

# Toxicology Operations Manual

## Table of Contents

<b>1</b>	<b>SCOPE</b>	<b>4</b>
<b>2</b>	<b>REQUESTS</b>	<b>4</b>
2.1	Customers	4
2.2	Request Types	4
2.2.1	<i>Postmortem</i>	4
2.2.2	<i>Drug-Facilitated Crime (DFC)</i>	5
2.2.3	<i>Driving Under the Influence (DUI)/Other Human Performance</i>	5
2.2.4	<i>General</i>	5
2.2.5	<i>Hair/Alternative Matrices</i>	5
2.2.6	<i>Subject Matter Expert (SME)</i>	5
2.2.7	<i>Proficiency Tests (PT)</i>	6
2.3	Request Acceptance	6
2.3.1	<i>Routine</i>	6
2.3.2	<i>Non-Routine</i>	6
2.3.3	<i>Reexamination</i>	7
<b>3</b>	<b>SPECIMENS</b>	<b>7</b>
3.1	Types and Collection	7
3.1.1	<i>Recommended Collection Strategies</i>	8
3.1.2	<i>Specimen Labeling</i>	9
3.2	Transport	9
3.2.1	<i>Method</i>	9
3.2.2	<i>Packaging</i>	9
3.2.3	<i>Temperature</i>	9
3.2.4	<i>Light Protection</i>	9
3.3	Receipt	10
3.3.1	<i>Storage</i>	10
3.3.2	<i>Single Unit Submission (SUS)</i>	10
3.3.3	<i>Multiple Unit Submission (MUS)</i>	10
3.4	Inventory/Check-In	10
3.4.1	<i>Special Considerations</i>	10
3.4.2	<i>Functional Equivalence of Specimens</i>	11
3.5	Storage	12
3.5.1	<i>PT Material Retention</i>	12
3.6	Sample Disposal	12
<b>4</b>	<b>EXAMINATIONS</b>	<b>12</b>
4.1	Screening / Confirmation / Quantitation	12

4.1.1	Screening.....	12
4.1.2	Confirmation.....	13
4.1.3	Quantitation.....	13
4.2	Scopes of Analysis.....	13
4.2.1	Postmortem.....	13
4.2.2	DFC.....	14
4.2.3	DUI/Human Performance.....	15
4.2.4	General.....	15
4.2.5	Hair.....	15
4.2.6	Proficiency Tests.....	16
4.2.7	Updates to the Scopes of Exams.....	16
4.3	Exam Assignment.....	16
4.3.1	Responsibilities.....	16
4.3.2	Minimum Sample Requirements.....	16
4.3.3	Scope Specification.....	17
4.4	Sample Selection.....	17
4.4.1	Specimen Type and Location.....	17
4.4.2	Representative Sample Considerations.....	17
4.4.3	Homogeneity.....	18
4.4.4	Heterogeneity.....	18
4.4.5	Homogenization Methods.....	18
4.5	Performing Exams.....	19
4.5.1	Exam Records.....	19
4.5.2	Batch Review.....	19
4.5.3	Data Distribution.....	20
4.5.4	Examiner Review.....	20
4.5.5	Exam Completion.....	20
<b>5</b>	<b>REPORTING.....</b>	<b>20</b>
5.1	Exam Summary.....	20
5.2	Report Generation.....	21
5.3	General Guidelines.....	21
5.3.1	Sampling.....	21
5.3.2	Split or Equivalent Samples.....	22
5.3.3	Drugs and Metabolites.....	22
5.3.4	Decision Criteria.....	23
5.3.5	Analytes Not Reported.....	23
5.3.6	Exams Not Performed.....	23
5.4	Conclusion Types.....	24
5.4.1	Not Detected.....	24
5.4.2	Identified.....	24

5.4.3	<i>Detected</i> .....	24
5.4.4	<i>Inconclusive</i> .....	25
5.5	Report Sections .....	25
5.5.1	<i>Results of Examinations</i> .....	25
5.5.2	<i>Remarks</i> .....	27
5.6	Elements of a <i>Laboratory Report</i> .....	27
<b>6</b>	<b>REVIEW</b> .....	<b>27</b>
6.1	Data Packet Reviews .....	28
6.2	Technical Reviews .....	28
6.3	Administrative Reviews.....	28
<b>7</b>	<b>VALIDATION</b> .....	<b>28</b>
7.1	Method Development.....	28
7.2	Validation .....	28
7.2.1	<i>Cross-Instrument Validations</i> .....	29
7.3	Records.....	29
<b>8</b>	<b>MEASUREMENT TRACEABILITY</b> .....	<b>29</b>
<b>9</b>	<b>SAFETY</b> .....	<b>29</b>
9.1	Biological Hazards .....	29
9.2	Chemical Hazards .....	30
<b>10</b>	<b>OPERATIONAL DETAILS</b> .....	<b>30</b>
10.1	Mission Statement.....	30
10.2	Data Management.....	30
10.2.1	<i>Toxic Database</i> .....	30
10.2.2	<i>Method Development and Validation Data</i> .....	30
10.3	Research Material Availability .....	30
10.4	Roles and Responsibilities .....	31
10.4.1	<i>Technical Leader</i> .....	31
10.4.2	<i>Validation and Quality Control Manager (VQCM)</i> .....	31
10.4.3	<i>Supervisory Role</i> .....	31
10.4.4	<i>Forensic Examiner (FE)</i> .....	31
10.4.5	<i>Chemist</i> .....	31
<b>11</b>	<b>REFERENCES</b> .....	<b>31</b>
<b>12</b>	<b>REVISION HISTORY</b> .....	<b>32</b>
<b>APPENDIX A1</b> .....		<b>33</b>
<b>APPENDIX A2</b> .....		<b>35</b>
<b>APPENDIX A3</b> .....		<b>36</b>
<b>APPENDIX A4</b> .....		<b>39</b>

# Toxicology Operations Manual

## 1 SCOPE

This document provides general guidelines for toxicology operations in the Chemistry Unit (CU) of the FBI Laboratory. The document applies to individuals authorized to perform work in, or in support of, toxicology investigations.

## 2 REQUESTS

The FBI Laboratory Toxicology discipline receives varied requests for assistance from the FBI, an array of local law enforcement agencies, medical examiners, as well as other Federal and international partners.

### 2.1 Customers

Customers may include, but are not limited to, the following categories:

- The FBI
- A local agency or institution (Police Department, Medical Examiner's Office)
- Another United States Federal agency or institution (Indian Reservation, National Park Service)
- Another nation through FBI LEGAT or diplomatic channels

### 2.2 Request Types

The request types received by the toxicology discipline can vary significantly. Generally, the request can be described by one or more of the following categories:

#### 2.2.1 Postmortem

Requests of this type generally fall into one of the following subcategories, singly or in combination:

- A. Suspected Toxicological Cause of Death (COD)  
Circumstances indicate there is a nexus with drug/analyte use or exposure.

*Example:*

*The decedent, a known drug addict, is found unresponsive with miscellaneous drug paraphernalia.*

- B. Known Anatomical COD  
Circumstances indicate there is a probable or confirmed anatomical/physical COD.

*Example:*

*The decedent was found unresponsive hanging from a rope in their hotel room.*

C. General COD

Circumstances indicate that there is no specific set of circumstances that categorize the death as toxicological or anatomical.

*Example:*

*The decedent was found unresponsive in their home. History includes a variety of health issues and no knowledge of suspicious circumstances.*

D. Directed Analysis

Circumstances point towards a certain analyte or class of analytes. May also include situations in which previous toxicological exams have ruled out analytes/analyte classes and the additional scope of exams will be focused.

*Example:*

*The decedent was found unresponsive after a gas heater malfunction.*

2.2.2 Drug-Facilitated Crime (DFC)

Requests of this type generally include scenarios in which incapacitating/intoxicating analyte(s) may have been used to facilitate a crime. Circumstances can include sexual assault, robbery, and other scenarios.

2.2.3 Driving Under the Influence (DUI)/Other Human Performance

Requests of this type typically involve drivers suspected of being impaired due to ethanol or other analytes. This scenario may include other performance-based investigations.

2.2.4 General

Requests of this type can include scenarios not well categorized by the other categories. It may include antemortem or postmortem specimens, as well as other types of material.

2.2.5 Hair/Alternative Matrices

Requests can include the analysis of hair specimens for analytes including drugs, drug metabolites, and heavy metals. DFC and poisoning investigations are common scenarios.

2.2.6 Subject Matter Expert (SME)

SME requests may be:

- Informal or formal
- In a verbal, electronic, or written format
- Originate from internal or external entities

Typical scenarios for a SME request include:

- Threat Credibility Evaluation (TCE)
- External lab report review
- Law enforcement/Investigation consultation
- Non-work product testimony
- Medical record review
- Drug information request

### 2.2.7 Proficiency Tests (PT)

Proficiency tests typically have scenarios that align with one of the other request categories.

## 2.3 Request Acceptance

Externally provided information helpful to determining case acceptance includes:

- A. Case scenario
- B. Available specimens
- C. Specimen condition
- D. Reports, such as:
  - Medical
  - Law Enforcement
  - Laboratory

### 2.3.1 Routine

Routine requests require no additional concurrence for acceptance, assuming that there are sufficient resources to address the request. Routine requests include scenarios for which the following parameters have been established:

- A. Validated procedure exists for submitted specimen type(s)
- B. Authorization(s) to perform required task(s)
- C. Authorization(s) to complete any required review(s) of performed task(s)

For exam-based requests, if all of the above are not determined, then a request is considered non-routine.

For SME-based requests requiring review, if listed authorizations are not determined, then a request is considered non-routine.

### 2.3.2 Non-Routine

Non-routine requests may represent additional opportunities for validation, resource utilization, and authorization. Generally, acceptance of non-routine requests will be determined through consultation with the Supervisor or Technical Leader (TL). If the request appears to represent a significant involvement of resources, the UC should also be consulted. Upon or prior to acceptance, the TL should determine if method development, validation, authorization(s), or other activities are required.

### 2.3.3 Reexamination

Generally, the FBI Laboratory does not “reexamine” specimens that have already been examined by another laboratory. However, the scope of examinations from one toxicology laboratory to the next may vary considerably; the definition of what constitutes a “reexamination” may also vary on a case-by-case basis.

*Example:*

*For a DFC investigation, an external laboratory employed an immunoassay with limited assay cross-reactivity or relatively high cut-off concentrations. The FBI toxicology analysis would provide a more sensitive and specific examination outcome and would therefore be appropriate for case acceptance.*

The TL will evaluate requests of this type to determine if additional exams are appropriate; concurrence from a resource standpoint will follow from the supervisory and/or UC roles.

True reanalysis requests require Laboratory Director approval.

## **3 SPECIMENS**

### **3.1 Types and Collection**

The proper selection, collection, and submission of biological and other specimens for toxicology analyses are important for scientifically sound interpretation of analytical results. While there are recommended amounts of specific specimens desired to accomplish routine toxicology examinations, specimen amount may be limited. In these cases, the type and amount of specimen submitted may dictate the exams that are performed.

### 3.1.1 Recommended Collection Strategies

Each case may have specific recommendations for specimen collection. The following table serves as a general guideline for most scenarios.

Type	Recommended Collection Amount	Container Type	Preservative
Blood	10 mL	GSV (gray stoppered vial)/LSV (lavender stoppered vial)	Potassium Oxalate/Sodium Fluoride or K <sub>2</sub> /EDTA
Serum/Plasma	10 mL	GSV/LSV	Potassium Oxalate/Sodium Fluoride or K <sub>2</sub> /EDTA, Serum Separator Type
Vitreous	2 mL	GSV/LSV	Potassium Oxalate/Sodium Fluoride or K <sub>2</sub> /EDTA
Urine	50 mL	Leak proof	Generally not required
Tissue	50 g	Leak proof	N/A; formalin fixing reagents or embalming fluids may preclude any toxicology analysis
Gastric/Vomit	25 mL	Leak proof	N/A
Hair	2 pencil width, bound bundles cut from the vertex	foil	N/A
Food Products	Varies	Leak proof	N/A
Clothing/Bedding	Entire item when possible	Cardboard box/paper	N/A

Some exam types may require specific container types or preservative presence/absence. In those situations, the appropriate technical procedure will list the specific requirements. The specific requirements are provided to the contributor in advance, if possible. If collection requirements are not met, it may affect the ability to perform the exam(s) or the conclusion(s) of any exams that are performed.



### 3.1.2 Specimen Labeling

The specimen is ideally labeled with the following information, as appropriate for a case scenario:

- A. Specimen type (e.g., gastric, vitreous, blood)
- B. Anatomical site of collection for postmortem cases (central, peripheral)
- C. Collection date and time
- D. Donor name

Additional inquiry to the contributor may provide additional or clarifying information.

## 3.2 Transport

In order to ensure specimen integrity, several factors should be considered prior to the transport of specimens to the FBI Laboratory. Most routine toxicology exams generally do not require advance communication with a contributor. For some exams or scenarios, it may be appropriate to recommend specific transport conditions.

### 3.2.1 Method

Overnight shipping via a commercial carrier or hand delivery are the standard methods for transport of specimens to the FBI Laboratory. If overnight delivery is not available, the shortest possible method is recommended. Request only submissions and evidence received electronically will be directly forwarded to or received by the CU.

### 3.2.2 Packaging

The packaging surrounding the specimen containers should be sufficient to ensure the integrity of the specimen during transport. Commercially available specimen collection kits are normally satisfactory to prevent breakage or loss of material due to shock or vibration. A leak proof layer (e.g., sealed plastic bag) is recommended to contain biological material in the event of a container leak.

### 3.2.3 Temperature

For most routine toxicology exams, temperature control during overnight shipping is not required. For some exams or scenarios, it is recommended that samples be kept at refrigerator or freezer temperatures in order to maintain integrity. This may be accomplished by including freezer packs with the specimen and using an insulated container.

### 3.2.4 Light Protection

For most routine toxicology exams, protection from light is not required other than what is provided by the typical containers encountered. For some exams, it is recommended that samples have an extra layer to avoid excess exposure to light (e.g., containers wrapped in foil).

### **3.3 Receipt**

Receipt of specimens at the FBI Laboratory is performed by authorized individuals, typically in the Evidence Management Unit (EMU).

#### **3.3.1 Storage**

Most biological specimens are stored in EMU under refrigerated conditions until transfer to the CU where they are also stored refrigerated. Some specimens, such as hair, do not require refrigeration.

#### **3.3.2 Single Unit Submission (SUS)**

Most toxicology submissions are single unit, with no additional work required from other disciplines/subdisciplines within the FBI Laboratory. After the assignment of an FBI Laboratory Number, evidence from these cases is transferred directly from EMU to CU for inventory and toxicology exams.

#### **3.3.3 Multiple Unit Submission (MUS)**

Some submissions are multiple unit, and other disciplines/subdisciplines are involved in the examination process. MUS evidence is inventoried in EMU. The order of examination will vary by scenario, and the transfer of evidence for these cases may involve multiple disciplines/subdisciplines.

### **3.4 Inventory/Check-In**

After arrival in CU, specimens (and associated packaging) are inventoried. The FBI Laboratory Number and a primary item identifier are placed on each specimen and/or relevant packaging, unless already performed in EMU. (See LAB-200 for additional requirements)

During inventory in CU, specimen labeling is compared with incoming communication paperwork and any discrepancies are documented in the check-in notes. (See LAB-200 for additional requirements)

Additionally, the following are recorded in CU during toxicology inventory:

- Type of evidence received
- Type of specimen container(s) received
- Donor identity
- Date(s) and time(s) of collection
- Estimated amount of specimen

#### **3.4.1 Special Considerations**

If observed, the following will be documented during toxicology inventory:

- Limited specimen amounts
- Unusual specimen appearance
- Improper closures or container types

- Specimen leaks or damage (any observed damage will be documented in the case record per LD policy)

Such instances should be brought to the attention of the assigned Forensic Examiner (FE) or supervisor/TL. This may be accomplished verbally, electronically, or through the normal use of inventory documentation.

### 3.4.2 Functional Equivalence of Specimens

Specimens are sometimes received as a set, most frequently as a collection of tubes of blood and/or serum. If the specimens are functionally equivalent, then they are marked with the same primary item identifier and differentiated on the specimen container by A, B, C, etc. The primary item identifier is used for databases such as the Laboratory Information Management System (LIMS) and Toxicology Information Center (Toxic), as well as reporting. However, records shall indicate which tube was used from a set of equivalent items for a given exam. This is nominally recorded in Toxic for each exam by the performing analyst.

If the items are not functionally equivalent, then they shall have different primary item identifiers.

Some factors that may affect functional equivalence are:

- Specimen Type
- Specimen Location
- Collection Timing
- Collection Method/Container

Questions about this topic should be directed to the assigned FE or TL.

Examples:

- Two GSVs are received that each contain blood. They are marked with the same information (date, time, and donor). These may both be marked as Item 1 and differentiated by A and B. The final item designation used on exams would be Item 1A and Item 1B, but reported results would apply to Item 1.*
- Two GSVs are received; one contains blood and the other vitreous fluid. They are marked with the same information (date, time, and donor). These would be marked as Item 1 and Item 2 since they contain different sample types.*
- Two GSVs are received that each contain blood. They are marked with the same donor information; the date and time information indicate a 12-hour gap between the collections. These would be marked as Item 1 and Item 2 since the toxicological scenario is markedly different between the first and second blood collection.*
- Two blood collection tubes are received; each contains a blood specimen. They are marked with the same information (date, time, and donor). One tube is the GSV type;*

*the other is a “royal blue” stoppered tube appropriate for trace elemental exams. The tubes would be marked as Item 1 and Item 2 since the container type is not functionally equivalent. Assigning an elemental exam to Item 1 instead of Item 2 is likely to produce a different (non-equivalent) analytical result.*

### **3.5 Storage**

The specimens received are stored securely according to the specimen type. Most routine toxicology evidence is stored under refrigerated conditions. In some instances, a portion of or the entire specimen may be stored under freezer conditions. Hair is stored at room temperature in a dry environment, such as an unrefrigerated evidence locker. Associated packaging may be securely stored separately at room temperature.

#### **3.5.1 PT Material Retention**

Upon inventory, at least one portion (e.g., ~5 mL) of each PT specimen (other than volatiles PT samples) shall be aliquoted, transferred to a labeled container, and then stored in a freezer. The portion is retained for a minimum of one year. This separate aliquot may be used for PT analysis, training/evaluation, or other activities.

### **3.6 Sample Disposal**

Upon completion of all examinations and release of the final *Laboratory Report*, the remaining biological samples may be stored refrigerated or frozen for six months. Within one month after release of the report, the samples will be placed under proper seal. Within six months after release of the report, samples may be disposed of as deemed permissible through prior approval from and/or at the request of the customer. The approval will be retained physically and/or electronically in a system of record (i.e., Sentinel). [LAB-200]

Permissible specimen disposal may include, but is not limited to, destruction and/or retainment after deidentification to include removal of any personal identifiable information, as well as unique specimen and case numbers. Per routine shipping procedures, the evidence may also be returned to the customer, as necessary.

## **4 EXAMINATIONS**

### **4.1 Screening / Confirmation / Quantitation**

Similar procedures may be employed for both screening and confirmation. For example, an initial LC/MS exam may be used to screen for broad classes of analytes. A follow-up/confirmation exam may also employ LC/MS but target/quantitate only the initially detected analyte. Therefore, exams may be utilized as initial screens or confirmation depending upon the scenario encountered.

#### **4.1.1 Screening**

Generally, the purpose of a technique employed for screening is to rule out the presence of analytes or to indicate when further testing may be warranted. Techniques used for screening

should have appropriate LODs for analytes of interest. The selection of the screening technique(s) utilized will depend upon the case history, the available specimen, and available technology.

#### 4.1.2 Confirmation

The confirmatory test for the target analyte may be more specific than the first assay. Given the power of modern analytical methods, using the same technique to screen and confirm analyte(s) is permissible as long as there are separate portions of the specimen(s) used for each exam.

The confirmatory test shall include analysis of positive and negative controls for the analyte of interest.

#### 4.1.3 Quantitation

Quantitative analysis may provide additional interpretive value for toxicology scenarios. Performing quantitative analysis is not always required. The completion of such quantitative analysis is dependent upon circumstance specific variables, such as:

- Case scenario
- Specimens received
- Amount of specimen remaining
- Timeframe of incident to specimen collection
- Availability of equipment and technical procedures
- Turnaround time constraints

## 4.2 **Scopes of Analysis**

Additional or fewer exams (both qualitative and quantitative) may be performed depending upon case specific information including:

- Specific case scenario
- Specific target analytes
- Specimen type, amount, and/or condition
- Incident to specimen collection interval
- Results of initial screening

#### 4.2.1 Postmortem

##### A. Suspected Toxicological COD

For routine drug-related investigations, blood is usually the preferred specimen, and the exams performed to provide a more comprehensive analysis are typically:

Exam Code	Exam Title
TOX200	Common Volatiles Analysis by Headspace GC-MSD/FID (also performed on vitreous humor, if submitted)

TOX215	Exclusionary Drug Screen by UPLC-ESI-FTMS
TOX203	Solid Phase Extraction (SPE) of Alkaline Drugs from Biological Fluids
TOX201	Direct Solvent Extraction of Acid/Neutral Drugs from Biological Fluids
TOX430	Analysis of Cannabinoids from Biological Specimens by LC/MS/MS
TOX426	Benzodiazepines and Metabolites from Blood and Urine by LC-MS (MRM)

See Appendix A1 for a full list of analytes routinely included in testing for Postmortem – Suspected Toxicological COD (Full Postmortem Testing). Additional analytes may be added based on case history or special request.

#### B. Known Anatomical COD

This scenario generally requires a less comprehensive analysis, since the COD is thought to be anatomical, physical, or at least lacking any specific nexus to drug involvement. Blood is usually the preferred specimen. Additional assays may be added as appropriate for the specific case history.

Exam Code	Exam Title
TOX200	Common Volatiles Analysis by Headspace GC-MSD/FID (also performed on vitreous humor, if submitted)
TOX215	Exclusionary Drug Screen by UPLC-ESI-FTMS
TOX203	Solid Phase Extraction (SPE) of Alkaline Drugs from Biological Fluids
TOX430	Analysis of Cannabinoids from Biological Specimens by LC/MS/MS

See Appendix A2 for a full list of analytes routinely included in testing for Postmortem – Known Anatomical COD (Scoped Postmortem Testing). Additional analytes may be added based on case history or special request.

#### C. Directed Analysis

The exams performed for this scenario are largely case specific. The exams employed may vary at the discretion of the FE.

#### 4.2.2 DFC

Selections from the following exams are normally performed, depending upon case scenario. If collected within 120 hours of an alleged incident, urine is the preferred specimen. If urine is unavailable, blood may be tested if collected within 24 hours of an alleged incident. Longer collection times may allow for testing of drugs with a long half-life. Analytes identified in the urine are usually screened for in a paired blood specimen, if available.

Exam Code	Exam Title
TOX200	Common Volatiles Analysis by Headspace GC-MSD/FID (routinely performed on any specimen(s) collected within 24 hours of the alleged incident)
TOX215	Exclusionary Drug Screen by UPLC-ESI-FTMS
TOX203	Solid Phase Extraction (SPE) of Alkaline Drugs from Biological Fluids
TOX201	Direct Solvent Extraction of Acid/Neutral Drugs from Biological Fluids
TOX408	GHB and GBL from Biological Fluids by Headspace GC-MS(EI) (performed on urine specimens only when collected within 12 hours of an alleged incident)
TOX426	Benzodiazepines and Metabolites from Blood and Urine by LC/MS (MRM)
TOX430	Analysis of Cannabinoids from Biological Specimens by LC/MS/MS
TOX426	Benzodiazepines and Metabolites from Blood and Urine by LC-MS (MRM)

See Appendix A3 for a full list of analytes routinely included in DFC Testing of urine specimens. Additional analytes may be added based on case history or special request.

#### 4.2.3 DUI/Human Performance

Blood is the preferred specimen for this testing. The following exams are normally performed:

Exam Code	Exam Title
TOX200	Common Volatiles Analysis by Headspace GC-MSD/FID
TOX215	Exclusionary Drug Screen by UPLC-ESI-FTMS
TOX203	Solid Phase Extraction (SPE) of Alkaline Drugs from Biological Fluids
TOX201	Direct Solvent Extraction of Acid/Neutral Drugs from Biological Fluids
TOX430	Analysis of Cannabinoids from Biological Specimens by LC/MS/MS
TOX426	Benzodiazepines and Metabolites from Blood and Urine by LC-MS (MRM)

See Appendix A4 for a full list of analytes routinely included in DUI Testing. Additional analytes may be added based on case history or special request.

#### 4.2.4 General

The examination scope will vary according to the case scenario and specimens received. Exams should be assigned at the discretion of the FE in a manner that addresses the investigative needs.

#### 4.2.5 Hair

The scope of exams performed on hair specimens will vary on a case-by-case basis. The process of analyte incorporation into or onto hair matrix generally restricts its use to scenarios involving periods of time longer than those encountered with routine specimen collections, such as blood

or urine. Scenarios commonly include DFC or poisoning cases with delayed sample collection and overlap with other scopes. Exams employed can include:

Exam Code	Exam Title
TOX320	Arsenic in Urine and Hair by ICP/MS
TOX321	Thallium in Hair by ICP/MS

#### 4.2.6 Proficiency Tests

The scope of exams performed on PTs will vary by test or by the specimen scenarios provided. Exams employed on PTs will generally correspond with the scope used for the same request type in casework.

#### 4.2.7 Updates to the Scopes of Exams

The scope of exams will be reviewed annually. Plans to update the scope of exams will be documented in the annual document review for the toxicology discipline. The implementation of the updated scopes is contingent upon discipline workload, available analysts, and instrumentation.

### 4.3 Exam Assignment

Exam assignment and progress is tracked through ToxIC.

#### 4.3.1 Responsibilities

FEs are responsible for assigning exams to specimens within cases. This is usually performed upon the start of examinations after request review. Updates to the exam assignments take place as exams are completed or more information is acquired.

FEs and Chemists are responsible for updating exam stages, including starting and completing batch processes, batch details, and reviews.

FEs are responsible for recording exam conclusions, such as qualitative and quantitative results.

#### 4.3.2 Minimum Sample Requirements

Each exam has specified minimum sample requirements. Depending upon the exam, the guidance may be more or less specific.

##### 4.3.2.1 Minimum Amount

For initial analysis/screening exams, the minimum sample amount shall be followed as stated.

For subsequent analyses, the amount of specimen used may be reduced for one or a combination of the following reasons:

- A. Qualitative confirmation of an analyte that has been previously estimated to be present in high concentrations in the specimen or a paired specimen.



- B. Quantitative confirmation of an analyte that is estimated to be above the validated linear range of the exam.
- C. Preservation of specimen amount in order to perform additional exams.

Use of specimen amounts greater than specified is not performed without method validation.

#### 4.3.2.2 *Specimen Type*

Each technical procedure has descriptions of which specimen types may be utilized. Performing exams on other matrix types may require additional validation.

#### 4.3.3 Scope Specification

The use of a particular exam may vary. For example, an LC/MS exam could be used as a screening exam for one specimen, and a confirmation exam for another specimen within the same batch. FEs may specify a desired scope of an exam in ToxIC depending upon the needs of a specific situation.

### 4.4 **Sample Selection**

For the scope of this document, sampling refers to portions of matrix material removed from received specimens.

#### 4.4.1 Specimen Type and Location

Some specimens may be thought of as equivalent and interchangeable, such as two specimens of central compartment blood sampled within a similar period and collected in the same manner.

Accordingly, it may not be necessary to examine all received specimens in a given case scenario. Some received specimens may be more preferred than another, depending upon the case scenario. For example, a red top (unpreserved) blood specimen may be suitable for a cocaine/metabolite screen. However, if a preserved (e.g., sodium fluoride) blood tube was available, this tube would be preferred for any quantitative measurements of cocaine/metabolite due the potential for hydrolysis.

Guidance regarding the selection of specimens is provided by the assigned FE or TL when required.

#### 4.4.2 Representative Sample Considerations

Efforts shall be made to ensure that samples from received specimens are representative and appropriate for the examination(s) to be performed.

##### 4.4.2.1 *Methods of Sampling*

Exams will specify the preferred method of sampling. Generally, there are two methods of sampling encountered in routine toxicology exams:

- A. Aliquot of a liquid sample via a pipette or other volumetric device. This is most often used and is the default method of sampling.
- B. Weighing of a solid sample via a balance. This is less often encountered.

If difficulty is encountered in the aliquot of a liquid specimen due to factors such as viscosity, then the sample may be weighed by balance. However, if the method of sampling differs from the method(s) used during validation, effects upon validation parameters including quantitative uncertainty calculations shall be considered, and additional validation may be required.

#### 4.4.3 Homogeneity

Normally homogeneous specimens include:

- A. Whole blood (unclotted)
- B. Vitreous
- C. Serum/Plasma
- D. Urine
- E. Beverages

Other than simple inversion or vortexing of the specimen container, these specimen types typically do not require any additional considerations prior to sampling.

#### 4.4.4 Heterogeneity

Normally heterogeneous specimens include:

- A. Tissue
- B. Clotted Blood
- C. Gastric
- D. Hair
- E. Food

These specimen types typically require some degree of homogenization in order to ensure a representative sample can be obtained. When the total amount of an analyte in a specimen is needed for interpretative reasons, the whole item will be homogenized, if feasible, prior to examination.

#### 4.4.5 Homogenization Methods

The method of homogenization may vary by the examination(s) performed. Methods may include:

- Tissue Grinding
- Blender
- Microbead/Tissue Disruption
- Cryogrinding

## 4.5 Performing Exams

Exams may be completed as a single action, or a sequence of exam stages. Here, the term exam refers to either the complete exam process or stage(s) within an exam sequence.

### 4.5.1 Exam Records

Analysts will record the following information through ToxIC, LIMS, Chemicals and Materials System (CAMS), case notes or other means:

- A. Analyst performing the exam
- B. Start and completion dates
- C. Amounts of specimen used
- D. Observations of specimen or exam conditions that may affect the outcome
- E. Equipment utilized for the exam, as applicable
  - 1. Instrument Related
    - i. Instrument identifier
    - ii. Autosampler sequence or equivalent
    - iii. Acquisition method or equivalent
  - 2. Reagents, chemicals, and products related
    - i. Material identifier (external or internal lot#)
- F. Exam data, as applicable
  - 1. Cover page(s)
  - 2. Analytical data (e.g., chromatograms, mass spectra, photos, measurements)
  - 3. Analytical data derivations, such as:
    - i. Retention time comparisons
    - ii. Ion ratio calculations
    - iii. Mass tolerance calculations
    - iv. Concentration estimates
    - v. Quantitative data

It is not required that the completion of individual steps in a given exam sequence are recorded (e.g., if the exam is completed without deviating from the approved sequence, then no additional recording is required).

#### 4.5.1.1 Minor Deviations

Minor deviations are tracked within ToxIC for toxicology.

### 4.5.2 Batch Review

Upon completion of the data analysis, the following steps are performed:

- A. Collation of all relevant batch documents
- B. Request for batch review in ToxIC
- C. Completion of the batch review in ToxIC

#### 4.5.2.1 *Batch Review Functions within ToxIC*

- A. Recording of the batch reviewer and date of review
- B. Result of the batch review
- C. Comments
- D. Historical review of completed exams

#### 4.5.3 *Data Distribution*

Upon completion of the batch review, the following steps are performed:

- A. Data packet assembly (includes case specific and batch documentation)
- B. Distribution of the data packet to the assigned FE(s) for review
- C. Copy (where appropriate) selected batch documents to a physical or electronic file
- D. Provide control data to the Validation and Quality Control Manager (VQCM) as appropriate.

Depending upon the exam, selected batch documents may be copied to a LIMS Case Record or an additional repository, such as a physical file or electronic database. Such separately maintained batch records are kept available for quality assurance and discovery purposes.

#### 4.5.4 *Examiner Review*

Upon receipt of the data packet, the assigned FE performs the following steps:

- A. Data packet review
- B. Documentation of review via initials or secure electronic equivalent
- C. Acknowledgement in ToxIC of the packet review date

#### 4.5.5 *Exam Completion*

The assigned FE will determine when all necessary exams have been completed for a case. The number of exams required will vary on a case-by-case basis.

## 5 REPORTING

The primary method for dissemination of toxicology exam conclusions is through a *Laboratory Report* (7-1, 7-1 LIMS). Reference LAB-200 and CHEM-100 for guidance for Expedited Results.

### 5.1 Exam Summary

Typically, prior to generation of a *Laboratory Report*, the FE will generate an exam summary by a function in ToxIC. The exam summary is retained in the case record and the following information is included:

- A. Brief case description
- B. Specimen identifiers
- C. Exams performed
- D. Dates of exams
- E. Personnel performing exams

F. Qualitative and quantitative findings

**5.2 Report Generation**

Prior to request for a case technical review, the FE will generate a *Laboratory Report*. This may be accomplished with a template generated through the LIMS, ToxIC, manually or other means so long as the report adheres to Level 1 and Level 2 requirements.

**5.3 General Guidelines**

Reporting guidelines specified in an individual technical procedure may override guidance in this document.

**5.3.1 Sampling**

Generally, toxicology exams do not utilize statistical sampling as defined by LAB-200. If statistical sampling is used in a toxicology examination, then the requirements set forth in LAB-200 shall apply.

**5.3.1.1 *Number of Aliquots/Portions***

- A. In order to express the “not detected” or “inconclusive” conclusion types, a minimum of one portion or aliquot of a specimen shall be examined.
- B. In order to express the “detected” or “identified” conclusion types, a minimum of two portions or aliquots of a specimen/equivalent specimen shall be examined.

**5.3.1.2 *Homogeneity***

Homogeneous specimens require no additional sampling statements in the *Laboratory Report*.

If an entire heterogeneous specimen was homogenized/processed, then no additional sampling statement is required in the *Laboratory Report*.

If a portion of a heterogeneous specimen is selected for analysis without homogenizing/processing the entire specimen, then a statement in the *Laboratory Report* shall state the conclusions are limited to the portion of the specimen that was examined.

*Example:*

*A portion of the Item 1 gastric specimen was removed for testing. The results for the Item 1 gastric specimen are limited to the portion that was selected and examined.*

**5.3.1.3 *Specimen Volume***

If the specified minimum required amount of specimen was not used for screening/initial analyses, the report shall include a statement that the LOD of the exam may have been adversely affected.

*Example:*

*Due to limited specimen amount, less specimen was used for screening techniques, which may lead to elevated limits of detection for the target analytes.*

#### 5.3.1.4 *Reported Units*

The method of sampling will be reflected in the reported units for quantitative measurements. For example, if a blood sample was weighed on a laboratory balance instead of dispensed volumetrically using a pipette, the reported units will be in weight/weight instead of weight/volume.

#### 5.3.2 *Split or Equivalent Samples*

When a screening technique indicates the possible presence of an analyte in one biological specimen (e.g., urine), confirmation of the identity of the analyte in a second specimen from the same individual (e.g., blood) within a similar timeframe is acceptable.

Functionally equivalent samples may also be used to screen and confirm analytes.

#### 5.3.3 *Drugs and Metabolites*

If initial testing indicates the presence of a drug, and further testing confirms the presence of the drug and its metabolite(s), both the drug and its metabolite(s) may be reported as identified.

Similarly, if initial testing indicates the presence of a metabolite, and further testing confirms the presence of the drug and its metabolite(s), the drug and its metabolites(s) may be reported as identified.

*Example:*

*Clonazepam is indicated in an initial exam. Both clonazepam and 7-aminoclonazepam are detected in the subsequent exam. 7-aminoclonazepam can be reported without an additional confirmatory test for 7-aminoclonazepam since it is a clonazepam metabolite.*

Situations may also occur where both a drug and metabolite(s) are indicated in initial testing, yet only the drug or its metabolite(s) are confirmed in the second test.

As long as confirmatory testing detects the drug and/or metabolite(s), both may be reported as identified.

*Example:*

*If zolpidem and its primary metabolite are indicated in an alkaline drug screen, and zolpidem is subsequently confirmed via a method that is not expressly designed to detect the metabolite (such as the alkaline drug quantitation), both may be reported without an additional confirmatory test for the zolpidem metabolite.*

##### 5.3.3.1 *Common Metabolites*

Some analytes degrade or metabolize into analytes common to other target analytes. Additional examinations may be required to attempt to resolve the analyte-to-metabolite scenario. It also may not be possible to associate a specific parent analyte from a detected metabolite. Technical procedures will highlight these issues where applicable and known; reports shall include language to help clarify where necessary.

#### 5.3.4 Decision Criteria

Each technical procedure shall have a section that contains decision criteria. Some technical procedures may share common decision criteria.

#### 5.3.5 Analytes Not Reported

Depending upon the scenario, some analytes may not be reported. This may be due to case specific criteria such as:

- Estimated concentration
- Relevance to the scenario

The decision not to report or pursue confirmation of analytes is at the discretion of the assigned FE, in combination with exam specific reporting criteria and the scope of analysis.

*Example:*

*Diphenhydramine is detected in an initial exam for a postmortem case. The estimated level is considered toxicologically insignificant. The analyte is not confirmed or reported.*

##### 5.3.5.1 Analytes Commonly Not Reported

Some commonly encountered analytes most often have limited relevance to a given scenario. FEs may choose not to confirm or report analytes in this situation without further justification or required documentation. Automated data analysis schemes are another method of excluding the reporting of such analytes. Such analytes can include but are not limited to:

- Caffeine and metabolites
- Nicotine and metabolites
- Quinine/quinidine
- Non-impairing drugs
- Low levels of acetone, acetaldehyde, or other endogenous analytes
- Lidocaine, naloxone, and atropine
- Other analytes with no relevance to the case scenario

#### 5.3.6 Exams Not Performed

The FE may report that no exams were performed. This includes scenarios in which visual or other types of preliminary assessments of the evidence received precludes any further probative laboratory examinations.

*Example:*

*No examinations were conducted on the Item 1 blood specimen. The amount received was insufficient to perform examinations.*

##### 5.3.6.1 Specific Exams Not Performed

As long as the FE has clearly communicated the intended scope of exams to the contributor before or during the exam process (e.g., an acknowledgement email or call), the FE is not required to describe every exam that was not performed on a given case. Where specimen or

examination circumstances modified the original intended scope, those exams not performed should be described.

## 5.4 Conclusion Types

An FE may offer any of the following conclusion types in a *Laboratory Report*:

### 5.4.1 Not Detected

'Not detected' is an FE's conclusion that the analyte or class of analytes was tested for but not detected and/or confirmed. The basis for this conclusion is based upon exam-based reporting criteria.

### 5.4.2 Identified

'Identified' is an FE's conclusion that the scientific data supports the presence of an analyte in a questioned sample. The basis for an 'identification' conclusion is an examiner's determination that all of the following are met:

- A. A specific analyte was detected in a questioned sample using orthogonal techniques, at least one of which provides chemical structure information about the analyte (e.g., tandem mass spectrometry).
- B. A specific analyte was detected in more than one aliquot of a specimen, or in single aliquots of multiple specimens collected from the same individual at the same time.
- C. Predefined decision criteria set forth in the relevant technical procedure(s) and/or exams were satisfied.
- D. The exams included the use of positive and negative controls (where applicable).

### 5.4.3 Detected

The basis for a 'detected' conclusion is an FE's determination that the exams employed do not support the *identification* of an analyte in a questioned sample but do provide sufficient reliable information regarding the presence of the analyte. The basis includes that the following are met:

- A. A specific analyte was detected in a questioned sample using orthogonal techniques, but none of the techniques applied provide chemical structure information about the analyte.
- B. A specific analyte was detected in more than one aliquot of a specimen, or in single aliquots of multiple specimens collected from the same individual at the same time.
- C. Predefined decision criteria set forth in the relevant technical procedures and/or exams were satisfied.
- D. The exams included the use of positive and negative controls (where applicable); or, if positive controls are unavailable, the results were compared to a reliable library/database reference or to peer reviewed literature.



#### 5.4.4 Inconclusive

'Inconclusive' is an examiner's conclusion that the scientific data does not meet the criteria for other reporting conclusion types, or testing results are unsuitable due to analytical interferences or condition of the sample.

When an inconclusive result is reported, the reason(s) why will be clearly stated in the *Laboratory Report*.

### 5.5 Report Sections

The sections employed for a given case scenario/report may vary.

#### 5.5.1 Results of Examinations

This section will be consistent with the Exam Summary; this section may contain additional information. The format of the information may vary by case type. Generation of any information may be performed manually by the FE, via a template, or from a ToxIC function. This section may contain all or selections of the following information:

##### 5.5.1.1 *Methods*

The methods used are briefly expressed:

- A. Include detail about sample pretreatment where it may aid technical review of the report (e.g., hydrolysis). It is not necessary to include all utilized techniques such as liquid-liquid extraction versus solid phase extraction.
- B. Include only enough detail about any instrumentation techniques where it may aid technical review of the report.

##### 5.5.1.2 *Results/Conclusions*

- A. Qualitative results will be expressed as not detected, detected, identified, or inconclusive.
- B. Quantitative results will follow (A) and be expressed in International System of Units (SI Units) appropriate for the exams performed. Quantitative findings will be expressed with the additional information required in LAB-200 and CHEM-100.

##### 5.5.1.3 *Opinions/Interpretations*

Opinions or interpretations will be clearly expressed. Citations for relevant literature references or sources may be expressed in the *Laboratory Report* or supporting documentation.

##### 5.5.1.4 *Descriptive or Interpretive Information*

Additional descriptive information may be included in the *Results of Examinations* Section or in the *Remarks* Section when applicable and appropriate. This information can be included when it may assist the intended reader(s) and is not required for all scenarios:

- Trade names (selected)
- Drug class
- Side effects

- Controlled Substance Schedules

The value of additional text should be balanced against the total volume of information, as well as the need to perform reviews on the additional content. When descriptive or interpretive information is provided, the *Laboratory Report* will state that the information provided is not exhaustive or meant to encompass all scenarios. The *Laboratory Report* will also state that the information is provided as a general guide and that to clarify information for any given case, consultation with the author of the *Laboratory Report* is recommended.

#### 5.5.1.5 Limitations

Limitations relevant to the specimens received, exams performed, and conclusions reached will be included in the *Results of Examinations* Section or in the *Remarks* Section when applicable and appropriate. If helpful, they may be expressed in a Section titled "Limitations". Generally, limitations are case scenario and/or exam specific and fall into one or more of the following categories:

##### 5.5.1.5.1 Exam Specific

Some exams will have specific limitations that are important to express. These limitations will be included within the *Laboratory Report* when appropriate.

*Example:*

*This method does not discriminate between nontoxic organic forms of arsenic and the toxic inorganic form of arsenic.*

##### 5.5.1.5.2 Isomers

If a reported analyte has relevant isomers that are not resolved by the exam(s) performed, a statement will be provided that expresses this limitation.

*Example:*

*The examinations performed do not distinguish between the dextro- and levo- isomers of methamphetamine.*

##### 5.5.1.5.3 Time Elapsed

The passage of time may limit the exams that are performed. Where appropriate, a statement may be provided. Common scenarios include:

- Metabolism of analytes
- Stability of analytes

*Example:*

*Examination of the Item 1 urine sample did not include analysis for GHB (gamma hydroxybutyrate) since the sample was collected more than 12 hours post-incident.*

#### 5.5.1.5.4 Amount or Condition of Specimen(s)

The as-received amount or condition of the specimen(s) may limit the exams that are ultimately performed, possibly changing the planned scope.

If the condition of the specimen(s) was unsuitable for analysis and/or may have compromised the results of the testing, this will be noted in the *Laboratory Report*.

If low specimen amount precluded any or all testing, that will be noted.

*Examples:*

*Due to the limited amount of specimen submitted, further examinations were not performed.*

*Due to the degraded condition of the Item 1 blood, quantitative examinations were not performed.*

*Due to the container type of the Item 2 urine specimen, elemental examinations were not performed.*

#### 5.5.1.5.5 Antemortem vs Postmortem Considerations

Any expressed opinions/interpretations should take into consideration analyte specific antemortem or postmortem factors, such as postmortem redistribution (PMR). The use of analyte concentrations based on antemortem literature to characterize postmortem concentrations should also be expressed as a limitation, when utilized.

*Example:*

*While the quantitated value of doxylamine in the Item 1 specimen is associated with toxic levels in relevant case literature, the analyte is also known to undergo postmortem redistribution (PMR). PMR is a process that occurs after death that can alter the analyte concentrations from what was present at the time of death.*

#### 5.5.2 Remarks

See LAB-200 for required Remarks.

### 5.6 Elements of a *Laboratory Report*

The toxicology discipline follows ANSI/ASB STANDARD 053 Standard for Report Content in Forensic Toxicology, with the exception of requirement 4.2, e. (information is recorded in the case file, but not included in the *Laboratory Report*).

## 6 REVIEW

Each report that includes results from examinations performed in the CU undergoes a technical review and an administrative review. Reports that do not contain results undergo an administrative review. This process is documented in the LIMS. See CHEM-100 for technical review requirements for outsourced examinations.

## 6.1 Data Packet Reviews

Due to the team-approach and batch-work used by toxicology, an additional data packet review may be required.

*Example:*

*FE-1 has completed the report draft for an assigned case. FE-2 performed a TOX-200 exam for the assigned case. If FE-2 were the assigned technical reviewer for FE-1's case, an additional reviewer would be needed for the TOX-200 exam packet since FE-2 shall not review their own work. FE-3 (or another authorized individual) is provided the TOX-200 exam packet for technical review.*

This additional data packet review shall be documented by one of the following approaches, and include the initials/secure electronic equivalent and date:

- A. Hand-written review of the data packet on a cover sheet
- B. Electronically applied review of the data packet on the first page of bound records
- C. Review of the data packet within ToxIC or the LIMS

## 6.2 Technical Reviews

Technical reviews are completed by individuals whose scope of authorizations is commensurate with the examinations and tasks contained in the case record.

The completion of a case record level technical review in the LIMS is sufficient to document that the reviewing individual concurs with all conclusions and the supporting data. Individual marking of examination pages or packets is not required to document a technical review at the case record level.

Technical reviewers shall consider the analytical data, conclusions, and report within the context of the case. Case context is provided by incoming request documentation, communications, references and other information. This information is normally a part of the case record available during the review process.

## 6.3 Administrative Reviews

Administrative reviews are completed by authorized individuals.

## 7 VALIDATION

### 7.1 Method Development

Method development is considered a preliminary, planned step in the validation process. See CHEM-100 for further details.

### 7.2 Validation

Validations initiated after April 27, 2022, meet criteria within ANSI/ASB Standard 036 Standard Practices for Method Validation. For validations performed prior to April 27, 2022, refer to the validation records for the criteria that were used.

### 7.2.1 Cross-Instrument Validations

The discipline operates a variety of instruments; some instruments may share common components or use-cases. In order to characterize performance characteristics across platforms, cross-instrument validation plans will include the following minimum parameters:

- Unique instrument identifiers (e.g., name, serial number)
- Dates of validation activities
- Analysts participating in validation activities
- Appropriate levels of quality control analysis to cover the scope of technical procedures to be applied

Selection of validation activities will vary depending upon the scenario. For example, a shorter validation set may be selected if a technical procedure is being transferred from one instrument to the same instrument from the same supplier. Additional considerations may apply if the supplier is different, or if a component relies on fundamentally different technology. Quantitative use-cases will require additional considerations as compared to qualitative applications. Cross-instrument validation activities may occur in tandem or at different times.

### 7.3 Records

Toxicology validation records are stored in at least one of three formats:

- Physical binders/folders
- Electronic bound records/folders
- Validation summaries posted to the internet

## 8 MEASUREMENT TRACEABILITY

The toxicology discipline follows ANSI/ASB STANDARD 017 Standard Practices for Measurement Traceability in Forensic Toxicology, with the exceptions of requirements 5.2.1a and 5.2.1b, which the discipline is working towards, and the requirement of 6.2.5. Validations and casework performed after April 27, 2022, will use calibrated glassware for critical solutions to ensure traceability. See CHEM-100 for additional information.

## 9 SAFETY

Chemists and FEs will follow all safety guidance provided in the *FBI Laboratory Safety Manual*. General guidance is provided here for toxicology exams; specific exam types or situations may have additional safety requirements. Specific hazards will be documented in the relevant technical procedures.

### 9.1 Biological Hazards

Standard personal protective equipment (PPE) is required for most toxicology exams.

When opening a blood tube or other biological specimen container, the possibility of aerosolizing the contents exists. In order to prevent unwanted contact with the specimen, several different measures may be taken in addition to wearing appropriate PPE.

- A. Specimens may be opened and pipetted in a chemical fume hood.
- B. Specimens may be opened and pipetted behind a bench top shield.

## 9.2 Chemical Hazards

Many chemicals and reagents used in the laboratory can have harmful effects on human health. If any specific question or concern arises, analysts shall contact a CU or LD safety representative.

## 10 OPERATIONAL DETAILS

### 10.1 Mission Statement

Our mission is to provide timely, high quality toxicology examinations and expertise for the FBI, law enforcement agencies, and the forensic community by investing in our workers, leveraging technology, and utilizing efficient strategies.

### 10.2 Data Management

#### 10.2.1 Toxic Database

The Toxic Database Administrator (DBA) is primarily responsible for Toxic operations, including but not limited to:

- Updates and management of functions, tables, queries, code, and reports
- Maintaining the integrity of the database through backups and password protection
- Communicating updates and maintenance periods

##### 10.2.1.1 Backup Administration

One or more individuals serve as backups to the DBA.

##### 10.2.1.2 TL Responsibilities

To facilitate operations, the TL may (at a minimum), update:

- Batch information
- Exam information
- Chemical/analyte information

#### 10.2.2 Method Development and Validation Data

Data resulting from method development and validation activities are retained in accordance with CU, Laboratory Division, and FBI policy. Confirmation of data retention is performed as a part of method development and validation approval.

### 10.3 Research Material Availability

CU maintains a collection of textbooks and journals relevant to forensic toxicology. These additional sources are also available:

- A. CU/Toxicology Research Article Database

- B. FBI Academy Library
  - 1. Physical Library
  - 2. Librarian Assisted Reference Material Requests
- C. Staff subscriptions to relevant journals

## **10.4 Roles and Responsibilities**

### **10.4.1 Technical Leader**

The toxicology Technical Leader (TL) serves as a member of the technical management for the toxicology discipline.

#### **10.4.1.1 Acting TL**

Qualified FEs or SMEs in the toxicology discipline assigned to the CU may serve as Acting TL. Designation of Acting TL can be made through verbal or written methods via the TL or supervisory chain.

### **10.4.2 Validation and Quality Control Manager (VQCM)**

Designated to share responsibility for day-to-day management of quality control and validation operations.

### **10.4.3 Supervisory Role**

Toxicology staff may be supervised by an individual not within the toxicology discipline.

### **10.4.4 Forensic Examiner (FE)**

The FE role manages cases (SUS) or case records (SUS and MUS) when assigned. The FE role also participates in lab work, validation, data review, *Laboratory Report* generation, technical review, testimony, and other duties as assigned and authorized.

### **10.4.5 Chemist**

The Chemist role participates in lab work, validation, data review, and other duties as assigned and authorized.

## **11 REFERENCES**

ANSI/ASB Standard 036, 1<sup>st</sup> ed., Standard Practices for Method Validation in Forensic Toxicology

ANSI/ASB Standard 017, 1<sup>st</sup> ed., Standard Practices for Measurement Traceability in Forensic Toxicology

ANSI/ASB Standard 053, 1<sup>st</sup> ed., Standard for Report Content in Forensic Toxicology

## 12 REVISION HISTORY

Revision	Issued	Changes
12	03/15/2024	Removed reference to ABFT throughout document. 2.3.2 – Updated wording Added Section 3.6 4.2.1, 4.2.2, 4.2.3 – added TOX426 to scopes 8 – updated the exceptions from ASB017 10.4.1 – updated definition of TL Appendix A1 – corrected a typo



## APPENDIX A1

Following is a list of analytes routinely included in testing for Postmortem – Suspected Toxicological COD (Full Postmortem Testing)

### Volatiles

Acetone  
Ethanol  
Isopropanol  
Methanol

### Anticonvulsants

Carbamazepine  
Gabapentin  
Lamotrigine  
Levetiracetam  
Phenytoin

### Antidepressants

Amitriptyline  
Bupropion  
Hydroxybupropion  
Citalopram  
Desmethylcitalopram  
Clomipramine  
Desmethylclomipramine  
Desipramine  
Doxepin  
Desmethyldoxepin  
Duloxetine  
Fluoxetine  
Norfluoxetine  
Imipramine  
Mirtazapine  
Nortriptyline  
Paroxetine  
Sertraline  
Norsertaline  
Trazodone  
Venlafaxine  
Desmethylvenlafaxine

### Antihistamines/Antitussives/Misc.

Chlorpheniramine  
Diphenhydramine  
Doxylamine  
Cetirizine  
Hydroxyzine  
Methorphan  
Promethazine

### Antipsychotics

9-hydroxyrisperidone  
Risperidone  
Chlorpromazine  
Clozapine  
Desmethylclozapine  
Olanzapine  
Quetiapine  
OH-Quetiapine

### Barbiturates

Butalbital  
Phenobarbital  
Secobarbital  
Pentobarbital  
Amobarbital

### Benzodiazepines

Alprazolam  
OH-Alprazolam  
Clonazepam  
7-aminoclonazepam  
Lorazepam  
Diazepam  
Nordiazepam  
Oxazepam  
Temazepam

**Cannabinoids**

delta 9-tetrahydrocannabinol (THC)  
11-hydroxy-delta 9-tetrahydrocannabinol (THC-OH)  
11-nor-9-carboxy-delta 9-tetrahydrocannabinol (THC-COOH)

**CNS Depressants**

Carisoprodol  
Meprobamate  
Cyclobenzaprine  
Desmethylocyclobenzaprine  
Zolpidem

**CNS Stimulants**

Amphetamine  
Methamphetamine  
Methylenedioxyamphetamine (MDA)  
Methylenedioxymethamphetamine (MDMA)  
Cocaine  
Cocaethylene  
Benzoyllecgonine

**Dissociatives**

Ketamine  
Norketamine  
Phencyclidine (PCP)

**Narcotic Analgesics**

Buprenorphine  
Norbuprenorphine  
Codeine  
Fentanyl  
Hydrocodone  
Norhydrocodone  
Hydromorphone  
Methadone  
Morphine  
Normorphine  
6-monoacetylmorphine  
Oxycodone  
Oxymorphone  
Tramadol  
o-desmethyltramadol

**Over the Counter Medication**

Acetaminophen

## APPENDIX A2

Following is a list of analytes routinely included in testing for Postmortem – Known Anatomical COD (Scoped Postmortem Testing)

### Volatiles

Acetone  
Ethanol  
Isopropanol  
Methanol

### Benzodiazepines

Alprazolam  
OH-Alprazolam  
Clonazepam  
7-aminoclonazepam  
Diazepam  
Nordiazepam  
Oxazepam  
Temazepam  
Lorazepam

### Cannabinoids

delta 9-tetrahydrocannabinol (THC)  
11-hydroxy-delta 9-tetrahydrocannabinol (THC-OH)  
11-nor-9-carboxy-delta 9-tetrahydrocannabinol (THC-COOH)

### CNS Stimulants

Amphetamine  
Methamphetamine  
Cocaine  
Cocaethylene  
Benzoyllecgonine

### Narcotic Analgesics

Codeine  
Fentanyl  
Hydrocodone  
Norhydrocodone  
Morphine  
Normorphine  
6-monoacetylmorphine  
Oxycodone

### APPENDIX A3

Following is a list of analytes routinely included in testing of urine specimens in Drug-Facilitated Crimes

#### **Volatiles**

Acetone  
Ethanol  
Isopropanol  
Methanol

#### **Anticonvulsants**

Gabapentin  
Phenytoin

#### **Antidepressants**

Amitriptyline  
Citalopram  
Desmethylcitalopram  
Desipramine  
Doxepin  
Desmethyldoxepin  
Fluoxetine  
Norfluoxetine  
Imipramine  
Nortriptyline  
Paroxetine  
Sertraline  
Norsertaline  
Trazodone  
Venlafaxine  
Desmethylvenlafaxine

#### **Antihistamines/Antitussives/Misc.**

Brompheniramine  
Carbinoxamine  
Cetirizine  
Chlorpheniramine  
Clonidine  
Dextrophan  
Diphenhydramine  
Doxylamine  
Hydroxyzine  
Meclizine  
Methorphan  
Norchlorcyclizine  
Promethazine  
Scopolamine  
Tetrahydrozoline

#### **Antipsychotics**

Chlorpromazine  
Clozapine  
Desmethylclozapine  
Olanzapine  
Quetiapine  
OH-Quetiapine  
Norquetiapine  
Thioridazine  
Ziprasidone

**Barbiturates**

Amobarbital  
Butalbital  
Pentobarbital  
Phenobarbital  
Secobarbital

**Benzodiazepines**

Alprazolam  
OH-Alprazolam  
Bromazepam  
Chlordiazepoxide  
Norchlordiazepoxide  
Clonazepam  
7-aminoclonazepam  
Desalkylflurazepam  
Diazepam  
Nordiazepam  
Oxazepam  
Temazepam  
Estazolam  
Etizolam  
Flunitrazepam  
7-aminoflunitrazepam  
Flurazepam  
Lorazepam  
Midazolam  
OH-Midazolam  
Prazepam  
Tetraepam  
Triazolam  
OH-Triazolam

**Cannabinoids**

11-nor-9-carboxy-delta 9-tetrahydrocannabinol (THC-COOH)

**CNS Depressants**

Carisoprodol  
Cyclobenzaprine  
Desmethylocyclobenzaprine  
GHB  
Meprobamate  
Suvorexant  
Zolpidem  
Zolpidem Metabolite  
Zopiclone

**CNS Stimulants**

Amphetamine  
Methamphetamine  
Methylenedioxyamphetamine (MDA)  
Methylenedioxymethamphetamine (MDMA)  
Cocaine  
Cocaethylene  
Benzoylecgonine  
Ecgonine methyl ester  
Methylphenidate

**Dissociatives**

Ketamine  
Norketamine  
Phencyclidine (PCP)

**Narcotic Analgesics**

Buprenorphine

Norbuprenorphine

Codeine

Norcodeine

Dihydrocodeine

Fentanyl

Norfentanyl

Hydrocodone

Norhydrocodone

Hydromorphone

Meperidine

Normeperidine

Methadone

EDDP

Morphine

6-monoacetylmorphine

Normorphine

Oxycodone

Noroxycodone

Oxymorphone

Propoxyphene

Norpropoxyphene

Tapentadol

Desmethyltapentadol

Tramadol

n-desmethyltramadol

o-desmethyltramadol

## APPENDIX A4

Following is a list of analytes routinely included in testing of blood specimens in DUI/Human Performance Cases

### Volatiles

Acetone  
Ethanol  
Isopropanol  
Methanol

### Barbiturates

Amobarbital  
Butalbital  
Pentobarbital  
Phenobarbital  
Secobarbital

### Benzodiazepines

Alprazolam  
OH-Alprazolam  
Clonazepam  
7-aminoclonazepam  
Diazepam  
Nordiazepam  
Oxazepam  
Temazepam  
Lorazepam

### Cannabinoids

delta 9-tetrahydrocannabinol (THC)  
11-hydroxy-delta 9-tetrahydrocannabinol (THC-OH)  
11-nor-9-carboxy-delta 9-tetrahydrocannabinol (THC-COOH)

### CNS Depressants

Carisoprodol  
Meprobamate  
Zolpidem

### CNS Stimulants

Amphetamine  
Methamphetamine  
Methylenedioxyamphetamine (MDA)  
Methylenedioxymethamphetamine (MDMA)  
Cocaine  
Cocaethylene  
Benzoylcegonine

### Dissociatives/Hallucinogens

Ketamine  
Norketamine  
Lysergic Acid Diethylamide (LSD)  
Phencyclidine (PCP)

### Narcotic Analgesics

Buprenorphine  
Norbuprenorphine  
Codeine  
Fentanyl  
Hydrocodone  
Norhydrocodone  
Hydromorphone  
Methadone  
Morphine  
6-monoacetylmorphine  
Normorphine  
Oxycodone  
Oxymorphone  
Tramadol  
o-desmethyltramadol