Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0979344	08/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Office Of Forensic Toxicology Services	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	An onsite recertification survey was conducted from 08/27/2024 through 08/28/2024. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's procedure manual, manufacturer's instructions, direct observation, patient reports, collector instructions, and interview with technical supervisor 1, the laboratory failed to establish urine and oral fluid specimen handling written policies and procedures for 3 of 11 urine drug analytes and 2 of 9 oral fluid drug analytes. Findings included: 1. Review of the laboratory's procedure manual for urine drug analytes Ethyl Glucuronide (EtG), Synthetic Cannabinoids-3 (K2-3), and Fentanyl screened on the Beckman Coulter AU5800 did not include: a) specimen storage, preservation, stability, b) transport conditions, c) acceptability and rejection. ARK Diagnostics EtG, K2-3, and Fentanyl reagent manufacturer's instructions stated to store at "2-8C" and analyze "within 7 days of collection" or freeze samples at "-20 C." 2. Review of the laboratory's procedure manual for oral fluid drug analytes Ethyl Alcohol and Cocaine/Benzoylecgonine screened on the Beckman Coulter AU5800 did not include: a) specimen storage, preservation, stability, b) transport conditions, c) acceptability and rejection. Immunalysis Ethyl Alcohol reagent manufacturer's instructions did not include specimen requirements. Immunalysis Cocaine /Benzoylecgonine reagent manufacturer's instructions stated "Quantisal Oral Fluid

Collector" specimens were stable "for 10 days from time of collection if stored at room temperature (22-25C)." 3. During an observation on 08/27/2024 at 10:18 am, the laboratory received urine specimens from one of their local collectors for urine drug screening on the Beckman Coulter AU5800. The courier was observed delivering seven (7) cardboard boxes with 30 urine specimens in each box on a dolly. A sampling of those analyzed and reported were specimens # 38617804, 38618348, 38617827, 38617983, and 38618354 (collected 08/26/2024). The instructions provided to the collectors for oral fluids did not include specimen storage, preservation, stability, transport conditions, acceptability and rejection. The instructions provided to the collectors for the urine specimens stated, "The sample will then be placed in the box in the specimen refrigerator for transport." The storage temperature was not defined. Refer to D5317. 4. During an interview on 08/27/2024 at 4:30 pm, technical supervisor 1 was unable to provide oral fluid and urine specimen handling studies. She stated oral fluid specimens were not tested daily and are stored in the refrigerator awaiting testing. The laboratory procedures did not include refrigerator temperatures for oral fluids, the storage requirements were "room temperature (30C or 22-25C)" per the manufacturer. She confirmed there were no transport conditions instructions and urine specimens are delivered by the courier at room temperature. The laboratory's urine drug screen and oral fluid drug screen procedures did not include all established specimen handling requirements. II. Based on review of the laboratory's procedure manual, manufacturer's instructions, direct observation, patient test reports, and interview with technical supervisor 1, the laboratory failed to ensure their procedures included manufacturer's specimen requirements for 2 of 12 analytes (Ethyl Alcohol and Creatinine) tested on the Beckman Coulter AU5800. Findings included: 1. Review of the laboratory's procedure manual for urine creatinine stated, "If not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days following collection." Review of the Siemens Syva Creatinine Validity Test specimen manufacturer's instructions stated, "Analyze freshly collected urine specimens as soon as possible. Creatinine in urine is stable for 1-2 days when stored at 2-10C." Review of the laboratory's procedure manual for urine Ethyl Alcohol stated, "If not analyzed immediately, specimens may be stored unrefrigerated for up to 5 days following collection." The temperature for "unrefrigerated" was not defined. Review of the Siemens Syva Emit II Plus Ethyl Alcohol Assay specimen manufacturer's instructions stated, "For transporting, maintain the specimen temperature at 2-8C." 2. During an observation on 08/27/2024 at 10:18 am, the laboratory received urine specimens from one of their local collectors for urine drug screening on the Beckman Coulter AU5800. A sampling of those analyzed and reported for Ethyl Alcohol and Creatinine included specimens # 38617804, 38618348, 38617827, 38617983, 38618354 (collected 08/26/2024). The specimens were not transported in conditions of "2-10C" or "2-8C." 3. The laboratory was unable to provide urine stability studies to support their written procedure for storage at "unrefrigerated for up to 7 days" and "unrefrigerated for up to 5 days." 4. During an interview on 08/27/2024 at 4:30 pm, technical supervisor 1 confirmed there were no transport conditions instructions provided to collectors/couriers and urine specimens were delivered by the courier at room temperature. III. Based on review of laboratory's procedure manuals and direct observation, the laboratory failed to ensure urine specimen requirements were consistent for urine drug screen on the Beckman Coulter AU5800 and urine confirmation testing on the gas chromatography mass spectrometry (GC-MS) and liquid chromatography mass spectrometry (LCMS) for 7 of 11 drug analytes. Findings included: 1. Review of the laboratory's procedure manual for GCMS testing amphetamines, benzoylecgonine, 6-acetylmorphine, opiates, methadone, phencyclidine, delta9-tetrahydrocannabinol (THC), and LCMS testing fentanyl and norfentanyl stated, "It is recommended that urine specimens be

	stored at 2-8C. For prolonged storage, freezing of specimens is recommended." Review of the laboratory's procedure manual for Beckman Coulter AU5800 screening amphetamines, benzoylecgonine, 6-acetylmorphine, opiates, methadone, phencyclidine, and THC, stated, "If not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days following collection." Review of the laboratory's procedure manual for Beckman Coulter AU5800 screening fentanyl did not include specimen requirements. The urine specimen submitted for screening is used for confirmation testing upon request. The specimen storage requirements were not consistent with one another for screening and confirmation testing. 2. During an observation on 08/27/2024 at 10:18 am, the laboratory received urine specimens from one of their local collectors for urine drug screening on the Beckman Coulter AU5800. The specimens were not transported at "2-8C" as defined by the laboratory's GCMS and LCMS specimen requirements. The laboratory did not ensure specimen storage and handling requirements were consistent in their written procedures for Beckman Coulter AU5800 screening and GCMS and LCMS confirmation testing. Word Key: C = degree Celsius
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, interview with staff, Centers for Medicare & Medicaid Services-116 (CMS-116) database, and specimen tracking report, the laboratory failed to refer 163 of 163 synthetic cannabinoids-3 (K2-3) specimens for confirmation testing to a CLIA-certified laboratory. Findings included: 1. Review of the laboratory's test menu included screening K2-3 drug analyte on the Beckman Coulter AU5800. 2. During an interview on 08/28/2024 at 10:03 am, technical supervisor 1 and technical supervisor 2 stated K2-3 specimens were referred for confirmation testing to the District of Columbia (D.C.) Office of Chief Medical Examiner laboratory, who is accredited by the American Board Forensic Toxicology. 3. A search for the laboratory in the CMS-116 database did not include a CLIA number for the D.C. Office of Chief Medical Examiner laboratory. 4. According to a specimen tracking report from 01/01/2023 through 12/31/2023, a total of 163 K2-3 urine specimens were referred to the non-CLIA certified laboratory for confirmation testing.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of collection instructions, procedure manuals, and direct observation, the laboratory failed to include all specimen requirements in their instructions to collectors for urine and oral fluid drug testing. Findings included: 1. Review of "Drug Testing Protocol and Procedure for Urine Sample Collection" did not include the

	following: a) Specimen storage and preservation. The procedure stated, "The sample will then be placed in the box in the specimen refrigerator for transport." Storage temperature and stability was not defined. b) Conditions for specimen transportation. The laboratory's procedures included "unrefrigerated" for drug screen testing, "2-8C" for confirmation testing, or did not include any specimen handling requirements. Refer to D5311. c) Specimen acceptability and rejection criteria. The laboratory's "Specimen Processing" procedure stated, "Any discrepancy in specimen identity or integrity causes refusal of the specimen by the laboratory staff." 2. Review of the collection instructions for Oral Fluid did not include the following: a) Specimen labeling, including patient name or unique patient identifier and specimen source. b) Specimen storage and preservation. The instructions stated, "The collector is placed in a transport tube containing a buffer which stabilizes the specimen for shipping and storage." Storage and shipping conditions were not defined. The stability at a defined condition was not provided. c) Conditions for specimen transportation. The laboratory's procedures included defined "room temperatures" (22-25C or up to 30C) with stability or did not include any specimen handling requirements. Refer to D5311. d) Specimen acceptability and rejection criteria. The laboratory's "Specimen Processing" procedure stated, "Any discrepancy in specimen identity or integrity causes refusal of the specimen by the laboratory staff." 3. During an observation on 08 /27/2024 at 10:18 am, the laboratory received urine specimens from one of their local collectors for urine drug screening on the Beckman Coulter AU5800. A sampling of those analyzed and reported were specimens # 38617804, 38618348, 38617827, 38617983, 38618354 (collected 08/26/2024). The laboratory did not ensure all written specimen handling requirements were provided to the collectors for urine and oral fluids.
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 establishment studies, laboratory procedures, and interview with technical supervisor 1, the laboratory failed to establish urine specimen requirements for their new LCMSMS fentanyl and norfentanyl method effective 03/2024. Findings included: 1. Review of the laboratory's establishment studies for fentanyl and norfentanyl method on the LCMSMS included laboratory director signature and date of approval 01/29/2024 and effective 03/2024. The data and summary did not include specimen establishment requirements, storage temperature/s, stability, preservation, and conditions for transportation. 2. Review of the laboratory's "Initial Validation of Confirmatory GC/MS and LC-MS/MS Testing Method" procedure did not include methods for establishing specimen requirements. 3. Review of the laboratory's "LCMSMS-FENT" procedure stated, "It is recommended that urine specimens be

	stored at 2-8C. For prolonged storage, freezing of specimens is recommended." The laboratory did not have studies to support the defined specimen storage temperature. 4. During an interview on 08/27/2024 at 4:30 pm, technical supervisor 1 confirmed specimen stability studies had not been completed as part of the fentanyl and norfentanyl LCMSMS establishment protocol.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on interview with technical supervisor 1, review of temperature logs and the Rees Scientific system, the laboratory failed to have a quality assessment (QA) program that identified and corrected issues with their Rees Scientific temperature monitoring system for 175 of 308 days (10/2023 through 08/2024). Findings included: 1. During an interview on 08/28/2024 at 11:00 am, technical supervisor 1 displayed the Rees Scientific temperature monitoring system on the computer. She stated the laboratory's refrigerators, freezers, and rooms were monitored and documented electronically by this system every 15 minutes. In addition, the staff documented temperatures from thermometers on paper logs for refrigerators, freezers, and rooms. Temperature logs from 2023 and 2024 were reviewed for completion. 2. During a sampling review of the Rees Scientific temperature monitoring system included the "Walk-In Specimens" refrigerator (defined range 2-8C) from 01/21/23 through 08/27/2024. The Rees Scientific temperature monitoring system was not operational from 10/24/2023 through 01/31/2024, 03/14/2024 through 04/03/2024, and 05/07/2024 through 07/02/2024 (175 days). 3. During an interview on 08/28/2024 at 11:00 am, technical supervisor 1 was asked whether their QA program monitored the Rees System to ensure it was operational, she stated their QA had not monitored and identified this issue.