3, expiration 04/03 /2025) Fentanyl II (Lot #E52263, expiration 06/30/2025) EtG (Lot #WO19220, expiration date 05/31/2025) K2-3 (Lot #E52872) 4. During a tour of the laboratory on 08/28/2024 at 4:44 pm, reagents were observed stored in the refrigerator with the following opened dates: Amphetamines (Lot #9C958UL-S5, expiration 11/28/2024, opened 08/26/2024) Ethyl Alcohol (Lot #9K418UL-S5, expiration 05/28/2025, opened 08/21/2024) Methadone (Lot #9E418UL-S3, expiration date 10/06/2025, opened 05/13/2024) Opiate (Lot #9B418UL-T2, expiration 11/17/2025, opened 07/18 /2024) Creatinine (Lot #3T018UL-S2, expiration 07/26/2025, opened 08/10/2024) Cocaine (Lot #9H428UL-S9, expiration 12/15/2024, opened 08/08/2024) Cannabinoid (Lot #9N448UL-S5, expiration 04/24/2025, opened 08/16/2024) PCP (Lot #75061155, expiration 10/31/2026, opened 08/12/2024) 6-AM (Lot #9R318UL-S3, expiration 04/03/2025, opened 07/15/2024) Fentanyl II (Lot #E52263, expiration 06/30/2025, opened 08/06/2024) EtG (Lot #WO19220, expiration date 05/31/2025, opened 08/23/2024) 5. During an interview on 08/28/2024 at 4:15 pm, testing person 7 was asked how on-board reagents were handled at the end of the day (6 pm). She confirmed that reagents were left on the analyzer overnight, over the weekend, and uncapped. Word Key: C= degree Celsius F = degree Fahrenheit
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 manufacturer's instructions, laboratory's procedures, interview with staff, and review of preventive maintenance logs, the laboratory failed to document corrective actions when Beckman Coulter AU5800 reagent compartment

	temperatures were out of range (2-8C) for 127 of 439 days (04/2023 - 08/2024). Findings included: 1. Review of Siemens Syva Emit II Plus Amphetamines, Ethyl Alcohol, Methadone, Opiate, Creatinine, Cocaine, Cannabinoid, Phencyclidine (PCP), 6-Acetylmorpine (6-AM) Assays and ARK Diagnostics Fentanyl II, Ethyl Glucuronide (EtG), AB-PINACA (K2) Assays stated, "When not in use, reagents must be stored at 2-8C (36-46F), upright, and with screw caps tightly closed." 2. Review of the laboratory's procedures for Siemens Syva Emit II Plus Amphetamines, Ethyl Alcohol, Methadone, Opiate, Creatinine, Cocaine, Cannabinoid, Phencyclidine (PCP), 6-Acetylmorpine (6-AM) Assays and ARK Diagnostics Fentanyl II, Ethyl Glucuronide (EtG), AB-PINACA (K2) Assays included the above manufacturer's instructions. 3. During an interview on 08/28/2024 at 4:15 pm, testing person 7 was asked how on-board reagents were handled at the end of the day (6 pm). She confirmed that reagents were left on the analyzer overnight, over the weekend, and uncapped. 4. Review of the Beckman Coulter AU5800 analyzer preventive maintenance logs for 2023 and 2024 included daily documentation of reagent compartment temperatures. The preventive maintenance logs did not include an acceptable temperature range per the reagent storage manufacturer's instructions, 2-8C. There were 127 days the reagent compartments were beyond 8C, the following was a sampling of those months and days: 04/06/2023: 8.2C 04/13/2023: 8.1C 04/21/2023: 8.1C 05/22/2023: 8.3C 05/26/2023: 8.3C 05/27/2023: 8.1C 08/04/2023: 8.3C 08/05/2023: 8.1C 08/07/2023: 8.2C 11/01/2023: 8.2C 11/02/2023: 8.1C 11/16/2023: 8.3C 01/05/2024: 8.1C 01/08/2024: 8.4C 01/24/2024: 8.2C 04/04/2024: 8.1C 04/06/2024: 8.1C 04/08/2024: 8.3C 07/02/2024: 8.1C 07/09/2024: 8.2C 08/05/2024: 8.3C 08/27/2024: 8.2C 08/28/2024: 8.1C The laboratory did not have corrective action documentation for the 127 days the reagent compartment temperatures were above the manufacturer's defined range of 2-8C. 5. During an interview on 08/28/2024 at 4:40 pm, technical supervisor 1 and testing person 8 confirmed that no corrective action had been taken and documented for days when temperatures were >8C.