## MASTER DOCUMENT LIST

1. **Overview**

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<td>Overview of Toxicology (Drugs) Training Program</td>
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<td>TOX-TM-01a</td>
<td>Toxicology Training Units Matrix</td>
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2. **General Modules**

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<td>TOX-TM-GEN-05</td>
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<td>TOX-TM-GEN-06</td>
<td>Law, Pretrial Preparation and Court Testimony</td>
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3. **Blood Alcohol Modules**

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<tr>
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<td>Chemical Properties – Physiology - Pharmacology</td>
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<td>Fundamental Operations for Blood Alcohol</td>
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<td>Headspace Gas Chromatography</td>
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<td>TOX-TM-BA-04</td>
<td>Analytical Procedures for Blood Alcohol Analysis</td>
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4. **Toxicology Modules**

4.1 **Immunoassay**

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4.2 **GC/MS**

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## 4 Toxicology Modules

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<td>TOX-TM-GCMS-03</td>
<td>GCMS Confirmation (Target Compound Analysis)</td>
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### 4.3 LC/MS

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<td>Toxicology Immunoassay Screening Checklist</td>
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OVERVIEW OF TOXICOLOGY (DRUGS) TRAINING PROGRAM

1 Introduction

Approval for Toxicology analysis includes analysis of blood, urine, and other possible biological specimens for the presence or absence of drugs and their metabolites.

Individuals employed by the Texas Department of Public Safety (DPS) as Forensic Scientists in the Toxicology (Tox) section must meet specific qualifications as outlined in the Tox Training Manual before being qualified to perform independent casework.

Individuals employed by the Texas DPS as Technician in the Tox section must meet specific qualifications as outlined in the Tox Training Manual before being qualified to perform work.

2 Purpose

The Tox Training Manual is designed to provide the trainee with sufficient background, laboratory skills, education, competency, and supervised hands-on experience to adequately perform independent casework with minimal supervision. The training program is identified as containing a set of required modules.

A. Toxicology Technician Training – The trainee will be introduced to laboratory safety, fundamentals of forensic toxicology, basic functions of the laboratory, and relevant use of equipment and reagent preparation.

B. Toxicology Analysis Training – The trainee will be introduced to laboratory safety, general toxicology, fundamentals of forensic toxicology, and the relevant testing procedures. The appropriate instrument fundamental module must be taken prior to either the screening or the confirmation modules. A written exam will occur with each of the following modules:

1. Immunoassay Screening
2. GC/MS Fundamentals
3. GC/MS Screening
4. GC/MS Confirmation
5. LC/MS Fundamentals
6. LC/MS Screening
7. LC/MS Confirmation

Additional drug categories will be authorized for the respective instrument confirmation as a Continued Independent Authorization.

3 Training Roles and Responsibilities

Prior to beginning the training process, the trainer, technical leader, and supervisor should evaluate the trainee’s previous training and experience for possible modifications to the training plan. Modifications to the training will be approved by the Quality Manager. Meetings between the trainee, trainer, technical leader, and/or supervisor should be held periodically in order to evaluate the trainee’s progress, plan future study/practical assignments, and discuss any deficiencies which may require additional training.
3.1 **Trainee Responsibilities**

A. The trainee will be required to keep detailed records of his/her training in a training notebook.

B. The trainee will be required to take detailed notes and complete reading assignments on a self-study basis.

C. The trainee is responsible for adhering to the training schedule and informing the trainer, technical leader, and/or supervisor when problems arise at any time during the training period.

3.2 **Trainer Responsibilities**

A. The trainer is responsible for providing a training plan or outline to the trainee.

B. The trainer will evaluate and discuss with the trainee any notes taken during training and reading assignments.

C. The trainer will be responsible for instructing, evaluating progress, and assessing competency in each assigned module.

D. The trainer, technical leader, and/or supervisor will communicate to the trainee any deficiencies noted during the training process and will provide opportunities for the trainee to become competent in the required areas prior to completing each training module.

E. The trainer will review and approve training notebooks and other training records documenting completion of training requirements.

4 **Assessment**

Prior to beginning supervised casework the trainee must:

A. Pass comprehensive written examinations in safety, instrumentation theory, and/or relevant testing procedures.

B. Successfully demonstrate competency with simulated samples.

C. Be authorized to perform supervised casework.

5 **Approval to Perform Technical Review task**

A. Successful completion of the Immunoassay Screening module will allow for the analyst to perform the technical review task for Immunoassay Screening.

B. Successful completion of the Screening module will allow for the analyst to perform the technical review task for Screening for the respective instrument (GC/MS or LC/MS).

C. Successful completion of the Confirmation module will allow for the analyst to perform the technical review task for Confirmation for the respective instrument (GC/MS or LC/MS).

D. Approval for GC/MS Fundamentals module will allow for technical review of GC/MS Screening and/or Confirmation if the respective module is complete in LC/MS.

E. Approval for LC/MS Fundamentals module will allow for technical review of LC/MS Screening and/or Confirmation if the respective module is complete in GC/MS.
6 Supervised Casework

The trainee will examine at least two batches of casework under supervision.

7 Continued Authorization

Upon completion of the training modules, competency for additional categories may be accomplished by: observation of batches, supervised performance, and successful competency samples.
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<td>01</td>
<td>02/23/2011</td>
<td>Major Revision – Sections 2, 3, 4, 5, 6, 7, and 8</td>
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## TOXICOLOGY TRAINING UNITS MATRIX

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**Key:**
- **TECH** Toxicology Technician
- **TOX** Toxicology Analyst
## Revision History

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TOXICOLOGY SAFETY

Duration  2 days

Purpose  Orient and acquaint the trainee with toxicology specific laboratory safety practices to be followed in the laboratory.

Prerequisite  GLT-TM-FUN-01 to 06

1 Objectives

1.1 Theoretical

Safe handling of samples and the waste generated during analysis is critical to protect the health of all persons who may come into contact with samples or waste either within or outside of the laboratory. Safety training promotes healthy employees and minimizes liability to the agency.

1.2 Practical

Trainee will be able to:

A. Recognize specific hazards associated with performing toxicology analysis.
B. Locate and use SDS for chemicals used in analysis.
C. Understand and practice universal precautions for blood specimens and other body fluids, including use of required personal protective equipment (PPE).
D. Know local work practice controls such as how to properly handle and dispose of blood contaminated supplies and properly disinfect the work areas.
E. Understand local engineering controls such as hoods, chemical storage cabinets, chemical labeling and disposal, and proper handling of gas cylinders.

2 Training Outline

2.1 Lesson Plan (Refer to GLT-TM-FUN-02, specifically for Toxicology work area)

A. Bloodborne pathogen review
B. Protective measures review
   1. Universal precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus, and other bloodborne pathogens.
   2. PPE
   3. Hoods and snorkels
   4. Chemical storage cabinets location and use
   5. Pressurized gas cylinders
   6. Pressurized air outlets
   7. Gas generators
   8. Glass handling
9. Working with vacuum
10. Electrical
11. Flammable gas

C. Preventive practices for procedural risks
   1. Avoid contamination of documents
   2. Cutting seals (box cutter safety)
   3. Homogenizing sample using glass tissue grinder and proper clean-up
   4. Avoiding exposure resulting from pressure buildup in specimen containers
   5. SDS of chemicals used

D. Waste practices
   1. Disposable pipette tips, test tubes, gloves
   2. Laundry of lab coats
   3. Autoclave
   4. Chemical waste

E. Emergency
   1. Fire safety
   2. Spills

F. Shipping guidelines for biological specimens
   Proper packaging of biological specimens

2.2 Required Readings
   A. Safety Data Sheets (SDS) - Review for each solvent, drug and chemical used.
   B. Shipping guidelines for biological specimens
      1. Laboratory Customer Handbook, Chapter 15 – Case Acceptance and Analysis Policies, section 15.10 Toxicology (Alcohol/Volatiles and/or Drugs) Analysis
      2. Laboratory Customer Handbook Chapter 27 – Toxicology (Alcohol/Volatiles and/or Drugs) Analysis
      3. USPS Packaging Instruction 6G

3 Practice
3.1 Safety

Biological specimens may contain infectious agents. Chemicals used may be toxic and flammable. Use appropriate laboratory safety precautions and observe Universal Bloodborne Pathogens precautions:

   A. Wear gloves, a lab coat, and protective eyewear when working with biological specimens or during reagent preparation and testing.
   B. Clothing may protect unbroken skin; broken skin should be covered by a protective bandage.
C. The biological safety cabinet (laminar flow hood, biohood) should be used when handling potentially hazardous biological samples. Contents of the hood must not interfere with circulation.

D. Conventional fume hoods should be used when handling volatile chemicals during reagent preparation.

E. Use universal precautions during evidence handling. Care should be exercised during the use of cutting tools while handling evidence.

F. Hydrogen is a highly flammable gas. Leaks and proper cylinder handling are primary concerns.

G. Heated zones of the gas chromatograph require caution to avoid burns.

3.2 Observed performance

A. The trainer will lead the trainee on tour of the lab, identifying the location of related safety equipment. Proper use, storage, and disposal will be discussed.

Note: the following may be completed concurrent with later modules, at trainer's discretion

B. Trainee will observe when a pressurized gas cylinder is replaced.

C. Trainer will discuss and demonstrate safety issues associated with the use of hydrogen gas when using a pressurized gas cylinder and/or hydrogen generator.

4 Assessment

4.1 Written Examination

Written exam will be given by the trainer demonstrating knowledge of use and location for related safety equipment, devices, SDS, and local safety practices.

4.2 Assessment of training

Successful completion of this module is determined by the trainer and documented with the Toxicology Overview Checklist (LAB-TOX-TM-01).

4.3 Dependent modules

Successful completion of this module is a prerequisite for casework.
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INTRODUCTION TO FORENSIC TOXICOLOGY

Duration 2 to 3 days
Purpose Educate trainee on the overall procedures and terminology of forensic toxicology.
Prerequisite GLT-TM-FUN-01 to 06

1 Objectives

1.1 Theoretical
The ability to understand and use proper terminology is necessary for successful communication of forensic toxicology. The review of techniques used in forensic toxicology will provide a foundation to the processes used.

1.2 Practical
Trainee will be able to:

A. Define and understand basic toxicology and analytical chemistry terms.
B. Understand the function and responsibilities of the toxicology section.
C. Discuss the type of extraction processes for specific drugs.
D. Discuss the analytical toxicology testing technique including screening and confirmation.
E. Describe the limitations and advantages of immunoassay screening, GC/MS, and LC/MS.
F. Utilize references to answer specific questions.

2 Training Outline

2.1 Lesson Plan
A. Introduction to forensic toxicology: definition, significance, legal importance
   1. Postmortem forensic toxicology
   2. Human performance forensic toxicology
   3. Forensic urine drug testing

B. Overview of drugs
   1. Types of drugs
   2. Basic information on pharmacokinetics and pharmacodynamics

C. Overview of DPS Toxicology section’s functions and responsibilities
   1. Immunoassay screens
      Classes of drugs tested
   2. GC/MS and LC/MS screening
      a) Qualitative
      b) Common drugs
   3. GC/MS and LC/MS confirmation
      a) Quantitative
b) Qualitative

c) Drug categories tested

4. Types of Evidence/Cases
   a) Blood, urine, and serum
   b) Intoxication offense, sexual assault, homicide, and questioned death

D. Overview of DPS Toxicology Measurement Uncertainty policies and procedures
   1. Reporting of uncertainty values
   2. Method for uncertainty budgets

2.2 Required Readings

Note: Use of the most current edition is recommended. Review of reading acceptable if
previously required.

A. Levine, Barry. 2013. Principles of Forensic Toxicology, 4th Ed. American Association of
   Clinical Chemistry.
   1. Chapter 1 – Postmortem Forensic Toxicology
   2. Chapter 2 – Human Performance Toxicology
   3. Chapter 3 – Forensic Drug Testing
   5. Chapter 6 – Pharmacokinetics and Pharmacodynamics
   6. Chapter 31 – Postmortem Redistribution of Drugs

   Analysis of Drugs and Poisons, 4th Ed. Pharmaceutical Press
   1. Chapter 5 – Driving Under the Influence of Drugs
   2. Chapter 8 – Drug-facilitated Sexual Assault
   3. Chapter 9 – Forensic Toxicology
   4. Chapter 22 – Quality Control and Accreditation in the Toxicology Laboratory
   5. Chapter 23 – Measuring and Reporting Uncertainty
   6. Chapter 24 – Pharmacokinetics and Metabolism

C. Texas DPS Standard Operating Procedures
   1. TOX-01-01 – Toxicological Services and Examiner Approval
   2. TOX-01-03 – Drug Standards, Calibrators, and Internal Standards
   3. TOX-01-04 – Controls
   4. TOX-01-05 – Uncertainty of Measurement
   5. TOX-01-06 – Case Documentation
   6. TOX-01-06A – Approved Standard Abbreviations
2.3 Suggested References

*Note*: Use of the most current edition is recommended.


14. Commonly used internet resources and forums

3 Practice

3.1 Observed Performance

Trainer will review and discuss trainee’s notes regarding observations and required readings.

3.2 Supervised Performance

A. Complete the practice assignment “Introduction to Forensic Toxicology Exercise”. Discuss answers with trainer.

B. Review Toxicology Uncertainty Budget.
4 Assessment

Successful completion of this module is determined by the trainer and documented with the Toxicology Overview Checklist (LAB-TOX-TM-01).
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SAMPLE PREPARATION FOR ANALYSIS

Duration 2-4 days

Purpose Familiarize the trainee with an evidence analysis scheme used within the DPS that includes initial examination, sampling, volume determination, and sample preparation.

Prerequisite GLT-TM-FUN-01 to 06, TOX-TM-03

1 Objectives

1.1 Theoretical

When utilizing a consistent workflow in evidence examination, an analyst can ensure maximum efficiency and protect the integrity of evidence. An established workflow can also help to avoid mistakes and will allow the analyst to be able to describe these routine practices when testifying.

1.2 Practical

Trainee will be able to:

A. Describe the evidence workflow designed to protect the integrity of evidence.
B. Discuss identifying marks on interior and exterior packaging.
C. Discuss seals before and after analysis.
D. Discuss proper sampling techniques.
E. Discuss sample volume estimation techniques.
F. Discuss sample preparation and extraction theory and methodology.
G. Utilize LIMS to maintain chain of custody for evidence and folders.

2 Training Outline

2.1 Lesson Plan

The trainee will observe the trainer prepare samples for analysis. During the observation, the trainer will:

A. Demonstrate appropriate PPE.
B. Examine and sample evidence.
C. Mark external and internal packaging, and repackage the evidence if necessary.
D. Document case notes on batch worklist.
E. Demonstrate techniques used to protect integrity of evidence.
F. Estimate sample volume.
2.2 Required Readings

**Note:** Use of the most current edition recommended. Review of reading acceptable if previously required.


   1. Chapter 28 – Sampling, Storage and Stability
   2. Chapter 29 – Extraction

   1. Chapter 7 – Specimen Preparation
   2. Chapter 30 – Stability of Drugs of Abuse in Biological Specimens

D. Texas DPS Crime Laboratory Service Manual, Chapter 44 – Evidence and Database Sample Integrity

E. Texas DPS Standard Operating Procedures
   1. TOX-02-01 – Systematic Examination of Toxicological Specimens
   2. TOX-02-02 – Disposition of Toxicological Evidence
   3. LIMS-GEN-22 – Worklists/Batch Process

3 Practice

3.1 Observed Performance

A. Trainee will discuss his/her understanding of how cases should be handled (barcoding, sampling, marking, sealing, worklist completion).

B. Trainer will review and discuss trainee’s notes regarding observations and required readings.

4 Assessment

Successful completion of this module is determined by the trainer and documented with the Toxicology Overview Checklist (LAB-TOX-TM-01).
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EQUIPMENT FOR TOXICOLOGY

Duration 2 weeks

Purpose Familiarize the trainee with general equipment available in the laboratory for toxicology analysis. Enable trainee to safely operate, clean, and maintain laboratory equipment.

Prerequisite GLT-TM-FUN-01 to 06, TOX-TM-02

1 Objectives

1.1 Theoretical
The proper operation and maintenance of laboratory equipment is essential to good laboratory practice. All laboratory equipment must be cleaned, verified, and used correctly to ensure its reliability. Proper documentation of equipment calibration and maintenance is crucial to demonstrating quality control in the laboratory. Maintenance and calibration guidelines must be written and well understood by all users.

1.2 Practical
Trainee will be able to:

A. Weigh varying quantities of substances on balances in the laboratory. Demonstrate proper cleaning techniques for spilled substances on balances. Perform quality checks on balances.

B. Demonstrate proper techniques for measuring pH.

C. Demonstrate proper use of centrifuges.

D. Demonstrate proper use of the autoclave, including loading, operating, emptying, and cleaning.

E. Demonstrate proper use of hotplates/magnetic stirrers, heating block, sonicators, and mixers (vortex and platform rotator).

F. Demonstrate proper use of a positive pressure manifold/automated liquid dispenser (ALD).

G. Demonstrate proper use of an evaporator/concentrator.

H. Demonstrate proper use of DI water filtration system.

I. Demonstrate proper use of fume/exhaust hoods and biological safety cabinets..

J. Demonstrate proper use and handling of syringes.

K. Demonstrate proper use of refrigerators and freezers.

L. Demonstrate proper use of pipettes and bottle top dispensers.

M. Complete relevant documentation pertaining to equipment use, quality control checks, and verification checks.

2 Training Outline

2.1 Lesson Plan
A. Familiarize trainee with reference materials for equipment use.
B. Familiarize trainee with locations of equipment and logbook(s), if applicable.

C. Analytical Balances
   1. Instruction on operation and cleaning
   2. Familiarization with QC specifications, calibration, and documentation

D. Pipettes (e.g. disposable, volumetric, air displacement, and positive displacement)
   1. Instruction on choice of volume, operation, maintenance, cleaning/disposal, and storage
   2. Familiarization with QC specifications, calibration, and documentation

E. Automated Liquid Dispensers (ALD) - Instruction on operation and cleaning

F. Bottle top dispenser - Instruction on choice of volume, operation, maintenance, cleaning, and storage

G. pH Determination
   1. pH paper
   2. pH meter
      a) Instruction on operation, calibration, cleaning, and maintenance
      b) Familiarization with QC specifications and documentation

H. Centrifuge - Instruction on operation, maintenance, and cleaning

I. Hoods (e.g. chemical fume hoods, biological safety cabinets)
   1. Instruction on operation, maintenance, and cleaning
   2. Familiarization with QC documentation for calibration

J. Autoclave
   1. Instruction on operation, maintenance, and cleaning
   2. Instruction on proper labeling and disposal of biological waste
   3. Familiarization with logbook recording sterilization of biological waste

K. Refrigerators and Freezers
   1. Familiarization with temperature specifications and documentation
   2. Instruction on cleaning (routine and major)

L. Thermometers
   1. Instructions on handling, reading, and maintenance
   2. Familiarization with QC specifications, calibration, and documentation

M. Hotplates/magnetic stirrers, heating block, sonicators, and mixers (vortex and platform rotator) - Instruction on operation, maintenance, and cleaning

N. Positive pressure manifolds - Instruction on operation, maintenance, and cleaning

O. Evaporators/concentrators - Instruction on operation, maintenance, and cleaning

P. Vacuum oven - Instruction on operation, maintenance, and cleaning
Q. Laboratory glassware (e.g. volumetric flasks, graduated cylinders, tissue grinders, etc.)
   1. Instruction on use, cleaning, and maintenance
   2. Instruction on proper disposal of broken glassware (e.g. biohazard and clean glassware)

2.2 Required Readings

Note: Use of the most current edition recommended.

A. Texas DPS Crime Laboratory Service Manual, Chapter 48 – Laboratory Equipment
B. Texas DPS Standard Operating Procedures
   1. TOX-01-02 – Instruments and Equipment
   2. TOX-INS-03 – Cerex Pressure Processor Instructions
   3. TOX-INS-04 – Turbovap Evaporator Instructions
   4. TOX-INS-05 – Cerex Evaporator
   5. TOX-INS-06 – Centra MP4 Centrifuge Instructions
   6. TOX-INS-08 – IEC CL40 Centrifuge Instructions
   7. TOX-INS-10 – Analytical Balance Operation
   8. TOX-INS-11 – Semi-Micro Balance Operation
   9. TOX-INS-12 – Top-Loader Balance Operation
   10. TOX-INS-14 – Sorvall ST40 Centrifuge Instructions
   11. TOX-INS-15 – Thermo Scientific Vacuum Oven Instructions
   12. TOX-INS-16 – Cerex ALD-III Pressure Processor Instructions
   13. TOX-INS-17 – XcelVap Evaporator System Instructions
   14. TOX-INS-18 – pH Meter
   15. LAB-TOX-27 – pH Meter Calibration
   16. LAB-TOX-31 – Post-Calibration Pipette Check Report
   17. LAB-TOX-32 – Pipette Performance Verification Report
   18. LAB-TOX-34 – Toxicology Pipette Log
   19. LAB-TOX-38 – Balance Check Log
   20. AUS-FRM-006 – Temperature Verification Log

C. User manuals for specific laboratory equipment (pipettes, balances, centrifuges, autoclaves, pH meters, biological safety cabinets, chemical fumes hoods, etc.)

3 Practice

3.1 Observed Performance

Trainer will:
   A. Demonstrate to the trainee proper technique for operating laboratory equipment.
B. Give instructions on documentation of quality control procedures and calibration of equipment.

C. Review and discuss trainee's notes regarding observations and required readings.

3.2 Independent Exercises

Trainee will:

A. Demonstrate proper use of each balance by measuring a weight set.

B. Calibrate the pH meter, measure pH of reference buffered solutions, and properly document in the logbook.

C. Pipette various volumes of water to check precision and accuracy using different pipettes.

D. Autoclave biological waste under the supervision of the trainer.

4 Assessment

4.1 Competency and Qualifying Examination

A pipette test will be given to demonstrate competency in using various mechanical pipettes commonly used in the toxicology laboratory.

4.2 Assessment of training

Successful completion of this module is determined by the trainer and documented with the Toxicology Overview Checklist (LAB-TOX-TM-01).
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REPORT WRITING

Duration 2-5 days

Purpose To familiarize the trainee with guidelines for toxicology report writing and case review.

Prerequisite GLT-TM-FUN-01 to 06; TOX-TM-01 to 05

1 Objectives

1.1 Theoretical

The laboratory report is used to communicate analytical results. The report should be correct including results and administrative information provided to the laboratory.

1.2 Practical

Trainee will be able to:

A. Enter the results from case analysis into LIMS.
B. Determine appropriate notes for a report.
C. Produce a report after the completion of a case.
D. Administratively and technically review a completed case folder.
E. Release the report to the agency representative(s).

2 Training Outline

2.1 Lesson Plan

A. Familiarize trainee with case documentation practices, including correspondence.
B. Familiarize trainee with result/note entry, including instruction on:
   1. Immunoassay result data entry
   2. Qualitative result data entry
   3. Quantitative result data entry
   4. Report notes, including evidence disposition
C. Familiarize trainee with reporting elements, including instruction on:
   1. Format of report
   2. Types of reports
      a) *Toxicology Analysis Report*
      b) *Supplemental Report*
      c) *Amended Report*
      d) *Closed Without Analysis Report*
   3. Report distribution
2.2 Required Readings

**Note:** Use of the most current edition recommended. Review of reading acceptable if previously required

A. Texas DPS Crime Laboratory Service Manual
   1. Chapter 55 – Review of Laboratory Records
   2. Chapter 53 – Laboratory Records
   3. Chapter 54 – Laboratory Reports, Letters, and Certificates
   4. Chapter 56 – Records Requests and Release of Laboratory Records and Information

B. LIMS Manual
   1. LIMS-ADM-01 – Laboratory Information Management System
   2. LIMS-ADM-03 – Offense Codes
   3. LIMS-GEN-01 – LIMS Login
   4. LIMS-GEN-02 – Case Info Tab
   5. LIMS-GEN-04 – Offense Tab
   6. LIMS-GEN-05 – Individuals Tab
   7. LIMS-GEN-06 – Evidence Tab
   8. LIMS-GEN-07 – Requests Tab
   9. LIMS-GEN-10 – Relating Cases
   10. LIMS-GEN-13 – Amended Reports
   11. LIMS-GEN-14 – Case Review
   12. LIMS-GEN-19 – Entry of Case Activities
   13. LIMS-GEN-21 – Autotext
   14. LIMS-GEN-29 – Statement of Qualifications and Disclosure Form
   15. TOX-01-06 – Case Documentation
   16. TOX-01-08 – Report Writing Guidelines

3 Practice

3.1 Observed Performance
Trainer will review and discuss trainee’s notes regarding observations and required readings.

3.2 Supervised Performance
Practice LIMS entry in LIMS software or on worksheets provided by trainer.

4 Assessment

A. Successful completion of this module is determined by the trainer and documented with the Toxicology Overview Checklist (LAB-TOX-TM-01).

B. Statement of Qualifications and Disclosure Form must be complete before casework may be started.
Revision History

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REAGENT AND SOLUTION PREPARATION

Duration  variable
Purpose  Familiarize the trainee with reagent and solution preparation techniques. This module applies specifically to the Toxicology Technician within the Toxicology section.
Prerequisite  GLT-TM-FUN-01 to 06, TOX-TM-02, TOX-TM-03

1 Objectives
1.1 Theoretical
To protect the integrity of extractions and analysis of cases, a good foundation for reagent and solution preparation needs to be understood by the preparer. An established method for preparations can help to avoid mistakes and will allow analysts to confidently utilize the prepared reagents and solution.

1.2 Practical
Trainee will be able to:
A. Accurately prepare reagents/solutions to be utilized by Toxicology analysts.
B. Label prepared reagents/solutions with complete labeling.
C. Document preparation of reagent/solution.
D. Store prepared reagent/solution in appropriate location.

2 Training Outline
2.1 Lesson Plan
The trainee will observe the trainer prepare a specific reagent or solution. During the observation, the trainer will:
A. Demonstrate appropriate PPE.
B. Mark appropriate logbooks and other documentation for preparation.
C. Label reagent/solution bottle with appropriate documentation.

2.2 Required Readings
Note: Use of the most current edition recommended. Review of reading acceptable if previously required.
A. Texas DPS Crime Laboratory Service Manual, Chapter 48 – Laboratory Equipment
B. Texas DPS Standard Operating Procedures, TOX SOP for specific reagent/solution preparation

3 Practice
3.1 Observed Performance
Trainee will discuss his/her understanding of how reagent/solution should be prepared and stored.
3.2 Supervised Performance
Trainee will prepare reagent/solution.

4 Assessment
4.1 Certification of Competency
The trainee and the trainer will complete a checklist and Work Authorization form (LAB-309) for each specific reagent/solution approved.
## Revision History

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IMMUNOASSAY SCREENING

Duration 2-4 weeks

Purpose Familiarize the trainee with theoretical and practical aspects of the common instruments utilized in the EMIT screening technique for blood and urine testing.

Prerequisite GLT-TM-FUN-01 to 06, GLT-TM-LAW-01 and 02, TOX-TM-01 to 05

1 Objectives

1.1 Theoretical

Enzyme Multiplied Immunoassay Technique (EMIT) is used to screen for classes of drugs that may be present in a biological sample.

EMIT results are presumptive and should be followed by mass spectrometry methods to identify specific drugs, when possible.

1.2 Practical

Following the completion of training the trainee will be able to:

A. Explain the difference between presumptive and confirmation methods.
B. Explain the theory and operation of the EMIT.
C. Explain the quality controls for utilized instrument/equipment.
D. Explain the limitations of EMIT testing and the cross-reactivity of assay methods to different drugs associated with each drug category.
E. Create a worklist for EMIT batch analysis.
F. Prepare/extract samples for analysis on the EMIT instrument.
G. Use the software associated with the EMIT instrument to analyze samples.
H. Evaluate results.
I. Demonstrate when confirmatory testing is needed.
J. Add cases to toxicology pending list for confirmatory testing or MS screening.
K. Close out negative cases including generation of reports.
L. Demonstrate proper disposition of evidence.
M. Properly maintain the EMIT instrument.

2 Training Outline

2.1 Lesson Plan

A. Introduction to qualitative and semi-quantitative analysis
B. Introduction to sample preparation
   1. Blood – protein precipitation
   2. Urine – direct sampling
C. Familiarization with reagents
   1. Extraction reagents
2. Instrument reagents

D. Familiarization with the EMIT instrument

1. Theory
   a) Advantages
   b) Disadvantages

2. Batch configuration
   a) Calibrators
   b) Unknown samples

3. Instrument operation
   a) Setup
   b) Analyze and verify acceptability of calibrators and quality control
   c) Analyze unknown samples
   d) Documentation of results
   e) Daily maintenance
   f) Monthly maintenance

4. Interpretation of results
   a) Evaluate batch acceptance
   b) Evaluate instrument response for a sample compared to calibrators and/or the cut-off sample

E. Familiarization with case workflow

   1. Negative results
   2. Presumptive positive results
   3. Case offense
   4. Suspected drugs
   5. Pending list

2.2 Required Readings

Note: Use of the most current edition recommended. Review of reading acceptable if previously required

   1. Chapter 7 – Specimen Preparation
   2. Chapter 10 – Immunoassay

C. Texas DPS Standard Operating Procedures
   1. TOX-01-03 – Drug Standards, Calibrators, and Internal Standards
   2. TOX-01-04 – Controls
   3. TOX-01-08 – Report Writing Guidelines
   4. TOX-01-09 – Guidelines for Batch Archive Review
   5. TOX-01-10 – Guidelines for Administrative and Technical Review
   6. TOX-02-01 – Systematic Examination of Toxicological Evidence
   7. TOX-02-02 – Disposition of Toxicological Evidence
   8. TOX-03-01 – Screening of Blood Samples by EMIT
      Including all SOPs in Related Documents section
   9. TOX-03-02 – Screening of Urine Samples by EMIT
      Including all SOPs in Related Documents section
  10. LAB-TOX-10 – Urine Immunoassay Reagent Log
  11. LAB-TOX-11 – Working Solution Log
  12. LAB-TOX-17 – Blood Immunoassay Reagent Log
  13. LAB-TOX-23 – EMIT Maintenance Log
  14. LAB-TOX-24 – Reagent Log
  15. LAB-TOX-26 – Toxicology Matrix Blank Verification Form
  16. LAB-TOX-35 – EMIT Results Page
  17. LAB-TOX-36 – EMIT Reagent Validation Form
  18. LAB-TOX-37 – EMIT Reagent Verification Checklists – Blood/Urine

D. MGC 240 Operating Manual
E. Current Reagent A and E manufacturer inserts
F. Safety Data Sheets- Review for each solvent, drug, and chemical used.

3 Practice

3.1 Safety

Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

3.2 Equipment

- Vortex Mixer
- MGC 240
- Centrifuge
- Turbovap Evaporator
3.3 Standards, Controls, Reagent Preparation

- Tris Buffer
- Tris Buffer:MeOH
- Acidified ethanol
- Working solutions
- Calibrators
- Cut-off sample

3.4 Observed Performance

A. The trainee will observe at least two batches of blood cases and one batch of urine cases. The trainee will observe the trainer or a qualified analyst as they work a batch of cases from start to finish. This includes making a worklist, gathering the evidence, sampling and documentation of each case, extraction, instrumental analysis, data analysis and entry, handling of case records, placing cases needing further analysis on the pending list, and writing reports on cases as necessary.

B. The trainee should observe the preparation of calibrator working solutions. The trainee may help prepare these working solutions under supervision. The preparation of working solutions does not need to be completed before approval for independent casework.

C. The trainer will review and discuss trainee’s notes regarding observations and required readings.

D. The trainee will observe the trainer perform a technical review of a batch archive and case records.

3.5 Supervised Performance

A. Evaporation Exercise

1. Extract 5 sets of EMIT calibrators including Hydrocodone cutoff with acidified ethanol. Each set of calibrators will be evaporated at different times and temperatures (see chart below).

2. Extract 5 sets of EMIT calibrators including Hydrocodone cutoff WITHOUT acidified ethanol. Each set of calibrators will be evaporated at different times and temperatures (see chart below).

<table>
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3. Evaluate results and document conclusions of findings.
B. The trainee will prepare reagents and solutions that are necessary for the analysis and perform verifications of prepared and purchased reagents.

1. Preparation of the following reagents by the trainee will occur during training.
   a) Tris Buffer
   b) Tris Buffer:MeOH
   c) Acidified ethanol

2. Preparation of calibrators and cut-off samples may occur during supervised performance or at a later date:
   a) Working solutions
   b) Calibrators
   c) Cut-off sample

3. Verifications may occur during supervised performance or at a later date:
   a) Reagents
   b) Calibrators

C. The trainee will analyze a minimum of 15 unknown blood samples using the EMIT instrument under trainer’s supervision. This exercise includes entire case workflow.

D. The trainee will analyze a minimum of 15 unknown urine samples using the EMIT instrument under trainer’s supervision. This exercise includes entire case workflow.

4. Assessment

4.1 Practical Competency Samples
The trainee will independently examine competency samples containing various combinations of drugs and possible metabolites. This exercise includes entire case workflow.
   A. A minimum of 15 blood competency samples will be analyzed.
   B. A minimum of 15 urine competency samples will be analyzed.

4.2 Technical Review Competency
Successful completion of 5 mock technical reviews will allow for the analyst to review EMIT casework.

4.3 Written Examination
The trainee will pass a written test before supervised casework.

4.4 Assessment of Training
The trainee and trainer will complete a checklist and sign-off sheet.

4.5 Requirements for Use in Casework
Successful completion of this module is determined by the trainer and is a prerequisite for casework.

5. Requirements for Independent Authorization
Supervised casework will include at least 2 batches. At least 1 batch must be a standard size.
## Revision History

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FUNDAMENTALS OF GC/MS

Duration 4-8 weeks.

Purpose Familiarize the trainee with basic maintenance and operation of the GC/MS instrument for toxicology analysis.

Prerequisite TOX-TM-01 to 06, and TOX-TM-EMIT-01

1 Objectives

1.1 Theoretical
The proper use of the GC/MS for toxicology analysis is a necessity to enable the analyst to obtain accurate results when analyzing biological specimens for the presence or absence of drugs and/or metabolites.

1.2 Practical
Trainee will be able to:

A. Explain the theory and operation of the GC/MS.
B. Explain the ionization and fragmentation of specific drugs.
C. Describe the difference between Full Scan and Single Ion Monitoring (SIM) modes.
D. Perform extractions using proper techniques for processing samples.
E. Describe the different extraction techniques (liquid/liquid and solid phase).
F. Utilize GC/MS software program functions to perform basic instrument operation.
G. Perform routine maintenance of the GC/MS.
H. Explain common GC/MS troubleshooting techniques.
I. Assess reproducibility of GC/MS.

2 Training Outline

2.1 Lesson Plan
A. Familiarize trainee with GC/MS basics including:
   1. Operation/Instrument Software
      a) Perform and document tune of the mass spectrometer.
      b) Load and edit a sequence on the instrument.
      c) Load and run a data acquisition method on the instrument.
   2. Data Analysis Software
      a) Load data files.
      b) Label peaks on a chromatogram.
      c) Obtain extracted ion chromatogram.
      d) Obtain spectrum and perform background subtraction.
      e) Perform a library search.
f) Obtain a reference spectrum using parametric retrieval.

3. Hardware

4. Maintenance

   a) Gas Chromatograph
      i. Clean injection port.
      ii. Change injection port liner, septum, gold plate, and seal.
      iii. Perform column maintenance.
      iv. Perform and/or discuss replacement of the gas clean filter.

   b) Mass Spectrometer
      i. Clean mass spectrometer source.
      ii. Perform and/or discuss vacuum pump maintenance.

B. Familiarize trainee with extraction techniques

1. Liquid/Liquid Extraction
2. Solid Phase Extraction (SPE)

2.2 Required Readings/Videos

Note: Use of the most current edition recommended. Review of reading acceptable if previously required.

A. Read operation manual from specific manufacturer for the GC/MS used.

   1. Chapter 9 – Chromatography
      a) Chromatographic Fundamentals
      b) Gas Chromatography
   2. Chapter 11 – Mass Spectrometry
   3. Chapter 12 – Method Validation

   1. Chapter 20 – Method Development and Validation
   2. Chapter 29 – Extraction

D. Texas DPS Standard Operating Procedures
   1. TOX-INS-02 – GCMS Instructions
   2. Extraction SOPs for methods used in exercises – section 05
   3. Reagent preparation instructions for GCMS extraction methods used in exercises – section 07
   4. LAB-TOX-25 – Vacuum Pump Oil Level Log
5. LAB-TOX-28 – Instrument Log

E. Article, Ghost Peaks in Gas Chromatography Part 1: The Carrier Gas and Carrier Gas Lines

F. Read applicable instrument validation documentation for current instruments.

G. GCMS troubleshooting and other videos, as assigned by trainer

H. Safety Data Sheets- Review for each solvent, drug, and chemical used.

3 Practice

3.1 Safety

A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

B. Proper cylinder handling is a primary concern with the use of helium in the GC/MS. Heated zones of the MS require caution to avoid burns.

3.2 Observed Performance

Trainer will review and discuss trainee’s notes regarding exercises and required readings.

3.3 Supervised Performance

A. The trainee will print from available GC/MS data an extracted ion chromatogram containing 2 significant ions with a data header, a background subtracted mass spectrum, and a library search spectrum.

B. The trainee will predict from a drug structure the significant ions produced in Electron Ionization (EI) GC/MS.

C. For each exercise below, the trainee will prepare a batch worklist, prepare a sequence file, perform the analysis, and prepare the batch results summary for GC/MS.

1. Injection Port Conversion Exercise: The trainee will perform GC/MS analysis of a standard solution of ephedrine (10 mg/L) reconstituted with methanol and ephedrine (10 mg/L) reconstituted with ethyl acetate. The trainee will evaluate the importance of using the appropriate solvent to reconstitute after extraction.

2. Reproducibility Exercise: The trainee will perform analysis of 10 replicate injections of a 10 mg/L drug standard in organic solvent and a blank vial of the same organic solvent. The trainee will perform a spreadsheet calculation of the percent relative standard deviation (RSD) of the area measurements for the drug.

3. Carryover Exercise: The trainee will perform an exercise to evaluate drug carryover on the GC/MS. The trainee will prepare a sample vial with concentrations of drug comparable to high calibrators for diazepam, carisoprodol, and phenobarbital. The sample vial will be injected followed by an injection of the solvent blank and an injection of a matrix blank vial. This experiment will be repeated with a sample vial containing approximately two times the high calibrator concentration. The solvent and matrix blanks will be evaluated for any indications of carryover. The trainee will evaluate the need for blank and/or matrix samples injected between case samples.
4. **Recovery Exercise:** The trainee will perform an extraction and GC/MS analysis of a basic drug and a neutral drug. The samples are prepared with internal standard as follows: a sample spiked before extraction, a sample spiked after extraction, and a neat sample. The vials are injected on the GC/MS. Area counts and relative area counts are compared to determine recovery of drugs during extraction. The trainee will evaluate the effect of the extraction and the matrix on the sample and will also evaluate the importance of using internal standards.

4 Assessment

4.1 **Written Examination**

Written exam will be given by the trainer demonstrating knowledge of general maintenance, theory, and operation of the GC/MS instrument.

4.2 **Assessment of training**

Successful completion of this module is determined by the trainer and documented with the GC/MS Fundamentals Checklist (LAB-TOX-TM-GCMS-01).

4.3 **Requirements for use in casework**

Successful completion of this module is a prerequisite for casework.

4.4 **Requirements for technical review task (if applicable)**

A. Complete 5 mock technical reviews for Screenings and/or Confirmation (as applicable).

B. Successful completion of this module will allow for the analyst to review GC/MS casework provided the analyst has been authorized for the equivalent modules (LC/MS Screens and/or LC/MS Confirmation casework). Approval for technical review will be documented by the completion of the Work Authorization form (LAB-309).
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GC/MS SCREENING

Duration  4-8 weeks
Purpose  Familiarize the trainee with theoretical and practical aspects of the gas chromatograph/mass spectrometer (GC/MS) utilized in the screening analysis of forensic toxicology samples.

Prerequisite  TOX-TM-GCMS-01

1 Objectives

1.1 Theoretical

The GC/MS is generally accepted in the scientific community for screening analysis of toxicology samples. Proper use and maintenance of the instrument is essential to good laboratory practice. Proper documentation of equipment calibrations and maintenance is crucial to quality control in the laboratory. Maintenance and calibration guidelines must be written and well understood by all users.

1.2 Practical

Following the completion of training the trainee will be able to:

A. Explain the difference between screening analysis and target compound analysis
B. Determine when GC/MS screening is required on toxicology samples
C. Understand the benefits and limitations of GC/MS screening analysis
D. Explain the importance of quality controls
E. Operate the GC/MS and use the associated software
F. Prepare and extract samples for analysis on the GC/MS
G. Interpret the results of the analysis
H. Perform necessary dilutions and carryover assessments.
I. Establish Experimental Detection Threshold (EDT) and RRT for new analytes
J. Prepare data reports
K. Create batch archive
L. Enter results into LIMS

2 Training Outline

2.1 Lesson Plan

A. Sample preparation- GC/MS screening extraction
B. Introduction to GC/MS capabilities for toxicology screening
C. Familiarize the trainee with GC/MS operation
   1. Load method
   2. Instrument tune
   3. Load, edit, and simulate sequence
4. Start sequence
5. Data file archive

D. Familiarize the trainee with data analysis
   1. Use RRT to establish expected retention time
   2. Analyze library search report
   3. Plot ions to obtain sample spectra
   4. Compare sample spectra to spectra library
   5. Evaluate preceding solvent blank
   6. Print data and complete GCMS Data Screen Worksheet (LAB-TOX-12)

E. Familiarize the trainee with batch acceptability
   1. Analyze negative control(s)
   2. Analyze positive control(s) and re-injections

F. Familiarize the trainee with LIMS results entry

G. Familiarize the trainee with LIMS report writing

2.2 Required Reading

Note: Use of the most current edition recommended. Review of reading acceptable if previously required.

   1. Chapter 16 – Miscellaneous Central Nervous System Depressants
   2. Chapter 23 – Therapeutic Drugs II: Antidepressants
   3. Chapter 25 – Therapeutic Drugs IV: Antihistamines

B. Texas DPS Standard Operating Procedures including all SOPs in Related Documents section
   1. TOX-01-06 – Case Documentation
   2. TOX-01-09 – Guidelines for Batch Archive Review
   3. TOX-01-10 – Guidelines for Administrative and Technical Review
   4. TOX-05-06 – Extraction for GC/MS Screen
   5. TOX-06-01 – Screening by GC/MS

C. Read applicable DPS method validation documentation for extraction.

D. Baselt, Randall C. 2014. Disposition of Toxic Drugs and Chemicals in Man, 10th Ed. Biomedical Publications. – as assigned by trainer

E. Safety Data Sheets – Review for each solvent, drug, and chemical used.
3 Practice

3.1 Safety
A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

B. Proper cylinder handling is a primary concern with the use of helium in the GC/MS. Heated zones of the MS require caution to avoid burns.

3.2 Equipment
Refer to Module on Equipment for Toxicology (TOX-TM-05).

3.3 Standards, Controls, Reagent Preparation
As outlined in the Toxicology SOP appropriate for the specific method:
- Buffers for extraction
- Elution solvent
- Control working solution
- Internal standard solution

3.4 Observed Performance
A. The trainee will observe the trainer or a competent analyst as they work a batch of cases from start to finish. This includes making a worklist, gathering of evidence, aliquoting a sample from each case, extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainee will observe an additional batch of cases.

D. The trainee will observe the routine maintenance on the GC/MS, as needed.

E. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

F. Discussion or completion of verification and documentation of:
   1. Internal standard solution
   2. Control

3.5 Supervised Performance
A. Trainee will prepare the reagents and solutions necessary for the analysis as outlined in the Toxicology SOP appropriate for the specific method
   1. Preparation of the following reagents will occur during training:
      a) Buffers
      b) Elution solvent
2. Preparation of the following solutions may occur during supervised performance or at a later date:
   a) Control working solution
   b) Internal standard solution

B. The trainee will practice analyzing data from previously prepared samples. This exercise may be performed multiple times, at the discretion of the trainer.

C. The trainee will perform the routine maintenance on the GC/MS as needed.

D. The trainee will perform a batch analysis with controls and at least 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples. This exercise may be performed multiple times, at the discretion of the trainer.

E. The trainee will prepare drug summary sheets for common drugs.

4 Assessment

4.1 Practical Competency Samples
The trainee will independently extract and analyze a batch of controls and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

4.2 Written Examination
The trainee will pass a written test before supervised casework.

4.3 Requirements for technical review task (if applicable)
   A. Complete 5 mock technical reviews.
   B. Successful completion of this module will allow for the analyst to review GC/MS Screening casework. Approval for technical review will be documented by the completion of the Work Authorization form (LAB-309).

4.4 Certification of Competency
The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for supervised casework.

5 Requirements for New Independent Authorization
Supervised casework will include at least 2 batches.
## Revision History

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Major Revision – Prerequisite, Sections 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 2.4, 3.1-3.8, 4.1, 4.2 and 4.3. |
| 02        | 05/16/2019     | Revision – All sections                                                              |
GC/MS CONFIRMATION (TARGET COMPOUND ANALYSIS)

Duration 4-8 weeks

Purpose Familiarize the trainee with theoretical and practical aspects of the gas chromatograph/mass spectrometer (GC/MS) utilized in the confirmation (target compound/quantitation) analysis of forensic toxicology samples.

Prerequisite TOX-TM-GCMS-01

1 Objectives

1.1 Theoretical

The GC/MS is generally accepted by the scientific community for target analysis of toxicology samples. Proper use and maintenance of the instrument is essential to good laboratory practice. Proper documentation of equipment calibrations and maintenance is crucial to quality control in the laboratory. Maintenance and calibration guidelines must be written and well understood by all users.

1.2 Practical

Following the completion of training the trainee will be able to:

A. Describe the difference between quantitative and qualitative analysis
B. Explain the importance of quality controls.
C. Operate and use the software associated with the GC/MS to analyze samples.
D. Prepare and extract samples for analysis on the GC/MS.
E. Verify integrations, create calibration curves, and assess calibrator and control accuracy.
F. Interpret the results of the analysis.
G. Prepare data reports.
H. Create batch archive.
I. Enter results into LIMS.

2 Training Outline

2.1 Lesson Plan

A. Familiarize the trainee with qualitative and quantitative analysis using GC/MS.
B. Familiarize the trainee with sample preparation.
   1. Liquid/liquid extraction
   2. Solid phase extraction
C. Familiarize the trainee with GC/MS operation.
   1. Load acquisition method.
   2. Perform tune of mass spectrometer.
   3. Load, edit, and simulate sequence.
   4. Start sequence.
5. Perform data archiving.

D. Familiarize the trainee with batch acceptability.

1. Data analysis
   a) Verify integrations
   b) Create calibration curves
   c) Assess calibrator and control accuracy

2. Target report generation

E. Familiarize the trainee with data interpretation.

1. Create batch archive.
2. Enter results into LIMS.
3. Discuss LIMS report writing.

2.2 Required Readings

Note: Use of the most current edition recommended. Review of reading acceptable if previously required.

A. Texas DPS Standard Operating Procedures including all SOPs in Related Documents sections
   1. TOX-01-05 – Uncertainty of Measurement
   2. TOX-01-06 – Case Documentation
   3. TOX-01-09 – Guidelines for Batch Archive Review
   4. TOX-01-10 – Guidelines for Administrative and Technical Review
   5. Appropriate procedures for specified method for GC/MS Confirmation training
      a) TOX-05-12 – Extraction for 9-Carboxy-THC in Urine
      b) TOX-05-23 – Extraction for Barbiturates
      c) TOX-05-26 – Extraction for Amines in Blood by SPE
      d) TOX-05-27 – Extraction for Amines in Urine by SPE
   6. TOX-06-02 - Target Compound Analysis
   7. LAB-TOX-29 – Control Verification Worksheet
   8. LAB-TOX-30 – Drug Standard Log
   9. LAB-TOX-33 – Unconfirmed EMIT Positives Log

   1. Chapter 9 – Chromatography, section on Quantitation
   2. Chapter 11 – Mass Spectrometry
   3. Chapter 12 – Method Validation
   4. Part III. Analytes – Applicable chapters
C. Baselt, Randall C. 2014. Disposition of Toxic Drugs and Chemicals in Man, 10th Ed. Biomedical Publications. – as assigned by trainer

D. Read literature from specific manufacturer for the GC/MS used.

E. Safety Data Sheets – review for each solvent, drug, and chemical used.

F. Read applicable DPS method validation documentation for extraction.

3 Practice

3.1 Safety

A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

B. Proper cylinder handling is a primary concern with the use of helium in the GC/MS. Heated zones of the MS require caution to avoid burns.

3.2 Equipment

Refer to Module on Equipment for Toxicology (TOX-TM-05)

3.3 Standards, Controls, Reagent Preparation

As outlined in the Toxicology SOP appropriate for the specific method:

- Buffers for select extraction methods
- Elution solvent for select extraction methods
- Calibrator working solutions
- Control working solutions
- Internal standard solution

3.4 Observed Performance

A. The trainee will observe the trainer or a competent analyst as they work a batch of cases from start to finish. This includes making a worklist, gathering of evidence, aliquoting a sample from each case, extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainee will observe an additional batch of confirmation (target analysis) cases.

D. The trainee will observe the routine maintenance on the GC/MS, as needed.

E. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

F. Discussion or completion of verification and documentation of:
   1. Internal standard solution
   2. Calibrator working solutions
   3. Controls
3.5 Supervised Performance

A. Trainee will prepare the reagents and solutions necessary for the analysis as outlined in the Toxicology SOP appropriate for the specific method

1. Preparation of the following reagents will occur during training:
   a) Buffers
   b) Elution solvent

2. Preparation of the following solutions may occur during supervised performance or at a later date:
   a) Calibrator working solutions
   b) Control working solutions
   c) Internal standard solution

B. The trainee will perform an extraction, GC/MS data acquisition, and target compound analysis on calibrators and controls to become familiar with the procedure.

C. The trainee will perform the routine maintenance on the GC/MS, as needed.

D. The trainee will prepare drug summary sheets for common drugs.

E. The trainee will extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

F. The trainee will prepare a practice batch archive as assigned by trainer.

4 Assessment

4.1 Practical Competency Samples

The trainee will independently extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

4.2 Written Examination

The trainee will pass a written test before approval for supervised casework.

4.3 Requirements for technical review task (if applicable)

A. Complete 5 mock technical reviews.

B. Successful completion of this module will allow for the analyst to review GC/MS Confirmation casework. Approval for technical review will be documented by the completion of the Work Authorization Form (LAB-309).

4.4 Certification of Competency

The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for supervised casework.

5 Requirements for New Independent Authorization

Supervised casework will include at least 2 batches. At least 1 batch must be a standard size.
6 Requirements for Continued Independent Authorization

6.1 Required Readings

A. Texas DPS Standard Operating Procedures including all SOPs in Related Documents sections

1. Appropriate procedures for specified method for GC/MS Confirmation training
   a) TOX-05-12 – Extraction for 9-Carboxy-THC in Urine
   b) TOX-05-23 – Extraction for Barbiturates
   c) TOX-05-26 – Extraction for Amines in Blood by SPE
   d) TOX-05-27 – Extraction for Amines in Urine by SPE

   Part III. Analytes - Applicable chapters


D. Trainee will read and understand the DPS method validation documentation for each continued method.

6.2 Observed Performance

A. The trainee will observe the trainer or a competent analyst as they work a batch of cases. This includes extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

6.3 Supervised Performance

A. The trainee will extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

B. The trainee will prepare drug summary sheets for common drugs.

6.4 Competency Samples

The trainee will independently extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

6.5 Continued Independent Authorization

The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for casework.
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FUNDAMENTALS OF LC/MS

Duration 4-8 weeks.

Purpose Familiarize the trainee with basic maintenance and operation of the LC/MS instrument for toxicology analysis.

Prerequisite TOX-TM-01 to 06, TOX-TM-EMIT-01

1 Objectives

1.1 Theoretical

The proper use of the LC/MS for toxicology analysis is a necessity to enable the analyst to obtain accurate results when analyzing biological specimens for the presence or absence of drugs and/or metabolites.

1.2 Practical

Following the completion of training the trainee will be able to:

A. Explain the theory and operation of the LC/MS.
B. Explain the ionization and fragmentation of specific drugs.
C. Describe the difference between Enhanced Product Ion (EPI) Scan and Multiple Reaction Monitoring (MRM) modes.
D. Perform extractions using proper techniques for processing samples.
E. Describe the different extraction techniques (liquid/liquid and solid phase).
F. Utilize LC/MS software program functions to perform basic instrument operation.
G. Perform routine maintenance on the LC/MS.
H. Explain common LC/MS troubleshooting techniques.
I. Assess reproducibility of LC/MS.

2 Training Outline

2.1 Lesson Plan

A. Familiarize trainee with LC/MS basics including:

1. Operation/Instrument/Data Analysis Software
   a) Perform and document tune checks of the mass spectrometers.
      i. Q1
      ii. Q3
      iii. Linear ion trap (LIT)
   b) Load and edit a sequence on the instrument.
   c) Load and run a data acquisition method on the instrument.
   d) Load data files on the instrument.
   e) Discuss computer maintenance, including deleting tuning cache and .tmp files.
2. Hardware
3. Maintenance
   a) Liquid Chromatograph
      i. *Replace a cap frit and guard column.*
      ii. *Install and/or replace a column including proper storage of the replaced column.*
      iii. *Prepare mobile phases and properly place on the instrument.*
   b) Mass Spectrometer
      i. *Perform front end cleaning: clean curtain plate, orifice plate, skimmer, and Q0.*
      ii. *Perform and/or discuss vacuum pump maintenance.*

B. Familiarize trainee with extraction techniques
   1. Liquid/Liquid Extraction
   2. Solid Phase Extraction (SPE)

2.2 Required Readings

*Note:* Use of the most current edition recommended. Review of reading acceptable if previously required.

A. Polettini, Aldo. 2006. Applications of LC-MS in Toxicology. Pharmaceutical Press., Chapter 1 – Ionisation, Ion Separation, and Ion Detection in LC-MS

   1. Chapter 9 – Chromatography
      a) Chromatographic Fundamentals
      b) High-Performance Liquid Chromatography
   2. Chapter 11 – Mass Spectrometry
   3. Chapter 12 – Method Validation

   1. Chapter 20 – Method Development and Validation
   2. Chapter 29 – Extraction

D. Texas DPS Toxicology Standard Operating Procedures, including all SOPs in Related Documents sections.
   1. TOX-INS-01 – LCMS Instructions
   2. Extraction SOPs for methods used in exercises – section 05
   3. Reagent preparation instructions for LCMS extraction methods used in exercises – section 07
   4. LAB-TOX-25 – Vacuum Pump Oil Level Log
5. LAB-TOX-28 – Instrument Log

E. Read literature from specific manufacturer for the LC/MS used.
   1. Instrument manual
   3. Sciex Instrument Front-End Cleaning Procedure

F. Read applicable instrument validation documentation for current instruments.

G. Safety Data Sheets – Review for each solvent, drug, and chemical used.

2.3 Required Videos

Sciex Education – Introduction to LC-MS/MS
   1. Introduction to HPLC
   2. Introduction to Mass Spectrometry
   3. Triple Quadrupole and Linear Ion Trap MS

3 Practice

3.1 Safety

A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

B. Proper cylinder handling is a primary concern with the use of nitrogen in the LC/MS. Heated zones of the MS require caution to avoid burns. LC/MS ion source has a potential electrical shock hazard.

3.2 Standards, Controls, Reagent Preparation

- Mobile Phase A
- Mobile Phase B

3.3 Observed Performance

Trainer will review and discuss trainee’s notes regarding exercises and required readings

3.4 Supervised Performance

A. Trainee will prepare LC/MS Mobile Phase A and LC/MS Mobile Phase B as outlined in the Toxicology SOP appropriate for the specific method.

B. For each exercise below, the trainee will prepare a batch worklist, prepare a sequence file, perform the analysis, and prepare the batch results summary for LC/MS.

1. **Reproducibility Exercise**: The trainee will prepare a 10 mg/L drug standard in aqueous solution. The trainee will perform analysis of 10 replicate injections of a drug standard. The trainee will perform a spreadsheet calculation of the percent relative standard deviation (RSD) of the area measurements for the drug template.

2. **Carryover Exercise**: The trainee will perform an exercise to evaluate drug carryover on the LC/MS. The trainee will prepare a sample vial with
concentrations of drug comparable to high calibrators for diazepam, carisoprodol, and meprobamate. The sample vial will be injected followed by two injections of a matrix blank vial. This experiment will be repeated with a sample vial containing approximately two times the high calibrator concentration. The matrix blanks will be evaluated for any indications of carryover. The trainee will evaluate the need for blank samples injected between case samples.

3. **Recovery Exercise:** The trainee will perform an extraction and LC/MS analysis of a basic drug and a neutral drug. The samples are prepared with internal standard as follows: a sample spiked before extraction, a sample spiked after extraction, and a neat sample. The vials are injected on the LC/MS. Area counts and relative area counts are compared to determine recovery of drugs during extraction. The trainee will evaluate the effect of the extraction and the matrix on the sample and will also evaluate the importance of using internal standards.

4. **Assessment**

4.1 **Written Examination**

Written exam will be given by the trainer demonstrating knowledge of general maintenance, theory, and operation of the LC/MS instrument.

4.2 **Assessment of training**

Successful completion of this module is determined by the trainer and documented with the LC/MS Fundamentals Checklist (LAB-TOX-TM-LCMS-01).

4.3 **Requirements for use in casework**

Successful completion of this module is a prerequisite for casework.

4.4 **Requirements for technical review task (if applicable)**

A. Complete 5 mock technical reviews.

B. Successful completion of this module will allow for the analyst to review LC/MS casework provided the analyst has been authorized for the equivalent modules (GC/MS Screens and/or GC/MS Confirmation casework). Approval for technical review will be documented by the completion of the Work Authorization form (LAB-309).
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LC/MS SCREENING

Duration  4-8 weeks
Purpose  Familiarize the trainee with theoretical and practical aspects of the liquid chromatograph/mass spectrometer (LC/MS) utilized in the screening analysis of forensic toxicology samples.
Prerequisite  TOX-LCMS-01

1 Objectives

1.1 Theoretical

The LC/MS is generally accepted in the scientific community for screening analysis of toxicology samples. Proper use and maintenance of the instrument is essential to good laboratory practice. Proper documentation of equipment calibrations and maintenance is crucial to quality control in the laboratory. Maintenance and calibration guidelines must be written and well understood by all users.

1.2 Practical

Following the completion of training the trainee will be able to:

A. Explain the difference between screening analysis and target compound analysis
B. Determine when LC/MS screening is required on toxicology samples
C. Understand the benefits and limitations of LC/MS screening analysis
D. Explain the importance of quality controls
E. Operate the LC/MS and use the associated software
F. Prepare and extract samples for analysis on the LC/MS
G. Interpret the results of the analysis
H. Update RRT for analytes
I. Prepare data reports
J. Create batch archive
K. Enter results into LIMS

2 Training Outline

2.1 Lesson Plan

A. Sample preparation - LC/MS screening extraction
B. Introduction to LC/MS capabilities for toxicology screening
C. Familiarize the trainee with LC/MS operation
   1. Q1 and Q3 positive PPG tune check
   2. Linear Ion Trap (LIT) tune check
   3. Load and edit sequence
   4. Load and start data acquisition method
5. Data file archive

D. Familiarize the trainee with data analysis
   1. Use RRT to establish expected retention time
   2. Analyze information dependent acquisition (IDA) data
   3. Compare sample spectra to compound library
   4. Print data and complete LCMS Data Screen Worksheet (LAB-TOX-13)

E. Familiarize the trainee with batch acceptability
   1. Analyze negative control
   2. Analyze positive control and re-injections

F. Familiarize the trainee with LIMS results entry

G. Familiarize the trainee with LIMS report writing

2.2 Required Readings

Note: Use of the most current edition recommended. Review of reading acceptable if previously required.

   1. Chapter 16 – Miscellaneous Central Nervous System Depressants
   2. Chapter 23 – Therapeutic Drugs II: Antidepressants
   3. Chapter 25 – Therapeutic Drugs IV: Antihistamines

B. Texas DPS Standard Operating Procedures, including all SOPs in Related Documents section
   1. TOX-01-06 – Case Documentation
   2. TOX-01-09 – Guidelines for Batch Archive Review
   3. TOX-01-10 – Guidelines for Administrative and Technical Review
   4. TOX-05-20 – Extraction for LC/MS Screen
   5. TOX-06-03 – Screening by LC/MS

C. Read applicable DPS method validation documentation for extraction.

D. Baselt, Randall C. 2014. Disposition of Toxic Drugs and Chemicals in Man, 10th Ed. Biomedical Publications. – as assigned by trainer

E. Safety Data Sheets- Review for each solvent, drug, and chemical used.

3 Practice

3.1 Safety

A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.
B. Proper cylinder handling is a primary concern with the use of nitrogen in the LC/MS. Heated zones of the MS require caution to avoid burns. LC/MS ion source has a potential electrical shock hazard.

### 3.2 Equipment

Refer to Module on Equipment for Toxicology (TOX-TM-05).

#### 3.3 Standards, Controls, Reagent Preparation

As outlined in the Toxicology SOP appropriate for the specific method:

- Buffers
- Reagents for extraction
- Mobile phase
- Control working solution
- Internal standard solution

### 3.4 Observed Performance

A. The trainee will observe the trainer or a competent analyst as they work a batch of cases from start to finish. This includes making a worklist, gathering of evidence, aliquoting a sample from each case, extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainee will observe an additional batch of cases.

D. The trainee will observe the routine maintenance on the LC/MS, as needed.

E. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

F. Discussion or completion of verification and documentation of:
   1. Internal standard solution
   2. Control

### 3.5 Supervised Performance

A. Trainee will prepare the reagents and solutions necessary for the analysis as outlined in the Toxicology SOP appropriate for the specific method

   1. Preparation of the following reagents will occur during training:
      a) Buffers
      b) Extraction reagents
      c) Mobile phase

   2. Preparation of the following solutions may occur during supervised performance or at a later date:
      a) Control working solution
      b) Internal standard solution
B. The trainee will practice analyzing data from previously prepared samples. This exercise may be performed multiple times, at the discretion of the trainer.

C. The trainee will perform the routine maintenance on the LC/MS as needed.

D. The trainee will perform a batch analysis with controls and at least 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples. This exercise may be performed multiple times, at the discretion of the trainer.

E. The trainee will prepare drug summary sheets for common drugs.

4 Assessment

4.1 Practical Competency Samples

The trainee will independently extract and analyze a batch of controls and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

4.2 Written Examination

The trainee will pass a written test before approval for supervised casework.

4.3 Requirements for Technical Review Task (if applicable)

A. Complete 5 mock technical reviews.

B. Successful completion of this module will allow for the analyst to review LC/MS Screening casework. Approval for technical review will be documented by the completion of the Work Authorization form (LAB-309).

4.4 Certification of Competency

The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for supervised casework.

5 Requirements for New Independent Authorization

Supervised casework will include at least 2 batches.
Revision History

<table>
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<tr>
<th>Version #</th>
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<tr>
<td>01</td>
<td>05/16/2019</td>
<td>Revision – All sections</td>
</tr>
</tbody>
</table>
LC/MS CONFIRMATION (TARGET COMPOUND ANALYSIS)

Duration  4-8 weeks

Purpose  Familiarize the trainee with theoretical and practical aspects of the liquid chromatograph/mass spectrometer (LC/MS) utilized in the confirmation (target compound/quantitation) analysis of forensic toxicology samples.

Prerequisite  TOX-TM-LCMS-01

1  Objectives

1.1  Theoretical

The LC/MS is generally accepted in the scientific community for target analysis of toxicology samples. Proper use and maintenance of the instrument is essential to good laboratory practice. Proper documentation of equipment calibrations and maintenance is crucial to quality control in the laboratory. Maintenance and calibration guidelines must be written and well understood by all users.

1.2  Practical

Following the completion of training the trainee will be able to:

A. Describe the difference between quantitative and qualitative analysis
B. Explain the importance of quality controls.
C. Operate and use the software associated with the LC/MS to analyze samples.
D. Prepare and extract samples for analysis on the LC/MS.
E. Verify integrations, create calibration curves, and assess calibrator and control accuracy.
F. Interpret the results of the analysis.
G. Prepare data reports.
H. Create batch archive.
I. Enter results into LIMS.

2  Training Outline

2.1  Lesson Plan

A. Familiarize the trainee with qualitative and quantitative analysis using LC/MS.
B. Familiarize the trainee with sample preparation.
   1. Liquid/liquid extraction
   2. Solid phase extraction
C. Familiarize the trainee with LC/MS operation.
   1. Perform Q1 and Q3 positive PPG tune check of mass spectrometers.
   2. Load and edit sequence.
   3. Load and start data acquisition method.
   4. Perform data archiving.
D. Familiarize the trainee with batch acceptability
   1. Data analysis
      a) Verify integrations
      b) Create calibration curves
      c) Assess calibrator and control accuracy
   2. Target report generation

E. Familiarize the trainee with data interpretation
   1. Create batch archive.
   2. Enter results into LIMS.
   3. Discuss LIMS report writing.

2.2 Required Readings

Note: Use of the most current edition recommended. Review of reading acceptable if previously required.

A. Texas DPS Standard Operating Procedures, including all SOPs in Related Documents sections
   1. TOX-01-05 – Uncertainty of Measurement
   2. TOX-01-06 – Case Documentation
   3. TOX-01-09 – Guidelines for Batch Archive Review
   4. TOX-01-10 – Guidelines for Administrative and Technical Review
   5. Appropriate procedures for specified method for LC/MS Confirmation training
      a) TOX-05-19 – SPE for Benzodiazepine Mix with LCMS
      b) TOX-05-22 – SPE for Opiates, Cocaine, and Cocaine Metabolites
      c) TOX-05-24 – LCMS Target Qualitative Analysis (TQUAL)
      d) TOX-05-25 – Extraction for Δ⁹-THC and Δ⁹-Carboxy-THC in Blood
   6. TOX-06-02 – Target Compound Analysis
   7. LAB-TOX-29 – Control Verification Worksheet
   8. LAB-TOX-30 – Drug Standard Log
   9. LAB-TOX-33 – Unconfirmed EMIT Positives Log

   1. Chapter 9 – Chromatography, section on Quantitation
   2. Chapter 11 – Mass Spectrometry
   3. Chapter 12 – Method Validation
   4. Part III. Analytes – Applicable chapters
C. Baselt, Randall C. 2014. Disposition of Toxic Drugs and Chemicals in Man, 10th Ed. Biomedical Publications. – as assigned by trainer

D. Read literature from specific manufacturer for the LC/MS used.

E. Safety Data Sheets – review for each solvent, drug, and chemical used.

F. Read applicable DPS method validation documentation for extraction.

3 Practice

3.1 Safety

A. Laboratory personnel shall wear appropriate personal protective equipment. Open cuts and broken skin must be covered with a suitable means of protection. A lab coat and eye protection is recommended at all times. Chemicals used may be carcinogenic or caustic. Use universal precautions and biological hood during evidence handling.

B. Proper cylinder handling is a primary concern with the use of nitrogen in the LC/MS. Heated zones of the MS require caution to avoid burns. LC/MS ion source has a potential electrical shock hazard.

3.2 Equipment

Refer to Module on Equipment for Toxicology (TOX-TM-05).

3.3 Standards, Controls, Reagent Preparation

As outlined in the Toxicology SOP appropriate for the specific method.

- Buffers for select extraction methods
- Elution solution for select extraction methods
- Mobile phase
- Reconstitution solution for select extraction methods

3.4 Observed Performance

A. The trainee will observe the trainer or a competent analyst as they work a batch of cases from start to finish. This includes making a worklist, gathering of evidence, aliquoting a sample from each case, extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainee will observe an additional batch of confirmation (target analysis) cases.

D. The trainee will observe the routine maintenance on the LC/MS, as needed.

E. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

F. Discussion or completion of verification and documentation of:
   1. Internal standard solution
   2. Calibrator working solutions
   3. Controls
3.5 Supervised Performance

A. Trainee will prepare the reagents and solutions necessary for the analysis as outlined in the Toxicology SOP appropriate for the specific method

1. Preparation of the following reagents will occur during training:
   a) Buffers
   b) Elution solvent
   c) Mobile phase
   d) Reconstitution solution

2. Preparation of the following solutions may occur during supervised performance or at a later date:
   a) Calibrator working solutions
   b) Control working solutions
   c) Internal standard solution

B. The trainee will perform an extraction, LC/MS data acquisition, and target compound analysis on calibrators and controls to become familiar with the procedure.

C. The trainee will perform the routine maintenance on the LC/MS, as needed.

D. The trainee will prepare drug summary sheets for common drugs.

E. The trainee will extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

F. The trainee will prepare a practice batch archive as assigned by trainer.

4 Assessment

4.1 Practical Competency Samples

The trainee will independently extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

4.2 Written Examination

The trainee will pass a written test before supervised casework.

4.3 Certification of Competency

The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for supervised casework.

5 Requirements for New Independent Authorization

Supervised casework will include at least 2 batches. At least 1 batch must be a standard size.
6 Requirements for Continued Independent Authorization

6.1 Required Reading

A. Trainee will read and understand the DPS method validation documentation for each continued method.
   1. Appropriate procedures for specified method for LC/MS Confirmation training
      a) TOX-05-19 – SPE for Benzodiazepine Mix with LCMS
      b) TOX-05-22 – SPE for Opiates, Cocaine, and Cocaine Metabolites
      c) TOX-05-24 – LCMS Target Qualitative Analysis (TQUAL)
      d) TOX-05-25 – Extraction for \( \Delta^9\)-THC and \( \Delta^9\)-Carboxy-THC in Blood


6.2 Observed Performance

A. The trainee will observe the trainer or a competent analyst as they work a batch of cases. This includes extraction, instrumental analysis, data analysis, handling of case records, and generating case reports.

B. The trainer will discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues.

C. The trainer will review and discuss the trainee’s notes regarding observations and required readings.

6.3 Supervised Performance

A. The trainee will extract and analyze a batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

B. The trainee will prepare drug summary sheets for common drugs.

6.4 Assessment

The trainee will independently extract and analyze a competency batch of calibrators, controls, and a minimum of 15 unknown samples. These unknowns should cover the range of analytes that are included in the method and should also simulate actual case samples.

6.5 Continued Independent Authorization

The trainee and the trainer will complete a checklist and sign-off sheet. Successful completion of this module is determined by the trainer and is a prerequisite for casework.
## Revision History

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<tr>
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</table>
# Toxicology Overview Checklist

**Trainee Name** __________________________  **Date Training Began** ________________

## TOX-TM-02 – Toxicology Safety

<table>
<thead>
<tr>
<th>Lesson Plan</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/Evaluation</th>
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<tbody>
<tr>
<td>Bloodborne pathogen review</td>
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<td>Protective measures review</td>
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<td>Preventive practices for procedural risks</td>
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<td>Waste practices</td>
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<td>Emergency</td>
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<tr>
<td>Shipping guidelines for biological specimens</td>
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</table>

### Required Readings

- Safety Data Sheets
- Laboratory Customer Handbook, Chapter 15 – Case Acceptance and Analysis Policies [Toxicology (Alcohol/Volatiles and/or Drugs) Analysis]
- Laboratory Customer Handbook, Chapters 15, 27 – Toxicology (Alcohol/Volatiles and/or Drugs) Analysis
- USPS Packaging Instruction 6G

### Observed Performance

- Tour lab with trainer
- Observe trainer change out pressurized gas cylinder
- Discuss/observe hydrogen gas safety issues

### Assessment

- Written Exam

## TOX-TM-03 – Introduction to Forensic Toxicology

<table>
<thead>
<tr>
<th>Lesson Plan</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/Evaluation</th>
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<td>Introduction to forensic toxicology</td>
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<tr>
<td>Overview of drugs</td>
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<tr>
<td>Overview of DPS Toxicology section's functions and responsibilities</td>
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<tr>
<td>Overview of DPS Toxicology Measurement Uncertainty policies and procedures</td>
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</table>

### Required Readings

- Levine, Barry - Principles of Forensic Toxicology
  - Ch. 1 – Postmortem Forensic Toxicology
  - Ch. 2 – Human Performance Toxicology
### TOX-TM-03 – Introduction to Forensic Toxicology

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
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<tbody>
<tr>
<td>Ch. 3 – Forensic Drug Testing</td>
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<td>Ch. 5 – Drug Testing in Pain Management</td>
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<tr>
<td>Ch. 6 – Pharmacokinetics and Pharmacodynamics</td>
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<tr>
<td>Ch. 31 – Postmortem Redistribution of Drugs</td>
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<tr>
<td>Moffatt, Anthony C. - Clarke’s Analysis of Drugs and Poisons</td>
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<tr>
<td>Ch. 5 – Driving Under the Influence of Drugs</td>
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<td>Ch. 8 – Drug-facilitated Sexual Assault</td>
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<td>Ch. 9 – Forensic Toxicology</td>
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<td>Ch. 22 – Quality Control and Accreditation in the Toxicology Laboratory</td>
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<td>Ch. 23 – Measuring and Reporting Uncertainty</td>
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<td>Ch. 24 – Pharmacokinetics and Metabolism</td>
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<tr>
<td>Texas DPS Standard Operating Procedures</td>
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<tr>
<td>TOX-01-01 – Toxicological Services and Examiner Approval</td>
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<td>TOX-01-03 – Drug Standards, Calibrators, and Internal Standards</td>
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<td>TOX-01-04 – Controls</td>
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<td>TOX-01-05 – Uncertainty of Measurement</td>
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<td>TOX-01-06 – Case Documentation</td>
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<td>TOX-01-06A – Approved Standard Abbreviations</td>
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</table>

### Observed Performance

- Review and discuss notes with trainer

### Supervised Performance

- Introduction to Forensic Toxicology Exercise
- Review Toxicology Uncertainty Budget documents

### TOX-TM-04 – Sample Preparation for Analysis

<table>
<thead>
<tr>
<th>Lesson Plan</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
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<tbody>
<tr>
<td>Observe trainer prepare samples</td>
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<tr>
<td>□ Demonstrate appropriate PPE.</td>
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<tr>
<td>□ Examine and sample evidence.</td>
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<tr>
<td>□ Mark external and internal packaging, and repackage.</td>
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<tr>
<td>□ Document case notes on batch worklist.</td>
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<tr>
<td>□ Demonstrate techniques used to protect integrity of evidence.</td>
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<tr>
<td>□ Estimate sample volume.</td>
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</table>
### TOX-TM-04 – Sample Preparation for Analysis

<table>
<thead>
<tr>
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<th>Trainer Initials/ Evaluation</th>
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<tr>
<td>Saferstein, Richard - Criminalistics: An Introduction to Forensic Science</td>
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<td>Ch. 9 – Forensic Toxicology</td>
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<td>Moffatt, Anthony C. - Clarke's Analysis of Drugs and Poisons</td>
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<tr>
<td>Ch. 28 – Sampling, Storage and Stability</td>
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<td>Ch. 29 - Extraction</td>
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<td>Levine, Barry. - Principles of Forensic Toxicology</td>
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<td>Ch. 7 – Specimen Preparation</td>
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<td>Ch. 30 – Stability of Drugs of Abuse in Biological Specimens</td>
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<td>Texas DPS Standard Operating Procedures</td>
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<td>Crime Laboratory Service Manual, Chapter 44 – Evidence and Database Sample Integrity</td>
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<td>TOX-02-01 - Systematic Examination of Toxicological Specimens</td>
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<td>TOX-02-02 – Disposition of Toxicological Evidence</td>
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<tr>
<td>LIMS-GEN-22 – Worklists/Batch Process</td>
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</table>

**Observed Performance**

- Discuss understanding of case handling
- Review and discuss notes with trainer

### TOX-TM-05 – Equipment for Toxicology

<table>
<thead>
<tr>
<th>Lesson Plan</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
</tr>
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<tbody>
<tr>
<td>Familiarize trainee with reference materials for basic equipment</td>
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<tr>
<td>Familiarize trainee with locations of basic equipment and logbook(s)</td>
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<tr>
<td>Analytical Balances</td>
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<td>Pipettes</td>
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<td>Automated Liquid Dispensers (ALD)</td>
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<td>Bottle top dispenser</td>
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<td>pH Determination</td>
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<td>Centrifuges</td>
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<td>Hoods</td>
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<td>Autoclave</td>
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<td>Refrigerators and Freezers</td>
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<td>Thermometers</td>
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### TOX-TM-05 – Equipment for Toxicology

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
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<tbody>
<tr>
<td>Hotplates/magnetic stirrers, heating block, sonicators, and mixers</td>
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<tr>
<td>Positive pressure manifolds</td>
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<tr>
<td>Evaporators/concentrators</td>
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<tr>
<td>Vacuum oven</td>
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<tr>
<td>Laboratory glassware</td>
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</table>

#### Required Readings

- Texas DPS Standard Operating Procedures
- Crime Laboratory Service Manual, Chapter 48 – Laboratory Equipment
- TOX-01-02 – Instruments and Equipment
- TOX-INS-03 – Cerex Pressure Processor Instructions
- TOX-INS-04 – Turbovap Evaporator Instructions
- TOX-INS-05 – Cerex Evaporator
- TOX-INS-06 – Centra MP4 Centrifuge Instructions
- TOX-INS-08 – IEC CL40 Centrifuge Instructions
- TOX-INS-10 – Analytical Balance Operation
- TOX-INS-11 – Semi-Micro Balance Operation
- TOX-INS-12 – Top-Loader Balance Operation
- TOX-INS-14 – Sorvall ST40 Centrifuge Instructions
- TOX-INS-15 – Thermo Scientific Vacuum Oven Instructions
- TOX-INS-16 – Cerex ALD-III Pressure Processor Instructions
- TOX-INS-17 – XcelVap Evaporator System Instructions
- TOX-INS-18 – pH Meter
- LAB-TOX-27 – pH Meter Calibration
- LAB-TOX-31 – Post-Calibration Pipette Check Report
- LAB-TOX-32 – Pipette Performance Verification Report
- LAB-TOX-34 – Toxicology Pipette Log
- LAB-TOX-38 – Balance Check Log
- AUS-FRM-006 – Temperature Verification Log

#### Observed Performance

- Demonstrate proper technique for operating laboratory equipment
- Documentation of quality control procedures and calibration of equipment
- Review and discuss notes with trainer
<table>
<thead>
<tr>
<th>TOX-TM-05 – Equipment for Toxicology</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
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<tbody>
<tr>
<td><strong>Independent Exercises</strong></td>
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<tr>
<td>Measure a weight set on each type of balance</td>
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<td>Calibrate the pH meter, measure pH of referenced buffered solutions, and document</td>
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<tr>
<td>Pipette various volumes using different pipettes</td>
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<td>Autoclave biological waste</td>
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<td><strong>Assessment</strong></td>
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<tr>
<td><strong>Lesson Plan</strong></td>
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<tr>
<td>Familiarize trainee with case documentation practices.</td>
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<tr>
<td>Familiarize trainee with case correspondence documentation</td>
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<td>Familiarize trainee with result/note entry, including instruction on</td>
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<td>- Immunoassay result data entry</td>
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<td>- Qualitative result data entry</td>
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<td>- Quantitative result data entry</td>
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<td>- Report notes, including disposition</td>
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<tr>
<td>Familiarize trainee with reporting elements</td>
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<td>LIMS Manual, applicable sections</td>
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<td><strong>Observed Performance</strong></td>
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<tr>
<td>Review and discuss notes with trainer</td>
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<td><strong>Supervised Performance</strong></td>
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<td>Practice LIMS entry</td>
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# Toxicology Reagent and Solution Preparation Checklist

**Trainee Name ___________________________  Date Training Began ________________**

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<thead>
<tr>
<th>TOX-TM-07 – Reagent and Solution Preparation</th>
<th>Trainee Initials</th>
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<td>BA-03-03 – Preparation NaCl/n-Propanol Internal Standard Solution</td>
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<td>BA-03-04 – Preparation of Volatile Mixture Standard</td>
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<td>TOX-07-01 – Preparation of Borate Buffer</td>
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<td>TOX-07-02 – Preparation of Acidified Ethanol</td>
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<td>TOX-07-03 – Preparation of 20% Sodium Hydroxide</td>
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<td>TOX-07-04 – Preparation of 1M Potassium Hydroxide</td>
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<td>TOX-07-06 – Preparation of 0.1M Potassium Phosphate Buffer</td>
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<td>TOX-07-07 – Preparation of Sodium Acetate Buffer</td>
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<td>TOX-07-14 – Preparation of Maleic Acid Solution</td>
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<td>TOX-07-16 – Preparation of Dilute Phosphoric Acid</td>
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<td>TOX-07-24 – Preparation of Ammonium Formate</td>
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<td>TOX-07-25 – Preparation of PPG Dilution Solution</td>
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<td>TOX-07-26 – Preparation of Potassium Carbonate Buffer</td>
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<td>TOX-07-29 – Preparation of 0.1M Hydrochloric Acid</td>
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<td>TOX-07-33 – Preparation of 1M Acetic Acid</td>
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<td>TOX-07-34 – Preparation of Acidified Methanol</td>
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<td>TOX-07-35 – Preparation of Sodium Phosphate Buffer</td>
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<td>TOX-07-36 – Preparation of Tris Buffer</td>
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<td>TOX-07-37 – Preparation of Tris Buffer in Methanol</td>
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Trainee Name ___________________________  Date Training Began ________________

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<tr>
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<th>Trainee Initials</th>
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<tr>
<td><strong>Lesson Plan</strong></td>
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<td>Introduction to qualitative and semi-quantitative analysis using instrumentation</td>
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<td><strong>Sample Preparation</strong></td>
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<td>☐ Blood - Protein precipitation</td>
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<td>☐ Extraction reagents</td>
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<td>☐ Instrument reagents</td>
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<td><strong>EMIT Instrument</strong></td>
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<td>☐ Theory - Advantages, disadvantages</td>
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<td>☐ Batch configuration - Calibrators, unknown samples</td>
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<td>☐ Instrument operation – Setup, analyze calibrators and quality control, analyze unknown samples, documentation of results, daily maintenance, monthly maintenance</td>
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<td>☐ Interpretation of results – evaluate batch acceptance, evaluate instrument response</td>
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<td><strong>Case Workflow</strong></td>
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<td>☐ Negative results</td>
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<td>☐ Presumptive positive results</td>
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<td>☐ Case offense</td>
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<td>☐ Suspected drugs</td>
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<td>☐ Pending list</td>
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<td>Levine, Barry - Principles of Forensic Toxicology</td>
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<td>Ch. 7 – Specimen Preparation</td>
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<td>Moffatt, Anthony C. - Clarke’s Analysis of Drugs and Poisons</td>
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<td>Ch. 31 - Immunoassays</td>
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<td>Texas DPS Standard Operating Procedures</td>
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<td>TOX-01-09 – Case Review</td>
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<td>TOX-01-10 – Batch Summary Review</td>
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<td>TOX-02-01 – Systematic Examination of Toxicological Evidence</td>
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<td>TOX-02-02 – Disposition of Toxicological Evidence</td>
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<td>TOX-03-01 – Screening of Blood Samples by EMIT* including all SOPs in Related Documents</td>
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<tr>
<td>TOX-03-02 – Screening of Urine Samples by EMIT* including all SOPs in Related Documents</td>
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<td>LAB-TOX Forms, applicable forms</td>
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<td>MGC 240 Operating Manual</td>
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<td>Current Reagent A and E manufacturer inserts</td>
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<td>SDSs</td>
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**Observed Performance**

- Observe blood batch
- Observe blood batch
- Observe urine batch
- Observe preparation of calibrator working solutions
- Review and discuss notes
- Observe trainer perform technical review of batch archive and case records

**Supervised Performance**

- Evaporation Exercise
  - Extract with acidified ethanol
  - Extract without acidified ethanol

Prepare reagents and solutions necessary for analysis and/or perform verifications
- Tris Buffer
- Tris Buffer:MeOH
- Acidified Ethanol
- Preparation of working solutions for blood and urine*

*Note: TOX-03-01 and TOX-03-02 may also include specified procedures for preparing and handling samples, such as extraction methods, ensuring accuracy, and record-keeping for both blood and urine samples.
<table>
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<tr>
<th>TOX-TM-EMIT-01 – Immunoassay Screening</th>
<th>Trainee Initials</th>
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<th>Trainer Initials/ Evaluation</th>
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<tr>
<td>Preparation of calibrators for blood and urine*</td>
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<td>Preparation of cut-off sample*</td>
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<td>Verification of Reagents*</td>
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<td>Verification of Calibrators*</td>
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<td>*may occur during supervised performance or at a later date</td>
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Analyze minimum of 15 unknown blood samples

Analyze minimum of 15 unknown urine samples

**Assessment**

Analyze minimum of 15 blood competency samples

Analyze minimum of 15 urine competency samples

Technical review competency samples

Written Examination
## TOX-TM-GCMS-01 – Fundamentals of GC/MS

### Lesson Plan

- **GC/MS Basics**
- **Operation/Instrument Software**
- **Data Analysis Software**
- **Hardware**
- **Maintenance**

### Extraction Techniques

- **Liquid/Liquid Extraction**
- **Solid Phase Extraction (SPE)**

### Required Readings/Videos

- **GC/MS Operation Manual**
- **Levine, Barry - Principles of Forensic Toxicology**
  - Ch. 9 – Chromatography
  - Ch. 11 – Mass Spectrometry
  - Ch. 12 – Method Validation
- **Moffatt, Anthony C. - Clarke’s Analysis of Drugs and Poisons**
  - Ch. 20 – Method Development and Validation
  - Ch. 29 – Extraction
- **Texas DPS Standard Operating Procedures**
- **TOX-INS-02 – GCMS Instructions**
- **Extraction SOPs for methods used in exercises**
- **Reagent preparation instructions for methods used in exercises**
- **LAB-TOX-25 – Vacuum Pump Oil Level Log**
- **LAB-TOX-28 – Instrument Log**
- **Ghost Peaks in Gas Chromatography Part 1: The carrier gas and carrier gas lines**
- **DPS instrument validation documentation**
- **GCMS troubleshooting and other videos**
- **SDSs**

### Observed Performance

- **Review and discuss notes**
# Tox-TM-GCMS-01 – Fundamentals of GC/MS

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<th>Trainee Initials</th>
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<td>Printed GC/MS data – EIC, mass spectrum, and library search spectrum</td>
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<tr>
<td>Predict from a drug structure the significant ions produced in EI GC/MS</td>
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<td>Injection Port Conversion Exercise*</td>
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<td>Reproducibility Exercise*</td>
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<td>Carryover Exercise*</td>
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<tr>
<td>Recovery Exercise*</td>
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* Prepare batch worklist, prepare sequence file on GC/MS, perform analysis, and prepare batch results summary

## Assessment

- **Written Examination**

**Requirements for Technical Review Task** *(trainer will mark if applicable)*

- Complete 5 mock technical reviews for Screenings and/or Confirmation

(trainer initials)
## TOX-TM-GCMS-02 – GC/MS Screening Module

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<td>□ GC/MS Screening extraction</td>
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<td>Introduction to GC/MS capabilities for toxicology screening</td>
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<td><strong>GCMS Operation</strong></td>
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<tr>
<td>□ Load method</td>
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<td>□ Instrument tune</td>
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<td>□ Load, edit, and simulate sequence</td>
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<td>□ Start sequence</td>
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<td>□ Data file archive</td>
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<td><strong>Data Analysis</strong></td>
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<td>□ Use RRT to establish expected retention time</td>
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<td>□ Analyze library search report</td>
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<td>□ Plot ions to obtain sample spectra</td>
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<td>□ Compare sample spectra to spectra library</td>
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<td>□ Evaluate preceding solvent blank</td>
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<td>□ Print data and complete GC/MS Data Screen Worksheet</td>
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<td><strong>Batch Acceptability</strong></td>
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<td>□ Analyze negative control(s)</td>
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<tr>
<td>□ Analyze positive control(s) and re-injections</td>
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<td><strong>LIMS results entry</strong></td>
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### Required Readings

Levine, Barry - Principles of Forensic Toxicology

- Ch. 16 – Miscellaneous Central Nervous System Depressants
- Ch. 23 – Therapeutic Drugs II: Antidepressants
- Ch. 25 – Therapeutic Drugs IV: Antihistamines
<table>
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<td>Texas DPS Standard Operating Procedures</td>
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<td>TOX-01-06 – Case Documentation</td>
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<td>TOX-01-09 – Guidelines for Batch Archive Review</td>
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<td>TOX-05-06 – Extraction for GC/MS Screen</td>
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<td>TOX-06-01 – Screening by GC/MS</td>
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<td>DPS method validation documentation</td>
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<tr>
<td>Baselt, Randall C. - Disposition of Toxic Drugs and Chemicals in Man, as assigned</td>
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<tr>
<td>SDSs</td>
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</tbody>
</table>

**Observed Performance**

- Observe trainer work a batch from start to finish
- Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues
- Observe additional batch of cases
- Observe routine maintenance of the GC/MS
- Review and discuss notes
- Verification and documentation
  - [ ] Internal standard solution
  - [ ] Control

**Supervised Performance**

- Preparation of reagents and solutions as outline in TOX-05-_____
  - [ ] Buffers
  - [ ] Elution solvent
  - [ ] Control working solution*
  - [ ] Internal standard solution*

*may occur during supervised performance or at a later date

- Practice analyzing data from previously prepared samples
- Perform routine maintenance on the GC/MS as needed
- Batch analysis with at least 15 unknown samples  ◊
- Prepare drug summary sheets for common drugs
**TOX-TM-GCMS-02 – GC/MS Screening Module**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/Evaluation</th>
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<tbody>
<tr>
<td>Practical Competency Samples – minimum of 15 unknown samples◊</td>
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<tr>
<td>Written examination</td>
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<tr>
<td>Requirements for Technical Review Task <em>(trainer will mark if applicable)</em></td>
<td></td>
<td></td>
<td><em>(trainer initials)</em></td>
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<tr>
<td>☐ Complete 5 mock technical reviews for Screenings and/or Confirmation</td>
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</table>

◊ Prepare batch worklist, prepare sequence file on GC/MS, perform analysis, and prepare batch results summary
# Toxicology GC/MS Confirmation Checklist (New)

**Trainee Name __________________________ Date Training Began ________________**

<table>
<thead>
<tr>
<th>Lesson Plan</th>
<th>Trainee Initials</th>
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<tbody>
<tr>
<td>Qualitative and quantitative analysis using GC/MS</td>
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<tr>
<td>Sample preparation</td>
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<tr>
<td>☐ Liquid/liquid extraction</td>
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<tr>
<td>☐ Solid phase extraction</td>
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<tr>
<td>GC/MS operation</td>
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<tr>
<td>☐ Load acquisition method</td>
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<tr>
<td>☐ Tune of mass spectrometer</td>
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<tr>
<td>☐ Load, edit, and simulate sequence</td>
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<tr>
<td>☐ Start sequence</td>
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<tr>
<td>☐ Data archiving</td>
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<tr>
<td><strong>Batch Acceptability</strong></td>
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<tr>
<td>☐ Data analysis – verify integrations, create calibration curves, assess calibrator &amp; control accuracy</td>
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<td>☐ Target report generation</td>
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<td><strong>Data Interpretation</strong></td>
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<tr>
<td>☐ Create batch archive</td>
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<tr>
<td>☐ Enter results into LIMS</td>
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<td>☐ Discuss LIMS reporting</td>
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<td><strong>Required Readings</strong></td>
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<td>Texas DPS Standard Operating Procedures</td>
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<td>TOX-01-05 – Uncertainty of Measurement</td>
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<td>TOX-06-02 – Target Compound Analysis</td>
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**TOX-TM-GCMS-03 – GC/MS Confirmation (New)**

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<td>LAB-TOX-29 – Control Verification Worksheet</td>
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<td>LAB-TOX-30 – Drug Standard Log</td>
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<td>LAB-TOX-33 – Unconfirmed EMIT Positives Log</td>
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<tr>
<td>Levine, Barry - Principles of Forensic Toxicology</td>
<td></td>
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<tr>
<td>Ch. 9 – Chromatography</td>
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<tr>
<td>Ch. 11 – Mass Spectrometry</td>
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<td>Ch. 12 – Method Validation</td>
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<td>Part III. Analytes – Applicable chapters</td>
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<td>Baselt, Randall C. - Disposition of Toxic Drugs and Chemicals in Man, as assigned</td>
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<tr>
<td>DPS method validation documentation</td>
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### Observed Performance

- Observe trainer work a batch from start to finish
- Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues
- Observe additional batch of cases
- Observe routine maintenance of the GC/MS
- Review and discuss notes
- Discussion or completion of solution verification and documentation

- [ ] Internal standard solution
- [ ] Calibrator working solutions
- [ ] Controls

### Supervised Performance

- Preparation of reagents and solutions as outlined in TOX-05-_____
- [ ] Buffers
- [ ] Elution solvent
- [ ] Calibrator working solutions*
- [ ] Control working solutions*
- [ ] Internal standard solution*

*may occur during supervised performance or at a later date
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<thead>
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<th>TOX-TM-GCMS-03 – GC/MS Confirmation (New)</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/ Evaluation</th>
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<tbody>
<tr>
<td>Perform extraction, GC/MS data acquisition, &amp; target compound analysis on calibrators and controls</td>
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<tr>
<td>Perform routine maintenance on the GC/MS, as needed</td>
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<tr>
<td>Prepare drug summary sheets for common drugs</td>
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<tr>
<td>Batch analysis with at least 15 unknown samples</td>
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<tr>
<td>Prepare a practice batch archive</td>
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**Assessment**

| Practical Competency Samples – minimum of 15 unknown samples | | | |
| Written examination | | | |

**Requirements for Technical Review Task (trainer will mark if applicable)**

- [ ] Complete 5 mock technical reviews for Screenings and/or Confirmation

◊ Prepare batch worklist, prepare sequence file on GC/MS, perform analysis, and prepare batch results summary
# Toxicology GC/MS Confirmation Checklist (Continued)

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## TOX-TM-GCMS-03 – GC/MS Confirmation (Continued)

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<tr>
<td>Texas DPS Standard Operating Procedures</td>
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<td>Appropriate procedure for specified method: TOX-05-___</td>
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<tr>
<td>Levine, Barry - Principles of Forensic Toxicology – Applicable chapters</td>
</tr>
<tr>
<td>Baselt, Randall C. - Disposition of Toxic Drugs and Chemicals in Man, as assigned</td>
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<td>DPS method validation documentation</td>
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<tbody>
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<td>Observe trainer work a batch from start to finish</td>
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<tr>
<td>Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues</td>
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<tr>
<td>Review and discuss notes</td>
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<table>
<thead>
<tr>
<th>Supervised Performance</th>
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<tbody>
<tr>
<td>Batch analysis with at least 15 unknown samples ♦</td>
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<td>Prepare drug summary sheets for common drugs</td>
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<th>Competency</th>
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♦ Prepare batch worklist, prepare sequence file on GC/MS, perform analysis, and prepare batch results summary
## TOX-TM-LCMS-01 – Fundamentals of LC/MS

<table>
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<th>Lesson Plan</th>
<th>Trainee Initials</th>
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<td>LC/MS Basics</td>
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<td>Operation/Instrument/Data Analysis Software</td>
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<td></td>
<td>Hardware</td>
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<td>Maintenance</td>
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<td>Extraction techniques</td>
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<td>Liquid/Liquid extraction</td>
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<td></td>
<td>Solid phase extraction (SPE)</td>
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</table>

## Required Reading/Media Materials

- Polettini, Aldo. - Applications of LC-MS in Toxicology
  - Ch. 1 – Ionisation, ion separation, and ion detection in LC-MS
- Levine, Barry - Principles of Forensic Toxicology
  - Ch. 9 – Chromatography
  - Ch. 11 – Mass Spectrometry
  - Ch. 12 – Method Validation
- Moffatt, Anthony C. - Clarke’s Analysis of Drugs and Poisons
  - Ch. 20 – Method Development and Validation
  - Ch. 29 – Extraction
- Texas DPS Standard Operating Procedures
  - TOX-INS-01 – LCMS Instructions
  - Extraction SOPs for methods used in exercises
  - Reagent preparation instructions
  - LAB-TOX-25 – Vacuum Pump Oil Level Log
  - LAB-TOX-28 – Instrument Log
  - Read literature from specific manufacturer for the LC/MS used
  - DPS instrument validation documentation
## TOX-TM-LCMS-01 – Fundamentals of LC/MS

<table>
<thead>
<tr>
<th>Activity</th>
<th>Trainee Initials</th>
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<tr>
<td>SDSs</td>
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<tr>
<td>Sciex Education – Introduction to LC-MS/MS videos</td>
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<tr>
<td>Introduction to HPLC</td>
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<tr>
<td>Introduction to Mass Spectrometry</td>
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<td>Triple Quadrupole and Linear Ion Trap MS</td>
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<tr>
<td><strong>Observed Performance</strong></td>
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<tr>
<td>Review and discuss notes</td>
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<td><strong>Supervised Performance</strong></td>
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<tr>
<td>Prepare Mobile Phases A and B</td>
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<tr>
<td>Reproducibility Exercise*</td>
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<td>Carryover Exercise*</td>
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<tr>
<td>Recovery Exercise*</td>
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<tr>
<td><strong>Assessment</strong></td>
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<tr>
<td>Written Examination</td>
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<tr>
<td>Requirements for Technical Review Task <em>(trainer will mark if applicable)</em></td>
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<tr>
<td>Complete 5 mock technical reviews for Screenings and/or Confirmation</td>
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<tbody>
<tr>
<td><strong>Lesson Plan</strong></td>
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<tr>
<td>Sample Preparation</td>
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<tr>
<td>☐ LC/MS Screening Extraction</td>
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<td>Introduction to LC/MS capabilities for toxicology screening</td>
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<td><strong>LC/MS Operation</strong></td>
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<tr>
<td>☐ Q1 and Q3 positive PPG Tune Check</td>
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<tr>
<td>☐ LIT tune check</td>
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<tr>
<td>☐ Load and edit sequence</td>
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<tr>
<td>☐ Load and start data acquisition method</td>
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<td>☐ Data file archive</td>
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<td><strong>Data Analysis</strong></td>
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<tr>
<td>☐ Use RRT to establish expected retention time</td>
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<tr>
<td>☐ Analyze information dependent acquisition data</td>
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<td>☐ Compare sample spectra to compound library</td>
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<td>☐ Print data and complete LC/MS Data Screen Worksheet</td>
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<td><strong>Batch Acceptability</strong></td>
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<td>☐ Analyze negative control</td>
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<tr>
<td>☐ Analyze positive control and re-injections</td>
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<td><strong>LIMS report writing</strong></td>
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<td>Levine, Barry - Principles of Forensic Toxicology</td>
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<td>Ch. 16 – Miscellaneous Central Nervous System Depressants</td>
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<td>Ch. 23 – Therapeutic Drugs II: Antidepressants</td>
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<td>Ch. 25 – Therapeutic Drugs IV: Antihistamines</td>
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<td>TOX-01-06 – Case Documentation</td>
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### TOX-TM-LCMS-02 – LC/MS Screening Module

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</table>

### Observed Performance

- Observe trainer work a batch from start to finish
- Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues
- Observe additional batch of cases
- Observe routine maintenance of the LC/MS
- Review and discuss notes

### Verification and documentation

- Internal standard solution
- Control

### Supervised Performance

- Preparation of reagents and solutions as outline in TOX-05-_____
  - Buffers
  - Extraction reagents
  - Mobile phase
  - Control working solution*
  - Internal standard solution*  
  
*may occur during supervised performance or at a later date

- Practice analyzing data from previously prepared samples
- Perform routine maintenance on the LC/MS as needed
- Batch analysis with at least 15 unknown samples
- Prepare drug summary sheets for common drugs
<table>
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<th>TOX-TM-LCMS-02 – LC/MS Screening Module</th>
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* Prepare batch worklist, prepare sequence file on LC/MS, perform analysis, and prepare batch results summary
# Toxicology LC/MS Confirmation Checklist (New)

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<thead>
<tr>
<th>TOX-TM-LCMS-03 – LC/MS Confirmation Module (New)</th>
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<td>□ Solid phase extraction</td>
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<tr>
<td><strong>LC/MS Operation</strong></td>
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<tr>
<td>□ Q1 and Q3 positive PPG Tune Check</td>
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<tr>
<td>□ Load and edit sequence</td>
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<tr>
<td>□ Load and data acquisition method</td>
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<td>□ Data file archive</td>
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<tr>
<td><strong>Batch Acceptability</strong></td>
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<td>□ Data analysis – verify integrations, create calibration curves, assess calibrator &amp; control accuracy</td>
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<td>□ Target report generation</td>
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<tr>
<td><strong>Data Interpretation</strong></td>
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<tr>
<td>□ Create batch archive</td>
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<tr>
<td>□ Enter results into LIMS</td>
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<tr>
<td>□ Discuss LIMS reporting</td>
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<td><strong>Required Reading/Media Materials</strong></td>
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<td>Texas DPS Standard Operating Procedures</td>
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<td>TOX-01-05 – Uncertainty of Measurement</td>
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<td>TOX-01-06 – Case Documentation</td>
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<td>TOX-01-09 – Guidelines for Batch Archive Review</td>
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<td>TOX-01-10 – Guidelines for Administrative and Technical Review</td>
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<td>Appropriate procedure for specified method: TOX-05-_____</td>
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<td>TOX-06-02 – Target Compound Analysis</td>
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<td>LAB-TOX-29 – Control Verification Worksheet</td>
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<td>LAB-TOX-30 – Drug Standard Log</td>
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<td>LAB-TOX-33 – Unconfirmed EMIT Positives Log</td>
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<td>Levine, Barry - Principles of Forensic Toxicology</td>
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<td>Ch. 9 – Chromatography</td>
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<td>TOX-TM-LCMS-03 – LC/MS Confirmation Module (New)</td>
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<td>Trainer Initials/Evaluation</td>
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<td>Ch. 12 – Method Validation</td>
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<td>Part III. Analytes – Applicable chapters</td>
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<td>Baselt, Randall C. - Disposition of Toxic Drugs and Chemicals in Man, as assigned</td>
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<td>LC/MS Operation Manual</td>
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<td>DPS method validation documentation</td>
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</table>

**Observed Performance**

- Observe trainer work a batch from start to finish
- Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues
- Observe additional batch of cases
- Observe routine maintenance of the LC/MS
- Review and discuss notes
- Discussion or completion of solution verification and documentation

- [ ] Internal standard solution
- [ ] Calibrator working solutions
- [ ] Controls

**Supervised Performance**

- Preparation of reagents and solutions as outlined in TOX-05-_____

- [ ] Buffers
- [ ] Elution solvent
- [ ] Mobile phase
- [ ] Reconstitution solution
- [ ] Calibrator working solutions*  
- [ ] Control working solutions*  
- [ ] Internal standard solution*

*may occur during supervised performance or at a later date

- Perform extraction, LC/MS data acquisition, & target compound analysis on calibrators and controls◊
- Perform routine maintenance on the LC/MS, as needed
- Prepare drug summary sheets for common drugs
- Batch analysis with at least 15 unknown samples◊
- Prepare a practice batch archive
<table>
<thead>
<tr>
<th>Assessment</th>
<th>Trainee Initials</th>
<th>Date Completed</th>
<th>Trainer Initials/Evaluation</th>
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<tr>
<td>Practical Competency Samples – minimum of 15 unknown samples[^1]</td>
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<td>Written examination</td>
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<tr>
<td>Requirements for Technical Review Task (trainer will mark if applicable)</td>
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<td>(trainer initials)</td>
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<td>□ Complete 5 mock technical reviews for Screenings and/or Confirmation</td>
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[^1]: Prepare batch worklist, prepare sequence file on LC/MS, perform analysis, and prepare batch results summary.
## Observed Performance

Observe trainer work a batch from start to finish

Discuss each extraction technique, data, interpretations, limitations, documentation, and safety issues

Review and discuss notes

## Supervised Performance

Batch analysis with at least 15 unknown samples◊

Prepare drug summary sheets for common drugs

## Assessment

Practical Competency Samples – minimum of 15 unknown samples◊

◊ Prepare batch worklist, prepare sequence file on LC/MS, perform analysis, and prepare batch results summary