FORENSIC CHEMISTRY

TOXICOLOGY SECTION
LC-MS/MS BLOOD DRUGS
TRAINING MANUAL

Introduction

This procedure details the training requirements that must be completed before any new employee in the Toxicology Section may be allowed to analyze case specimens without close supervision (i.e., independent casework).

Documented completion of each module within this manual, and completion of the safety training, satisfies all training requirements, and will allow the analyst to obtain the required State Certification for the analysis and detection of drugs in blood samples.

Following completion, certification, and authorization by the Forensic Lab Director, any new analyst is allowed full access to all case specimens within the laboratory and may contribute to the completion of a case in any way necessary, including case / batch technical review.

During the training period, if a trainee's performance is unacceptable in any specific section, the Training Coordinator shall notify the trainee and Forensic Lab Director / Quality Manger that performance is/was unacceptable. Notification of the unacceptable performance will be retained in the training binder along with all documentation indicating the trainee 'repeated the section'.

The Forensic Lab Director/Quality Manager may require the trainee to repeat the failed section, and/or augment the training material in the specific section, and/or take other appropriate action as management deems necessary (i.e., disciplinary). Appropriate documentation will be retained in the training binder. Subsequent failures, of either the original or additional modules during the training period will be brought to the attention of higher management by the Forensic Lab Director/Quality Manager. It should be noted that some complex tasks may require more than 1 attempt to learn and master (i.e., extraction). Such repetitions are not viewed as failing a module if the trainee is progressing and 'learning'. Rather, multiple attempts to master a task or module where repeated mistakes and the trainee is not progressing or 'learning' as determined by the trainer will be viewed as failing a task or module, as is the inability to complete the required tasks assigned within the module in a reasonable length of time or reasonable number of attempts.

MODULE 1:

Administrative Procedures and Orientation

Objectives:
Completion of this module will provide the trainee with relevant knowledge in the following administrative areas:

- Administrative policies and procedures for the State of Maine, Health and Environmental Testing Laboratory and Forensic Chemistry Section.

Required Tasks:

1. New employees will be processed through the State of Maine / Health and Environmental Testing Labs administrative offices prior to reporting to the Forensic Chemistry Laboratory.

2. The trainee will be given a tour of the HETL building, and specifically the Forensic Chemistry Lab, and introduced to lab personnel.

3. Assigned Training Coordinator will provide the trainee with an explanation of the purpose of the training program, the expected course of events and outcomes, instructions on maintenance of a training notebook / binder, and a copy of the approved training plan. Trainee will also have the opportunity to ask any questions related to training, and what is expected from all parties.

4. Trainee and Training Coordinator will meet with the Forensic Lab Director to discuss items outlined in the completion checklist below, and to answer any questions.

5. Trainees will be required to complete reading or viewing of the following materials:
   - **a.** Laboratory Quality Manual
   - **b.** Laboratory Standard Operating Procedures Manual
   - **c.** Relevant sectional Procedural Manuals
   - **d.** HETL Safety Program Manual, which includes sections on blood borne pathogens (SharePoint)
   - **e.** American Academy of Forensic Sciences Code of Ethics
   - **f.** American Board of Forensic Toxicology Code of Ethics
   - **g.** ASCLD/LAB Guiding Principles of Professional Responsibility
   - **h.** Current version of ASCLD/LAB manual under which the laboratory is currently accredited.

6. It should be noted that the Trainee may be working on multiple modules at the same time. Some modules, or requirements within a module may take a short time to complete, but other items may require more extensive practice and time for the trainee to master.

7. It is recognized that portions of this training program are identical to the Drugs in Urine Training program, the Blood Alcohol Training program, and very similar to the Solid Dose Drug Training program. If the trainee has already completed the drugs in urine, blood alcohol training and/or solid dose drug program, then repeating the same material again is not required. However, appropriate documentation shall be included within this training to reference and provide objective evidence that the material has been completed previously.

Retraining:

If a trainee's performance is unacceptable in any specific section, the Training Coordinator shall:

- ✓ Notify the trainee and Forensic Lab Director / Quality Manager that performance is/was unacceptable. (Notification of the unacceptable performance may be made by either email or personal communication, but a record will be retained in the training binder along with all documentation indicating the trainee 'successfully repeated the section and any additional work as determined by the Forensic Lab Director – see below).

- ✓ The Forensic Lab Director may require the trainee to simply repeat the failed section or may augment the training material in the specific section, and/or take other appropriate action as management deems necessary (i.e., disciplinary). Appropriate documentation will be retained in the training binder.

- ✓ Subsequent failures, of either the original or additional sections during the training period, will be brought to the attention of higher management by the Forensic Lab Director / Quality Manager.

Specific Criteria for acceptable performance are detailed within each specific section of the training.

Checklist: Orientation and Administration

1. Trainee has completed New Employee Processing

Trainee	Training Coordinator	Date

2. Trainee has completed State of Maine / HETL New Employee Orientation

Trainee	Training Coordinator	Date

3. Trainee has read the HETL Safety Program Manual. Trainee has toured the facility and is familiar with the location of fire extinguishers, emergency routes and exits, and the evacuation meeting locations. Trainee has discussed with the Forensic Lab Director the concept of Universal Precautions and the expectations for the proper use of PPE and safety equipment within the laboratory. Trainee understands the HETL policy for Hepatitis vaccinations.

Trainee	Training Coordinator	Date

4. Trainee has been provided an explanation of the training program, competency testing, instructions on maintenance of a training notebook, and a copy of the approved training plan.

Trainee	Training Coordinator	Date

5. Trainee has met with the Forensic Lab Director and discussed the following issues:

- Laboratory mission, structure, organization, and capabilities
- Types of casework commonly encountered
- ANAB procedures and oversight
- Aspects of the Toxicology Laboratory Quality Assurance Program
- Instrument maintenance and documentation
- Technical and administrative review of batch and case files
- Preparation, use, and documentation of calibrators/controls
- Proficiency Testing Program
- Forms currently in use in the laboratory
- Hours of operation
- Time and attendance, requests for time off
- Annual and sick leave
- Continuing education and travel requests
- Supply ordering and annual budget process
- Policies regarding confidentiality and reporting of results, including documentation of case communications, telephonic results, and inquiries from the press or other media
- Policies regarding testimony
- Request for pre-trial meetings or depositions in a criminal case
- Request to testify in a grand jury proceeding or preliminary hearing
- Providing lab reports to other agencies
- Discussing the results/conclusions of another analyst's work or the work performed in another section
- Discussing details regarding an on-going investigation, and DHHS policy regarding HIPAA
- Disclosure of case details or comments regarding HETL or HETL Toxicology section via current social networking means (such as: forensic websites, forums, Facebook, internet blogs, chat rooms, etc)
- The potential for re-examination of evidence
- Membership dues and attendance at professional meetings

_____	_____	_____
Trainee	Forensic Lab Director	Date

6. Trainee has completed reading of the following materials:

Orientation and Administration	Completion Date:	Trainee Initial
Quality Manual		
Standard Operating Procedures Manual		
American Academy of Forensic Sciences Code of Ethics		
American Board of Forensic Toxicology Code of Ethics		
ANAB Guiding Principles of Professional Responsibility		
Current ANAB Manual and Board Interpretations		

_____ _____ _____

Trainee Training Coordinator Date

Administrative Matters and Procedures documented, completed, and reviewed.

_____ _____ _____

Trainee Training Coordinator Date

Module 2:

Handling and Documentation of Physical Evidence

Objectives:

After completion of this module, the trainee will have the requisite knowledge, skills, and abilities involved in:

- Preservation of hard copy chain-of-custody for physical evidence
- Use of the laboratory LIMS system to document service requests and evidence receipt, and return.
- Compliance with Toxicology Laboratory policies regarding security, handling, packaging, labeling, and preservation of evidence to prevent loss, deterioration, or cross-contamination, including:
    - Security systems in place
    - Verification and documentation of evidence received
    - Sealing of evidence
    - Procedures in the event of receiving unsealed evidence
    - Marking of evidence
    - Evidence storage
    - Final disposition of evidence
- Examination documentation to include:
    - Initials or signature of analyst and toxicology laboratory case number
    - Procedures for strikethrough and interlineation
    - Detailed information on condition and description of the evidence
    - Analyses/examinations performed
    - Composition and disposition of case files

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to evidence handling, packaging, labeling, and preservation, chain of custody, and examination documentation.
- The trainee will observe utilization of the laboratory LIMS system to document service requests and evidence transfer.
- The trainee will observe the physical receipt, transfer, storage, and return of evidence, and the corresponding documentation of hard copy chain of custody.
- The trainee will observe the marking or labeling of physical evidence.
- When the trainee is comfortable with and understands the submission process, the training coordinator will pretend to be a customer submitting evidence, and the trainee shall receive said evidence, completing the contract for lab services and chain of custody documents. No labels printed, and this case will not be entered into StarLims.
- The trainee is required to read the relevant sections of the Quality Manual and Evidence Manual dealing with chain of custody, receipt and return of evidence.

Study Questions:

- Explain the chain of custody system used by the Toxicology section
- How is access to the building, the laboratory, and toxicology evidence controlled, secured, and documented?
- Define a proper seal
- Discuss the proper marking/labeling of evidence
- Who has access to the secured refrigerator in the laboratory?
- What information should be included on each page of your case file?
- How are spelling or other errors handled in note-taking?
- What documentation should be included in a case file?
- How are case files stored within the laboratory?
- How is batch and QC data stored within the laboratory?
- What is the final disposition of evidence when individual casework is completed?

Checklist/Evaluation for Handling of Physical Evidence

1. The trainee has met with the training coordinator and discussed the topics listed in the objectives as they relate to evidence handling, packaging, labeling, preservation, chain of custody, evidence disposition, and security.

Date	Trainee	Training Coordinator

2. Trainee has observed/assisted in receiving, transferring, and returning evidence and documenting on chain of custody form.

Date	Trainee	Training Coordinator

3. Trainee has observed/assisted in preserving and storing evidentiary materials.

Date	Trainee	Training Coordinator

4. Trainee has observed/assisted in marking of evidence, and description of evidence materials if warranted.

Date	Trainee	Training Coordinator

5. Trainee has provided satisfactory answers to oral study questions.

Date	Trainee	Training Coordinator

6. Trainee has demonstrated proficiency in use of the LIMS system and completed the exercise with the training coordinator and the submission of evidence.

Date	Trainee	Training Coordinator

7. Trainee has completed the required reading of the following:

Handling of Physical Evidence	Completion Date:	Trainee Initial
Evidence Manual		
Quality Manual – Sections dealing with Evidence, chain of custody, receipt / return of evidence		

_____ _____ _____
Date Trainee Training Coordinator

Handling and Documentation of Physical Evidence documented, completed, and reviewed.

_____ _____ _____
Date Trainee Training Coordinator

Module 3:

LC-MS/MS Drugs in Blood
Screening-Extraction-Confirmation-Report Writing

Objectives:

After completion of all sections of this module, the trainee with have the requisite knowledge, skills, and abilities involved in:

- LC-MS/MS maintenance and preparation of analyzer for analysis
- Sample check in to verify accurate information such as names, case number, etc.
- Initial screening of blood samples for drugs
- Preparation of Internal Standard, Working Stocks, and extraction reagents
- Preparation of calibration curve and associated quality controls
- Sample preparation and extraction
- Developing a batch list and running samples
- Analyzing the data generated and completing associated forms
- Proper LC-MS/MS integration and manual integration of data
- Entry of metadata and sample results into LIMS System
- Creating a final report for the customer
- Submitting all work within the 'batch' for technical and administrative review
- Signing the final report and sending report to customer

Recommended Readings:

- Baselt, R., *Drug Effects on Psychomotor Performance*. (Most recent edition available at HETL)
- Fenton, J., *Toxicology A Case-Orientated Approach*. (Most recent edition available at HETL)
- Randall, B., *Disposition of Toxic Drugs and Chemicals in Man*. (Most recent edition available at HETL)

3.1 Qualitative Screen for Drugs in Blood

Required Reading:

- HETL Qualitative Screen for Drugs in Blood by LC-MS/MS Analysis Procedure Manual.
- HETL Qualitative Screen for Drugs in Blood by LC-MS/MS Analysis Validation Plan Conclusion

- HETL LC-MS/MS Instrument Maintenance Procedure
- HETL LC-MS/MS Analysis Acceptance & Reporting Criteria
- Logan, B. et al. (2017), Recommendations for Toxicological Investigation of Drug-Impaired Driving and Motor Vehicle Fatalities. Journal of Analytical Toxicology-2017 Update.2017; 42:63-68.
- Verstraete, A. (2004), Detection Times of Drugs of Abuse in Blood, Urine, and Oral Fluid. The Journal of Therapeutic Drug Monitoring, 2004; 26: 22

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the qualitative screening for drugs in blood.
- The trainee shall practice pipetting using the Eppendorf repeat pipet until the trainee feels comfortable using the device.
- The trainee is required to read and follow the HETL Qualitative Screen for Drugs in Blood by LC-MS/MS Analysis Procedure and demonstrate the ability to follow that method and generate results.
- The trainee will observe the entire qualitative screen process as it is performed by the trainer.
- After watching the trainer complete the extraction and qualitative screen analysis process, the trainee will successfully complete the extraction and qualitative screen process, under direct observation by the trainer, of the appropriate quality controls and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- Independently without observation by the trainer the trainee will successfully complete the extraction and qualitative analysis process, of the appropriate quality controls and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If independent run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- The trainee shall prepare a lot of a QC Working Stock Solution with the trainer and test that the concentration is within the acceptable QC range. *This QC Working Stock Solution may be prepared for any of the drugs in blood assays and only needs to be performed once*. Trainee will retain the LC-MS/MS data in their training binder. The trainee will also locate and print the COA of the standards used to be placed in their training binder.

On the COA the trainee will circle the Lot number of standards, and expiration date.

- The trainee is required to watch and assist in the creation of toxicology reports using the LIMS system. There is no minimum established as it is recognized that mastering the LIMS software package may be quick, or lengthy depending on the computer literacy of the trainee.

3.2 Quantitative Detection of Cannabinoids in Blood

Required Reading:

- HETL Determination of Cannabinoids in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.
- HETL Determination of Cannabinoids in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion
- Hartman, R. & Huestis, M. (2013). Cannabis Effects on Driving Skills. *Clinical Chemistry,* Vol. 59(3) 478-492.
- Desrosiers, Ramaekers, Chauchard, Gorelick, & Huestis (2015) Smoked Cannabis' Psychomotor and Neurocognitive Effects in Occasional and Frequent Smokers. *Journal of Analytical Toxicology*, Vol.39 251-261.

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the quantitative detection confirmation of cannabinoids in whole blood assay.
- The trainee is required to read and follow the HETL Determination of Cannabinoids in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure and demonstrate the ability to follow that method and generate results.
- The trainee will observe the entire quantitative detection of cannabinoids in blood process as it is performed by the trainer.
- After watching the trainer complete the extraction and quantitative confirmation analysis for the quantitative confirmation of cannabinoids in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.

- Independently without observation by the trainer the trainee will successfully complete the extraction and quantitative confirmation analysis for the quantitative confirmation of cannabinoids in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and a minimum of five unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If independent run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- The trainee shall prepare a lot of a QC Working Stock Solution with the trainer and test that the concentration is within the acceptable QC range. *This QC Working Stock Solution may be prepared for any of the drugs in blood assays and only needs to be performed once*. Trainee will retain the LC-MS/MS data in their training binder. The trainee will also locate and print the COA of the standards used to be placed in their training binder. On the COA the trainee will circle the Lot number of standards, and expiration date.
- The trainee is required to watch and assist in the creation of toxicology reports using the LIMS system. There is no minimum established as it is recognized that mastering the LIMS software package may be quick, or lengthy depending on the computer literacy of the trainee.

3.3 Quantitative Detection of Narcotics in Blood

Required Reading:

- HETL Determination of Narcotics in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.
- HETL Determination of Narcotics in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the quantitative detection confirmation of narcotics in whole blood assay.
- The trainee is required to read and follow the HETL Determination of Narcotics in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure and demonstrate the ability to follow that method and generate results.
- The trainee will observe the entire quantitative detection of narcotics in blood process as it is performed by the trainer.

- After watching the trainer complete the extraction and quantitative confirmation analysis for the quantitative confirmation of narcotics in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- Independently without observation by the trainer the trainee will successfully complete the extraction and quantitative confirmation analysis for the quantitative confirmation of narcotics in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If independent run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- The trainee shall prepare a lot of a QC Working Stock Solution with the trainer and test that the concentration is within the acceptable QC range. *This QC Working Stock Solution may be prepared for any of the drugs in blood assays and only needs to be performed once*. Trainee will retain the LC-MS/MS data in their training binder. The trainee will also locate and print the COA of the standards used to be placed in their training binder. On the COA the trainee will circle the Lot number of standards, and expiration date.
- The trainee is required to watch and assist in the creation of toxicology reports using the LIMS system. There is no minimum established as it is recognized that mastering the LIMS software package may be quick, or lengthy depending on the computer literacy of the trainee.

3.4 Quantitative Detection of Benzodiazepines in Blood

Required Reading:

- HETL Determination of Benzodiazepines in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.
- HETL Determination of Benzodiazepines in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the quantitative detection confirmation of benzodiazepines in whole blood assay.
- The trainee is required to read and follow the HETL Determination of Benzodiazepines in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure and demonstrate the ability to follow that method and generate results.
- The trainee will observe the entire quantitative detection of benzodiazepines in blood process as it is performed by the trainer.
- After watching the trainer complete the extraction and quantitative confirmation analysis for the quantitative confirmation of benzodiazepines in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- Independently without observation by the trainer the trainee will successfully complete the extraction and quantitative confirmation analysis for the quantitative confirmation of benzodiazepines in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If independent run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- The trainee shall prepare a lot of a QC Working Stock Solution with the trainer and test that the concentration is within the acceptable QC range. *This QC Working Stock Solution may be prepared for any of the drugs in blood assays and only needs to be performed once*. Trainee will retain the LC-MS/MS data in their training binder. The trainee will also locate and print the COA of the standards used to be placed in their training binder. On the COA the trainee will circle the Lot number of standards, and expiration date.
- The trainee is required to watch and assist in the creation of toxicology reports using the LIMS system. There is no minimum established as it is recognized that mastering the LIMS software package may be quick, or lengthy depending on the computer literacy of the trainee.

3.5 Quantitative Detection of Stimulants in Blood

Required Reading:

- HETL Determination of Stimulants in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.
- HETL Determination of Stimulants in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion
- Jones, A. (2019) *Forensic Drug Profile: Cocaethylene*. Journal of Analytical Toxicology 2019; 43: 155-160.

Required Tasks:

- The trainer will discuss the topics listed in the objectives as they relate to the quantitative detection confirmation of stimulants in whole blood assay.
- The trainee is required to read and follow the HETL Determination of Stimulants in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure and demonstrate the ability to follow that method and generate results.
- The trainee will observe the entire quantitative detection of stimulants in blood process as it is performed by the trainer.
- After watching the trainer complete the extraction and quantitative confirmation analysis for the quantitative confirmation of stimulants in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- Independently without observation by the trainer the trainee will successfully complete the extraction and quantitative confirmation analysis for the quantitative confirmation of stimulants in blood process, the trainee will successfully complete the extraction and quantitative confirmation analysis process, under direct observation by the trainer, of the entire calibration curve, associated quality controls, and unknown samples. Trainee will successfully complete **at least 1** batch, complete all paperwork / forms, and submit to Trainer for review. StarLIMS reports will not be created. If independent run does not meet acceptability requirements, then the training coordinator will evaluate need for further training.
- The trainee shall prepare a lot of a QC Working Stock Solution with the trainer and test that the concentration is within the acceptable QC range. *This QC Working Stock Solution*

may be prepared for <u>any</u> of the drugs in blood assays and <u>only needs to be performed once</u>. Trainee will retain the LC-MS/MS data in their training binder. The trainee will also locate and print the COA of the standards used to be placed in their training binder. On the COA the trainee will circle the Lot number of standards, and expiration date.

- The trainee is required to watch and assist in the creation of toxicology reports using the LIMS system. There is no minimum established as it is recognized that mastering the LIMS software package may be quick, or lengthy depending on the computer literacy of the trainee.

3.6 Qualitative and Quantitative Detections of Drugs in Blood

<u>Study Questions:</u>

- How are samples checked to ensure accuracy once they are received in within the lab?
- Describe how the LC-MS/MS analyzer works.
- Explain the process and reasoning behind the LC-MS/MS maintenance, including frequency.
- Give an example of what could cause increased pump pressure on the LC-MS/MS and an example of what could cause decreased pump pressure on the LC-MS/MS?
- Describe the process of creating a batch list and running samples in the LC-MS/MS computer software.
- Describe the requirements a LC-MS/MS quantitative calibration curve and associate QC must meet before being used for casework.
- Describe the requirements the LC-MS/MS qualitative quality controls must meet before being used for casework.
- Describe the requirements/acceptance criteria for LC-MS/MS quantitative confirmation: Specifically, detailing retention time, S/N ratio, and chromatography appearance.
- Describe some examples of inacceptable chromatography integration.
- How is data reviewed and then how are results entered into the LIMS system?
- Explain the process for technical review. What needs to be included within the case folder before submitting it for technical review?

Checklist/Evaluation for Blood Drug Analysis

8. The trainee has met with the training coordinator and discussed the topics listed in the objectives as they relate to LC-MS/MS detection of drugs in blood assays.

_____ _____ _____
Date Trainee Training Coordinator

Qualitative Screen	Completion Date	Trainee Initials
HETL Qualitative Screen for Drugs in Blood by LC-MS/MS Analysis Procedure Manual.		
HETL Qualitative Screen for Drugs in Blood by LC-MS/MS Analysis Validation Plan Conclusion		
HETL LC-MS/MS Instrument Maintenance Procedure		
HETL LC-MS/MS Analysis Acceptance & Reporting Criteria		
Recommendations for Toxicological Investigation of Drug-Impaired Driving and Motor Vehicle Fatalities.		
Detection Times of Drugs of Abuse in Blood, Urine, and Oral Fluid.		
Observed Process		
Performed Process Under Observation		
Performed Process Independently		

_____ _____ _____
Date Trainee Training Coordinator

9. Trainee is able to:

Identify the location of procedures, worksheets, and user manuals?		
Identify test requirements including acceptable specimen type, volume, internal standards, and MRM transitions?		
Identify storage locations of reagents, supplies, QCs, stocks, and standards?		
Clean glassware and prepare mobile phases?		
Perform dilution procedures as needed?		
Perform Autotune/Checktune?		
Check LC column and replace as necessary?		
Complete maintenance log sheet?		
Create and verify sequence table?		
Perform data analysis? (inspect chromatograms, verify run performance (internal standard peak area, carryover, ion ratios))		
Perform or explain basic troubleshooting techniques?		

10. Trainee has read required reading material, observed the trainer perform each of the

Quantitative Detection of Drugs in Blood Procedures as well as successfully completed at least 1 batch using each of the Quantitative Detection of Drugs in Blood Procedures under observation from the trainer and has successfully completed independently at least 1 batch using each of the Quantitative Detection of Drugs in Blood Procedures.

Cannabinoids	**Completion Date**	**Trainee Initials**
HETL Determination of Cannabinoids in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.		
HETL Determination of Cannabinoids in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion		
Hartman, R. & Huestis, M. (2013). Cannabis Effects on Driving Skills. Clinical Chemistry, Vol. 59(3) 478-492.		
Desrosiers, Ramaekers, Chauchard, Gorelick, & Huestis (2015) Smoked Cannabis' Psychomotor and Neurocognitive Effects in Occasional and Frequent Smokers. Journal of Analytical Toxicology, Vol.39 251-261.		
Observed Process		
Performed Process Under Observation		
Performed Process Independently		

_____ _____ _____

Date Trainee Training Coordinator

Narcotics	**Completion Date**	**Trainee Initials**
HETL Determination of Narcotics in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.		
HETL Determination of Narcotics in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion		
Observed Process		
Performed Process Under Observation		
Performed Process Independently		

_____ _____ _____

Date Trainee Training Coordinator

Benzodiazepines	**Completion Date**	**Trainee Initials**
HETL Determination of Benzodiazepines in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.		
HETL Determination of Benzodiazepines in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion		
Observed Process		
Performed Process Under Observation		
Performed Process Independently		

_____ _____ _____

Date Trainee Training Coordinator

Stimulants	**Completion Date**	**Trainee Initials**
HETL Determination of Stimulants in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Procedure Manual.		
HETL Determination of Stimulants in Blood by Liquid-Liquid Extraction and LC-MS/MS Analysis Validation Plan Conclusion		
Jones, A. (2019) Forensic Drug Profile: Cocaethylene. Journal of Analytical Toxicology 2019; 43: 155-160.		
Observed Process		
Performed Process Under Observation		
Performed Process Independently		

_____ _____ _____

Date Trainee Training Coordinator

11. Trainee has prepared a lot of a QC working stock with the Trainer and confirmed the concentration is within the acceptable QC range by LC-MS/MS analysis. (Instrument data, and COA added to training binder).

_____ _____ _____

Date Trainee Training Coordinator

12. Trainee has provided satisfactory answers to oral/written (circle one) study questions.

_____ _____ _____

Date Trainee Training Coordinator

13. Trainee is able to demonstrate the following knowledge/skills:

	Trainee Initials	Trainer Initials
Identify the location of procedures, worksheets, and user manuals?		
Identify test requirements including acceptable specimen type, volume, internal standards, and MRM transitions?		
Identify storage locations of reagents, supplies, QCs, stocks, and standards?		
Clean glassware and prepare mobile phases?		
Perform dilution procedures as needed?		
Perform Autotune/Checktune?		
Check LC column and replace as necessary?		
Complete instrument maintenance log sheet?		
Create and verify sequence table?		
Perform data analysis? (inspect chromatograms, verify run performance (internal standard peak area, carryover, ion ratios))		
Perform or explain basic troubleshooting techniques?		
Proper disposal of chemical and biohazard waste?		

14. Trainee has demonstrated proficiency in use of the LIMS system, including the creation of reports.

_____ _____ _____

Date Trainee Training Coordinator

LC-MS/MS Detection of Drugs in Blood: completed and reviewed.

_____ _____ _____

Trainee Training Coordinator Date

MODULE 4:

Criminal and Civil Law, Procedures, and Testimony

Objectives:

Completion of this module will provide the trainee with relevant knowledge in the following areas of criminal and civil law and procedures:

- The structure of the court system in the state of Maine
- Current Maine Rules of Evidence concerning relevancy of forensic evidence and expert testimony
- Brady and Giglio material, analyst malfeasance
- Daubert Standard for Admissibility of Evidence

Completion of this module will also provide the trainee with the requisite knowledge, skills, and abilities to provide effective testimony regarding the analysis of forensic evidence, including courtroom procedures involving:

- Oath and subsequent direct examination, including
  - Qualifications and voir dire
  - Recognition and identification of evidence
  - Chain of Custody
  - Toxicology reports
  - Explanation of examinations and conclusions
- Cross examination and redirect
- Use of visual aids or presentation materials

Required Reading Materials:

The trainee is required to complete reading or viewing of the following materials / websites related to The Criminal Courts within the State of Maine and Brady / Giglio issues.

- Maine Court Systems (by County): http://www.courts.maine.gov/maine_courts/
- Current Rules of Evidence in Maine: http://www.courts.maine.gov/rules_adminorders/rules/text/mr_evid_2015-9-1.pdf
- Maine OUI Laws: http://www.maine.gov/dps/bhs/impaired-driving/laws.html
- Brady Disclosure: https://en.wikipedia.org/wiki/Brady_disclosure
- Practical Guide to Brady Motions: http://www.ncids.org/Defender%20Training/2008%20New%20Felony%20Defender%20Training/BradyHandout.pdf
- Giglio vs. United States: https://en.wikipedia.org/wiki/Giglio_v._United_States
- Impact of Daubert on Forensic Science: https://digitalcommons.pepperdine.edu/cgi/viewcontent.cgi?article=1273&context=plr

- U.S. Justice Department Policy on Giglio: https://www.justice.gov/archives/ag/policy-regarding-disclosure-prosecutors-potential-impeachment-information-concerning-law

Required Tasks:

1. Observe a minimum of 2 courtroom testimonies from a qualified examiner in the area of toxicology. Discuss the testimony with the appropriate examiner/analyst.
2. Trainee will meet with the Forensic Lab Director / Quality Manager after reviewing the required reading to discuss violations of Brady / Giglio, as well as general analyst malfeasance in the Forensic Sciences.

Study Questions:

- Who acts as the "gatekeeper" in determining the relevance and reliability of scientific evidence?
- List the criteria used by the Courts to determine if scientific evidence is reliable
- Briefly describe the structure of the Maine court system
- What is a Brady violation?
- Define the following terms:
  - Voir dire
  - Direct examination
  - Cross examination
  - Redirect
  - Chain of custody
  - Expert witness

Exercises:

- The trainee will prepare an up-to-date curriculum vitae
- The trainee will prepare written answers to the following questions:
  - Could you please introduce yourself to the jury?
  - How are you currently employed?
  - How long have you been employed by the State of Maine as a Chemist in the Tox section?
  - What are your duties/responsibilities as a Chemist in the Toxicology section?
  - Are you certified by the State of Maine, Dept of Health and Human services (DHHS) to examine blood samples for the presence of drugs?
  - What exactly does that mean, and how do you gain such certification?
  - Can anyone gain this certification?
  - Did you have to complete any training before getting this certification?
  - Can you tell us about that training? Who provided it and what did it cover?

- How were you employed before this position?
- Can you tell us a little about your educational background?
- Are you a member of any professional societies?
- You already described your basic duties/responsibilities a Chemist in the Toxicology section, but can you elaborate on the type of testing that is conducted within the toxicology section? Meaning how does the lab receive samples? From whom? How do they get to the lab and how do they move thru the lab?
- And you, on behalf of the laboratory, issue a report that details your findings?
- Does anyone in the lab review your findings before they are released? Who and how is that accomplished?
- Do all blood samples submitted to the lab contain drugs?
- What happens if you examine a sample that is supposedly from an OUI suspect, but you don't find any drugs?
- Can you tell us what a proficiency test is?
- Are you required to perform 'proficiency tests'?
- How often?
- Are results from proficiency tests reviewed? By whom?
- What happens if you 'fail' a proficiency test?
- Have you ever failed a proficiency test?
- Can you explain (in lay-terms) what a LC/MS/MS system is, and how it detects the presence of a drug in a blood sample?
- How do you know the result is really the drug you state it is?

- The trainee will satisfactorily complete a mock trail scenario(s), to include the following sections:
  - Qualifying information
  - Recognition and introduction of physical evidence
  - An explanation of the examinations conducted and their results, using visual aids and presentation materials as applicable
  - Conclusions and interpretations

Checklist: Criminal and Civil Law, Procedures, and Testimony

1. The trainee has observed at least 2 courtroom testimonies of a court qualified examiner within HETL, and at least 1 being in the toxicology discipline. Trainee has discussed the testimony with the analyst who testified after the case is completed.

Date	DA	Witness	Defendant	Court/Charge

Trainee _____ Training Coordinator _____ Date _____

2. The trainee has satisfactorily prepared an up-to-date curriculum vitae.

Trainee _____ Training Coordinator _____ Date _____

3. The trainee has prepared satisfactory written answers to the outlined qualifying questions.

Trainee _____ Training Coordinator _____ Date _____

4. The trainee has provided satisfactory written/oral (circle one) answers to the study questions.

Trainee _____ Training Coordinator _____ Date _____

5. The trainee has met with the Forensic Lab Director / Quality Manager to discuss Brady and Giglio issues, and analyst malfeasance in general.

Trainee _____ Training Coordinator _____ Date _____

6. The trainee has successfully completed mock trial(s) covering the following areas (attach documentation):

	Completion Date	Trainee Initials
Qualifications		
Recognition/ introduction of evidence		
Examination/results/presentation materials		
Conclusions and interpretations		

Trainee _____ Training Coordinator _____ Date _____

7. The trainee has completed required reading/viewing of the following materials:

	Completion Date	Trainee Initials
Maine Court Systems		
Current Rules of Evidence in Maine		
Maine OUI Laws		
Brady Disclosure		
Practical Guide to Brady Motions		
Giglio vs. United States		
U.S. Justice Department Policy on Giglio		

Trainee _____ Training Coordinator _____ Date _____

Criminal and Civil Law, Procedures, and Testimony documented, completed, and reviewed.

Trainee _____ Training Coordinator _____ Date _____

Blood Drug Training Manual Completed:

Training Coordinator _____ **Forensic Lab Director** _____ **Date** _____

REVISED BY	REV#	DATE	Revisions
EAF	1	8/26/20	Module 3: Objectives #2 changed "validate" to "verify". Module 3: Removed Shimadzu reference from the HETL LCMSMS maintenance procedure and the HETL LCMSMS analysis, acceptance, and reporting criteria procedure. Module 3: All book literature added "(Most recent edition available at HETL)" Module 3.1: Required reading updated "Logan et al" to most recent publication 2017. Module 3.1: Removed "Shimadzu Fundamental guide to LCMS" Module 3.6: Study questions #5 removed reference to "Labsolutions"