Training

1. Purpose

To describe the training and competency testing required for staff.

2. Summary

This protocol establishes the guidelines for training, re-training, and continuing education. The training program will provide the staff with the appropriate knowledge, skills, and training to perform testing, interpretation, or technical review.

3. Procedure

Roles and Responsibilities

1. The DNA Technical Leader (DNA TL) must ensure the competence of all staff that operate specific equipment, perform tests, evaluate results, and sign test reports. The DNA Technical Leader is responsible for maintaining and ensuring compliance with IMF policies and accreditation standards of all completed training records including documentation (i.e., checklists, competency tests, authorization letters) generated as part of the training program.

2. The Trainer is a qualified scientist in the discipline or a subject matter expert that will participate in the training program through providing lectures, preparation of practical exercises, supervised casework, mentored casework or other areas of the training program when assigned. The Trainer will work with appropriate member of management and the DNA Technical Leader and other subject matter experts to develop module evaluation tests and competency tests.

3. The Trainee is the scientist undergoing the training who is responsible for the timely completion of all assignments and maintenance of the training documentation (i.e., training checklists)

Overview of the Training Program

1. The DNA Technical Leader, in conjunction with the trainee's direct reporting manager, assigns the Trainer.
2. The trainee's direct reporting manager, the DNA Technical Leader, the Trainer, and the trainee will review the section training manual or determine the modified training plan and establish an appropriate timeline for completion.
    a. It is understood that the timeline may change throughout the course of training, however, significant delays and/or supplemental activities in a training program shall be communicated by the Trainer with the DNA Technical Leader and documented in the training records.
3. The trainee will be provided with the training manual and/or modified training plan and a copy of the associated timeline.
4. A training checklist will be used document progression throughout the training program.
    a. The checklist must contain at minimum:
        i. Trainee Name
        ii. Trainer Name
        iii. Module(s) Name(s)

iv. Start Date of the training program
v. End Date of the training program
vi. Scores of exam(s)
vii. Initials of evaluator of exam(s)

5. The DNA Technical Leader should meet with the Trainer and trainee periodically to ensure timely progression during training and identify any areas of deficiency or concern.
    a. Proper progression or deficiencies in training may be measured at any time with module testing including oral, written, or practical exams. This testing must be documented in the training documentation.
    b. If at any point in the training, any areas of weakness are identified with the trainee's performance, updated training objectives and an associated timeline should be developed. The updated training plan will be disseminated to the trainee and a copy placed in the training record.
    c. When potential areas of improvement are identified in the documented training program (training manual, practical exercises, etc.) they should be reported to the DNA Technical Leader and updated accordingly.
6. The training program will consist of modules specific to the different processes involved in Forensic Biology (e.g., Extraction, Quantification, etc.)
    a. The modules are outlined in the Appendix of this document.
    b. The sequence in which the modules are presented in the training program should not be considered the mandatory order of instruction. Training modules may be presented in any order if it is within the devised training plan and timeline.
    c. Training program modules included in the training plan may vary for each trainee, depending on previous experience, job title, and other duties as assigned. However, at a minimum, the following topics must be addressed in the training program:
        i. Technical Methods and Procedures applicable to the assigned job duties
        ii. Blood Borne Pathogen and Safety Training
        iii. Evidence Handling, Sample Selection, and Sample Collection
        iv. Professional Ethics
        v. Management System Documents
        vi. General Knowledge of Forensic Sciences
        vii. Report Writing/Note Taking
        viii. Criminal Law and Civil Law
        ix. Court Testimony (Factual Witness, Expert Witness, and courtroom etiquette)
        x. Case Review (Technical and Administrative), if applicable to the assigned job duties
    d. An individual who is hired that has previous training in Forensic Biology may have their previous training and casework experience taken into consideration and a modified training program developed for them.
        i. The following documentation should be supplied by the trainee to establish a modified training program:
            1. Documentation from their previous place of employment outlining the training that they have previously conducted to include instrumentation,

methodology, theory, and chemistry to allow for an appropriate evaluation of training experience.

2. Documentation from their previous place of employment that outlines what type of casework they were authorized to conduct and instrumentation they are authorized to use.

ii. The DNA Technical Leader will review the supplied documentation to establish a suitable modified training program, if possible.

iii. The modified training plan must indicate, at minimum, the modules/topics that will be included in the trainee's training program at IMF.

7. Supervised and Mentored Casework
   a. Based on the nature of the testing being performed or the experience level of the trainee, supervised or mentored casework may be a portion of the training program.
      i. Positions applicable to supervised casework: Forensic Molecular Biologist, Laboratory Manager, Genetic Genealogy Analyst
      ii. Positions applicable to mentored casework: Forensic DNA Analyst, Senior Forensic DNA Analyst
   b. At minimum, a practical examination must be successfully completed to enter into supervised or mentored casework.
   c. The casework authorization for supervised or mentored casework must include the scope of the supervision or mentoring period and the expectation that must be met to achieve authorization to perform independent casework.
      i. If the scope of the supervision/mentoring period is based on a number of cases, the trainee is responsible for maintaining a list of the cases completed under supervision/mentoring.
         1. The list must include sufficient detail to ensure all supervised/mentored requirements are met (example: If the individual is supervised on body fluid identification testing, the information must include the case number, the date the testing was performed and the type of testing (blood/semen/saliva).
      ii. If the scope of the supervision/mentoring period is based on a date, the trainee is responsible for notifying the DNA Technical Leader when the time period has been completed.
   d. See the Definitions section for a detailed definition of Supervised and Mentored Casework

Competency Testing

1. Competency Testing regarding casework responsibilities will assess all activities, procedures, and quality control measures regarding the testing of evidence and other casework related activities that impact the quality of testing activities, including the technical review of reports. The testing required for authorization of casework responsibility will include at a minimum:
   i. Oral and/or Written Exam
      1. 80% of questions in an oral or a written exam must be correct to achieve a passing score.
      2. A final oral exam may be delivered in a mock trial format, if testimony is to be included in the trainee's duties at the laboratory.

ii. Practical Exam

1. The practical exam must contain unknown samples that cover the full spectrum of casework responsibilities/testing to be authorized.
2. For technique-dependent skills, an observation-based practical exam may be utilized where the trainee is observed by a qualified individual in the relevant skill.
    a. Alternatively, at the DNA Technical Leader's discretion, an external proctor (not qualified to do work at IMF but with documented experience in the technique) can be utilized.
        i. Documentation of any external proctor's experience in the technique must be maintained as part of the practical exam documentation.
3. Report writing **must** be included in the competency testing for individuals whose job responsibilities include report writing /authoring.
4. A grade of 80% must be achieved to successfully pass a practical examination.

2. The contents of the exams and associated key/rubric will be prepared by the DNA Technical Leader or a designee (typically the trainer or a member of management)

Authorization to Perform Casework

1. Authorization to perform casework will be issued by the DNA Technical Leader after a review of all required training documentation, demonstrating the trainee has successfully completed of the training program by the trainee (i.e., training checklist(s), graded written exams with rubric, oral examination recording/documentation with rubric, practical exam evaluation with rubric)
2. When all of the documentation is in order, the DNA Technical Leader will issue an authorization form, or its equivalent, which is signed by the DNA Technical Leader and the trainer.
    a. If the authorization is for the DNA Technical Leader, it may be signed by the trainer and an appropriate member of management.
3. Applicable members of management and staff will be notified of the authorization, once it is completed.

Training Documentation and Records

1. The following documents must be maintained to demonstrate successful completion of the training program:
    a. Training Timeline (If different from the timeline estimates in the training modules)
    b. Modified Training Plan (if Applicable)
    c. Training Checklist
    d. Module Test with answers/rubric
    e. Competency Exams with answers/rubric
    f. Authorization Documentation
2. All training records that verify the relevant authorization(s), competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel will be maintained indefinitely.
3. Training Records will be maintained on the Laboratory shared drive in the Personnel File.

Training for New Technologies, Methods, or Interpretation Software

1. The training program for newly validated methods will be determined by the DNA Technical Leader and will include the following:
    a. Theory
        i. Which may be provided in the form of required reading, lectures, or online resources
    b. Review of laboratory protocol(s)
    c. Review of validation studies and results
    d. Bench work (demonstration and/or practical assignments)
    e. Practical Competency

Re-Training

1. Retraining of an individual may be necessary as a result of an unsatisfactory result on a proficiency test, an extended absence from casework, as part of corrective or preventative action, or when determined as necessary by the DNA Technical Leader.
2. The DNA TL is responsible for evaluating the need for and assessing the extent of re-training.
3. The re-training will be documented in writing and provided to the trainee, prior to initiation of the re-training program. At minimum, a practical competency exam relevant to the task must be completed. A written or oral exam may also be assigned, at the discretion of the DNA Technical Leader.

Technical Leader Training

1. When appropriate, a Technical Leader Training Program will be based on the previous training and experience of the appointed technical leader.
    a. The newly appointed Technical Leader must be a currently or previously qualified DNA analyst in each technology used or have documented training in each technology used within one year of their appointment.
2. In addition to becoming qualified or trained in any technologies not previously or currently qualified in, the newly appointed Technical Leaders must also:
    a. Complete the FBI DNA Auditor Training Program within one year of being appointed, if necessary.
    b. Review the validation studies and analytical procedures currently used by the laboratory in addition to the educational and training records of currently qualified analysts, including technical reviewers, within one year of appointment.

Bloodborne Pathogen Training

1. All laboratory personnel who handle evidence will receive Bloodborne Pathogen Training.
    a. If the individual has previous professional laboratory experience, this training may be waived.

Safety Training

1. All laboratory personnel who handle evidence or chemicals/reagents will receive training in Laboratory Safety.
    a. If the individual has previous professional laboratory experience, this training may be waived.

Initial Ethics Training

1. All laboratory personnel will complete a review of GD 3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel-6732-5 upon hire with Intermountain Forensics.
2. This review may be supplemented by additional ethics training, as available.

3. Refer to ADM-123 Professional Development for the Annual Ethics Training requirements.

4. References

ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel

5. Definitions

Supervised Casework: the period the trainee is working under the direct supervision of a senior qualified staff member. Trainees performing supervised casework will perform the testing of actual cases submitted to the Laboratory. All work will be done under the direct supervision of a qualified scientist assigned as the trainer/instructor in a respective discipline. The trainee will complete evidence testing and prepare case documentation.

Mentored Casework: the period when the work produced by the newly authorized staff member is under review by a senior qualified staff member. Individuals authorized to perform mentored casework will perform the data analysis and author and sign reports, but report will be reviewed by a senior qualified staff member prior to undergoing standard technical and administrative reviews.

Appendix – Training Modules

Module 1: Management System

Objective: To develop a basic understanding of the policies and procedures that establish Intermountain Forensics Management System

Estimated Time: 1 week, may be completed in conjunction with module 2.

Method of Instruction: The trainee shall read the required reading and attend a presentation by the DNA Technical Leader or a designee on the accreditation standards and IMF Management System. Questions on the contents of the required reading list may be completed with the trainer, direct report manager, or DNA Technical Leader.

Required Reading List		
ADM-100	Administration	Vision and Mission
ADM-101	Administration	Facilities and Security
ADM-102	Administration	Personnel
ADM-103	Administration	Documents
ADM-105	Administration	Validations
ADM-106	Administration	Audits
ADM-107	Administration	Training
ADM-108	Administration	Proficiency Testing
ADM-109	Administration	Corrective and Preventative Action Reports
ADM-112	Administration	Corporate Structure
ADM-113	Administration	Contracts and Requests
ADM-114	Administration	Complaints
ADM-116	Administration	Deviations
ADM-117	Administration	Confidentiality
ADM-119	Administration	Keepsake DNA Analysis Terms of Service
ADM-120	Administration	Externally Provided Products and Services
ADM-123	Administration	Professional Development
ORG-200	Administration	Organizational Chart- Structure
ORG-201	Administration	Organizational Chart- Active
ORG-203	Administration	Position Summary – DNA Technical Leader
ORG-204	Administration	Position Summary –Forensic DNA Supervisor
ORG-205	Administration	Position Summary – Laboratory Manager
ORG-206	Administration	Position Summary –Sr. Forensic DNA Analyst
ORG-207	Administration	Position Summary –Forensic DNA Analyst
ORG-208	Administration	Position Summary – Forensic Molecular Biologist
ORG-209	Administration	Position Summary –Director of Laboratory Operations

ORG-210	Administration	Position Summary –Director of Laboratory Development
ORG-211	Administration	Position Summary – Genetic Genealogy Analyst
ORG-212	Administration	Position Summary – Executive Director
ORG-213	Administration	Position Summary – Director of Bioinformatics
ORG-214	Administration	Position Summary – NY DOH Laboratory Director

Evaluation: The written/oral competency which may be a combination of topics covered in Modules 1 and 2.

Module 2: Safety

Objective: To develop a basic understanding general laboratory safety when handling evidence which contain possible blood borne pathogens and chemicals and reagents.

Estimated Time: 1 week, may be completed in conjunction with module 2

Method of Instruction: The trainee shall read the listed required reading prior to completing a written competency. Questions on the contents of required reading may be completed with the trainer.

Required Reading List		
ADM-110	Administration	General Laboratory Safety
LAB-101	Operations	Chemical Hygiene and Bloodborne Pathogens

Evaluation: The written competency may be combined with the competency exam provided for Module 1

Module 3: General Forensic Science and Legal Proceedings

Objective: To develop a basic understanding of the testing procedures and sampling methods of other forensic disciplines within the laboratory, the significance of that information, the interaction between laboratory sections, and the sharing of evidence for the purpose of case management of forensic testing.

Estimated Time: 2 weeks to complete modules 1 through 3

Method of Instruction: The trainee shall read the listed required reading prior to completing a written competency. Alternatively, the readings may be substituted with a lecture by laboratory management or a review of approved multi-media resources. Questions on the contents of required reading or multimedia resources may be completed with the trainer or DNA Technical Leader.

Required Reading List
Criminalistics: An Introduction to Forensic Science, Richard Saferstein – Chapter 1: Introduction; 4-25
Forensic Science Handbook Vol. I - Legal Aspects of Forensic Science (Saferstein)
Forensic Science Handbook Vol. II - Legal Standard for Admissibility of Novel Scientific Evidence (Saferstein)

Module 4: Evidence Handling

Objective: To develop a basic understanding of the policies and procedures that govern evidence handling.

Estimated Time: Will be combined in conjunction with other modules where mock evidence would be handled. Time period is dependent on completion of the testing modules.

Method of Instruction: The trainee shall read the listed required reading and observe evidence receiving, evidence return, and evidence sampling procedures prior to completing a practical competency. Questions on the contents of required reading review may be completed with the trainer.

Required Reading List		
ADM-118	Administration	Handling of Test Items - Astrea Santa Cruz (IMF-ASC)
ADM-121	Administration	Evidence Submission Guidelines
ADM-122	Administration	Handling of Test Items - Salt Lake City (IMF-SLC)
EVD-200	Processing	Evidence Receiving
EVD-202	Processing	JusticeTrax Evidence Storage
EVD-204	Processing	JusticeTrax Evidence Documentation
EVD-205	Processing	Evidence Return
LAB-100	Processing	General Laboratory Processing

Evaluation: A practical competency which includes evidence handling at all steps of the process.

Module 5: Specialized Sampling

Objective: To develop a basic understanding of the theory and procedures for sampling of evidence items using the MVAC and bone sampling.

Estimated Time: 1 week

Method of Instruction: The trainee shall read the listed required reading prior to performing the Exercises outlined in this module. The trainee will also observe a minimum of 3 items being processed with the MVAC by an authorized staff member.

Required Reading List		
Vickar, T., Bache, K., Daniel, B., & Frascione, N. (2018). The use of the M-Vac® wet-vacuum system as a method for DNA recovery. Science and Justice. https://doi.org/10.1016/j.scijus.2018.01.003		
McLamb J, Adams L, Kavlick, M. Comparison of the M-Vac Wet-Vacuum-Based Collection Method to a Wet-Swabbing Method for DNA Recovery on Diluted Bloodstained Substrates; J Forensic Science. https://doi.org/10.1111/1556-4029.14508		
EVI-V07	Validation	M-VAC
EVD-206	Processing	M-Vac Processing
DOC-314	Documents	Laboratory Note: MVac
EVI-V08	Validation	Qiagen TissueLyser II Bone and Teeth Pre-processing extraction
EXT-202	Processing	TissueLyser II and EZ1 DNA Investigator Kit Bone/Teeth Extraction – Sample Preparation And TissueLyser Operation Sections

EXERCISE 1: M-Vac Operation

1. Process one porous item using the M-Vac
2. Process one non-porous item using the M-Vac
3. Process swabs using the M-Vac

EXERCISE 2: Bone sampling

1. Cut a minimum of 5 bone samples from one or more non-evidence bones and process them using the TissueLyser Operation procedure.

Evaluation: An observation-based practical competency which includes processing items of evidence using the procedures and evidence handling at all steps of the process.

Module 6: Chemical Test for Presumptive Presence of Blood

Objective: To develop a basic understanding of the theory and procedures for presumptive blood testing and to become familiar with the sensitivity and specificity of the test utilized.

Estimated Time: 1 week

Method of Instruction: The trainee shall read the listed required reading prior to or in conjunction with performing the Exercises outlined in this module.

Required Reading List		
RGT-200	Operations	Reagents
SER-200	Processing	Substrate Removal and Supernatant Testing
SER-202	Processing	Phenolphthalein Presumptive Test
EVI-V11	Validations	Body Fluid Testing Validation Summary
Cox, M., "A Study of the Sensitivity and Specificity of Four Presumptive Tests for Blood," Journal of Forensic Sciences, JFSCA, Vol. 36, No. 5, Sept. 1991, pp. 1503-1511.		
Tobe S, Watson N, Daeid N. "Evaluation of 6 Presumptive Tests for Blood, Their Specificity, Sensitivity, and Effect on High Molecular Weight DNA", Journal of Forensic Sciences, JFSCA, Vol. 52, No. 1.		

EXERCISE 1: Dilution and Contaminant Preparation for Blood Tests

Materials:

- Fresh whole blood
- Deionized water
- Cotton swabs or filter paper
- A variety of contaminants (i.e., food items, cleaning products, dyes)
- Tubes

Procedure:

1. Make the serial dilutions as indicated in the table below using water as your diluent. Thoroughly mix after each step. Use a new pipette tip for each dilution. The dilutions will be made in labeled tubes.

1:2 – 1,000 µL whole blood + 1,000 µL water	1:10 – 200 µL whole blood + 1800 µL water
1:4 – 1,000 µL 1:2 + 1,000 µL water	1:100 – 100 µL 1:10 + 900 µL water
1:8 – 1,000 µL 1:4 + 1,000 µL water	1:1,000 – 100 µL 1:100+ 900 µL water
1:16 – 1,000 µL 1:8 + 1,000 µL water	1:10,000 – 100 µL 1:1,000 + 900 µL water
1:32 – 1,000 µL 1:16 + 1,000 µL water	1:100,000 – 100 µL 1:10,000 + 900 µL water
1:64 – 1,000 µL 1:32 + 1,000 µL water	1:1,000,000 – 100 µL 1:100,000 + 900 µL water
1:128 – 1,000 µL 1:64 + 1,000 µL water	
1:256 – 1,000 µL 1:128 + 1,000 µL water	
1:512 – 1,000 µL 1:256 + 1,000 µL water	
1:1024 – 1,000 µL 1:512 + 1,000 µL water	
1:2048 – 1,000 µL 1:1024 + 1,000 µL water	
1:4096 – 1,000 µL 1:2048 + 1,000 µL water	

The following samples will be prepared to determine the specificity of the tests:

1. Make labeled individual cotton swabs or filter paper of each contaminant then deposit the contaminants onto labeled filter paper. Allow the swabs or filter paper to air dry. Store in labeled containers.

2. Combine samples of each of the items in the contaminant panel in a 1:1 ratio with wet blood. Make labeled individual cotton swabs or filter paper with each 1:1 mixture and also deposit the 1:1 mixtures onto labeled filter paper. Allow the swabs or filter paper to air dry. Store in labeled containers.

3. Make labeled individual cotton swabs or filter paper and deposit the 1:2 and 1:10 blood dilutions on

them. Allow the swabs or filter papers to air dry. Store in labeled containers.

EXERCISE 2: The Phenolphthalein Test (Kastle-Meyer Test)

1. Test the prepared samples using SER-202 to determine the sensitivity and specificity levels of the Phenolphthalein Test.
2. Document the results.
3. Take pictures of the results.
4. Complete the following study questions or discuss with your trainer:
    a. What is the definition of a false positive?
    b. Were any false positives observed?
    c. What is the definition of a false negative?
    d. Were any false negatives observed?
    e. What was the observed detection limit of this test for each set of samples tested?

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. A written competency to evaluate comprehension of the theory of the procedure.

Module 7: Immunological Tests for Presence of Semen or Saliva

Objective: To develop a basic understanding of the theory and procedures for semen and saliva testing using the Rapid Stain Identification immunological cassette tests marketed by Independent Forensics and to become familiar with the sensitivity and specificity of each test utilized.

Estimated Time: 2 weeks

Method of Instruction: The trainee shall read the listed required reading prior to or in conjunction with performing the Exercises outlined in this module.

Required Reading List		
RGT-200	Operations	Reagents
SER-200	Processing	Substrate Removal and Supernatant Testing
SER-201	Processing	RSID Serology Testing Devices
EVI-V11	Validations	Body Fluid Testing Validation Summary
Old J et al. Developmental Validation of RSID™-Semen: A Lateral Flow Immunochromatographic Strip Test for the forensic Detection of Human Semen", Journal of Forensic Sciences, JFSCA, Vol. 57, No. 2.		
Old J et al. Developmental Validation of RSID™-Saliva: A Lateral Flow Immunochromatographic Strip Test for the Forensic Detection of Saliva", Journal of Forensic Sciences, JFSCA, Vol. 54, No. 4.		

EXERCISE 1: Dilution and Contaminant Preparation for Tests

Materials:

- Fresh whole semen
- Fresh whole saliva

- Deionized water
- Cotton swabs or filter paper
- A variety of contaminants (i.e., food items, cleaning products, dyes)
- Tubes

Procedure:
The dilutions in the table below may be used in conjunction with Laboratory procedure for determining the detection limit of the RSID™-Semen and RSID™-Saliva Lateral Flow Immunochromatographic Strip Test for the presence of semen or saliva.

1. Make the serial dilutions as indicated in the table below using water as your diluent. Thoroughly mix after each step. Use a new pipette tip for each dilution. The dilutions will be made in labeled tubes.

1:2 – 1,000 µL whole semen/saliva + 1,000 µL water
1:4 – 1,000 µL 1:2 + 1,000 µL water
1:8 – 1,000 µL 1:4 + 1,000 µL water
1:16 – 1,000 µL 1:8 + 1,000 µL water
1:32 – 1,000 µL 1:16 + 1,000 µL water
1:64 – 1,000 µL 1:32 + 1,000 µL water
1:128 – 1,000 µL 1:64 + 1,000 µL water
1:256 – 1,000 µL 1:128 + 1,000 µL water
1:512 – 1,000 µL 1:256 + 1,000 µL water
1:1024 – 1,000 µL 1:512 + 1,000 µL water
1:2048 – 1,000 µL 1:1024 + 1,000 µL water
1:4096 – 1,000 µL 1:2048 + 1,000 µL water

The following samples will be prepared to determine the sensitivity of the tests:

2. Make labeled individual cotton swabs or filter paper of each dilution of the semen and of the saliva then deposit the body fluid dilutions onto the labeled substrate. Allow the swabs or filter paper to air dry. Store in labeled containers.

EXERCISE 2: The RSID™-Semen and RSID™-Saliva Lateral Flow Immunochromatographic Strip Test

1. Test the prepared samples using SER-201 to determine the sensitivity levels of the Tests.
2. Document the results.
3. Take pictures of the results.
4. Complete the following study questions or discuss with your trainer:
    a. What was the observed detection limit of this test for each set of samples tested?
    b. What is the high dose hook effect?
    c. What step would you take if you believe the high does hook effect is occurring?

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. A written competency to evaluate comprehension of the theory of the procedure.

Module 8: Fundamentals of Biochemistry, Molecular Biology, and Human Genetics

Objective: To demonstrate a basic understanding of the scientific theory underpinning the general concept of forensic DNA analysis.

Estimated Time: 2 weeks

Method of Instruction: The trainee shall read references provided by their trainer on the fundamentals of biochemistry, molecular biology, and human genetics. The topics will then be discussed to ensure a solid understanding of the training questions below and an ability to orally communicate the concepts.

Training Questions

- What is DNA?
- Where is it found?
- What is its structure?
- What is the composition of DNA?
- What type of bonds hold the chain together?
- What is a chromosome? A gene? A codon?
- Do any two people have the same DNA?
- How is DNA inherited?
- Define the following: allele, gene, locus, genotype, phenotype
- Is DNA the same in every diploid cell? Can there be exceptions?
- Explain the DNA in a haploid cell.
- What other DNA sources in a cell are used for forensic purposes? How are they different than traditional STR typing?
- How is mitochondrial DNA inherited? Y DNA?

Module 9: Reagent Preparation and Instrument/Equipment Maintenance

Objective: To learn the procedures associated with reagent receiving, preparation, and storage as well as instrument and equipment maintenance.

Estimated Time: No time estimate due to dependency on occurrence of maintenance

Method of Instruction: The trainee shall read the listed required reading prior to observing instrument maintenance and reagent receiving, preparation, and storage procedures. Sign off is required prior to performing maintenance independently.

Required Reading List		
MNT-200	Operations	General Maintenance
MNT-201	Operations	Qiagen EZ1 Advanced XL Instrument Maintenance
MNT-202	Operations	ProFlex Thermal Cycler Maintenance
MNT-203	Operations	ABI 3500 Genetic Analyzer Maintenance
MNT-204	Operations	ABI Quant Studio 5 Maintenance
MNT-205	Operations	Qiagen QIAcube Connect Maintenance
MNT-206	Operations	Benchmark Thermal Cycler Maintenance
MNT-207	Operations	MiSeq FGx Maintenance
RGT-200	Operations	Reagents

Evaluation: Observation of instrument maintenance and reagent preparation prior to performing the tasks independently.

Module 10: Extraction

Objective: Develop a basic understanding of the theory and procedures of DNA isolation of a variety of samples, to become acquainted with the sensitivity and limitations of the isolation procedure, to become acquainted with the robots used in the extraction procedure, and to understand the proper use of controls in the extraction procedure.

Estimated Time: 2-4 weeks

Method of Instruction: The trainee shall read the listed required reading prior to observing the method being performed. After observation, the trainee will process a range of samples using the appropriate protocols:

- Touch samples from various sources
- Hairs
- Bone/Tissue samples
- Blood samples on various substrates, including diluted and compromised blood samples
- Saliva samples on various substrates
- Reference samples
- Semen containing samples, split between a minimum of 2 QIACube Differential Washes

Required Reading List		
EXT-200	Processing	Non-Differential Extraction - EZ1 DNA investigator
EXT-201	Processing	Differential Extraction - QIAcube EZ1 DNA Investigator
EXT-202	Processing	TissueLyser II and EZ1 DNA Investigator Kit Bone Extraction
EXT-V01	Validation	Qiagen EZ1 Extraction and All Supplementals

Training Questions

- How do you extract DNA from a blood sample? A semen sample?
- Explain the use of DTT in the isolation of DNA.
- What is the function of Proteinase K in the extraction procedure?
- What is the basic principle of the EZ1 extraction?
- What controls are required for an extraction? What is the purpose of each type of control?
- What is an inhibitor and provide examples of some inhibitors found in forensic samples?
- What function does the QIACube instrument serve in extractions of semen containing samples?
- How does silica-based purification work?

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. The samples will be evaluated at minimum through quantification to ensure that DNA was obtained from the expected samples and no contamination was observed in the negative controls. The practical competency will include samples that utilized the TissueLyser, EZ1 Advanced XL, and the QIACube Connect.

Module 11: Quantitation

Objective: Develop a basic understanding of the theory and procedures of DNA quantification and to understand the proper use of controls in the procedure.

Estimated Time: 2 weeks

Method of Instruction: The trainee shall read the listed required reading prior to observing the method being performed. After observation, the trainee will quantitate a variety of sample extracts using the appropriate protocols. A minimum of three quantification plates must be run. The quantification runs may also be completed using positive controls diluted at various concentrations (i.e., a standard curve).

Required Reading List		
QTY-200	Processing	Quantification Setup
QTY-201	Processing	Quantification Data Analysis
QTY-V02	Validation	rtPCR Quant Studio 5 Quantification

Training Questions

- What is the internal PCR control and how is it used?
- Define C_T and describe its relationship to the initial template level.
- What are the four (4) phases of amplification and in which phase would the threshold be set and why? Explain what is happening in each of the four phases.
- Explain the criteria by which the standard curve is established.
- What is the passive reference and what is its purpose?

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. The results obtained from the quantifications will be evaluated to ensure that the expected results were obtained from the unknown samples and the non-template controls are not contaminated.

Module 12: Amplification and Detection

Objective: Develop a basic understanding of the theory and procedures of DNA amplification and detection for sample set up and to understand the proper use of controls in the procedure.

Estimated Time: 4 weeks

Method of Instruction: The trainee shall read the listed required reading (for the detection method being trained in) prior to observing the method being performed. After observation, the trainee will amplify a variety of sample extracts using the appropriate protocols (must amplify samples with a specific typing test kit to be qualified on that kit). A minimum of three amplifications must be performed. The amplifications may also be completed using positive controls. The samples will then be loaded on the appropriate detection system.

Required Reading List		
AMP-200	Processing	ForenSeq DNA Signature Prep
AMP-201	Processing	MiSeq FGx Operation
AMP-202	Processing	Manual Capillary Electrophoresis Amplification Setup
AMP-203	Processing	ABI 3500 Instrument Load
AMP-204	Processing	Post Quant Normalization
AMP-V03	Validation	Traditional DNA 3500 Capillary Electrophoresis and all supplementals
AMP-V04	Validation	NGS ForenSeq Signature Prep-MiSeq FGx and all supplementals

CE Training Questions

- What controls need to be initiated at the amplification step and why?
- What is a DNA Polymerase?
- What is the name of the DNA Polymerase that we are using?
- What is a primer?
- What is the function of the primer?
- Explain denaturation, annealing, and extension of the DNA.
- What is preferential amplification? Why does it occur?
- What are some of the factors that inhibit amplification and why?
- What is an STR?
- What are the advantages of PCR-STR analysis?
- Explain multiplexing and why it is utilized in forensic biology.
- What is the purpose of the normalization step?
- What affects could be introduced when DNA quantities are above/below target template values of this laboratory?
- What is the purpose of the hold at the end of the thermal cycling parameters?

NGS Training Questions

- What is depth coverage?
- What is a read?
- What is a flow cell?

- What is the difference between a patterned and nonpatterned flow cell?
- Explain sequencing by synthesis.

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. The results obtained from the detection will be evaluated to ensure that the expected results were obtained from the unknown samples and the non-template controls are not contaminated.

Module 13: Library Preparation and Next Generation Sequencing for SNPs

Objective: Develop a basic understanding of the theory and procedures of Library Preparation and Next Generation Sequencing to understand the proper use of controls in the procedure.

Estimated Time: 4 weeks

Method of Instruction: The trainee shall read the listed required reading (for the platform being trained in) prior to observing the method being performed. After observation, the trainee will perform library preparation on a variety of sample extracts using the appropriate protocols. A minimum of 2 library pools must be created.

Required Reading List		
AMP-201	Processing	MiSeq FGx Operation
AMP-202	Processing	Manual Capillary Electrophoresis Amplification Setup
AMP-205	Processing	ForenSeq Kintelligence
LIB-200	Processing	SRSLY Library Preparation
WGS-200	Processing	NovaSeq 600 Setup
AMP-V10	Validation	Verogen Kintelligence and all supplementals
WGS-V11	Validation	NovaSeq 6000 and SRSLY Preparation Method

Evaluation: A practical competency on a variety of samples which includes performing the procedure and evidence handling at all steps of the process. The results obtained from quantitation and insert size evaluation (TapeStation automated electrophoresis) will be evaluated to ensure that the expected results were obtained from the unknown samples and the non-template controls are not contaminated, as applicable. An observation-based competency will be performed to assess the skills of loading the sequencer to progress to supervised casework with casework samples.

Module 14: Data Analysis

Objective: Develop a basic understanding of the theory and procedures of Library Preparation and Next Generation Sequencing to understand the proper use of controls in the procedure.

Estimated Time: 4 - 6 weeks

Method of Instruction: The trainee shall read the listed required reading (for the platform being trained in) prior to observing the data analysis being performed. After observation, the trainee will perform data analysis and complete any associated documentation or report writing using the applicable procedures. The data and

associated reports will be assigned by the trainer after approval by the DNA Technical Leader. The trainee must also observe the technical review process and review the Technical and Administrative Review procedure, if they are to be authorized in report writing.

Required Reading List		
AMP-V09	Validation	NicheVision ArmedXpert NGS Statistical Analysis
AMP-V04	Validation	NGS ForenSeq Signature Prep-MiSeq FGx and all supplementals
AMP-V03	Validation	Traditional DNA 3500 Capillary Electrophoresis and all supplementals
AMP-V10	Validation	Verogen Kintelligence and all supplementals
WGS-V11	Validation	NovaSeq 6000 and SRSLY Preparation Method
IAC-200	Analysis	ArmedXpert™ MixtureAce
IAC-202	Analysis	Autosomal STR Interpretation
IAC-203	Analysis	Data Assessment and Rework
IAC-204	Analysis	Y-STR Interpretation
IAC-205	Analysis	GeneMapper ID-X
IAC-206	Analysis	Bioinformatic Analysis for NovaSeq Data
IAC-201	Analysis	Technical and Administrative Review

Evaluation: A practical competency on a variety of samples which includes performing the analysis and associated documentation and report writing, where applicable. The results obtained from sequencing will be evaluated to ensure that the expected results were obtained from the unknown samples and all documentation/reports were completed within the associated interpretational guidelines.

Note: Authorization to complete report writing associated with data analysis will automatically authorize the individual to also perform technical reviews, unless otherwise noted in the authorization.

Module 15: Technical and Administrative Review

Objective: Develop a basic understanding of the procedures of technical and administrative review for individuals whose job duties are limited to just that process.

Estimated Time: 2 weeks

Method of Instruction: The trainee shall read the listed required reading (for the platform being trained in) prior to observing the technical and administrative review process. After observation, the trainee will perform data analysis and complete any associated documentation or report writing using the applicable procedures. The data and associated reports will be assigned by the trainer after approval by the DNA Technical Leader. The trainee must also observe the technical review process and review the Technical and Administrative Review procedure, if they are to be authorized in report writing.

Required Reading List		
AMP-V09	Validation	NicheVision ArmedXpert NGS Statistical Analysis
AMP-V04	Validation	NGS ForenSeq Signature Prep-MiSeq FGx and all supplementals
AMP-V03	Validation	Traditional DNA 3500 Capillary Electrophoresis and all supplementals
AMP-V10	Validation	Verogen Kintelligence and all supplementals
WGS-V11	Validation	NovaSeq 6000 and SRSLY Preparation Method
IAC-200	Analysis	ArmedXpert™ MixtureAce
IAC-202	Analysis	Autosomal STR Interpretation
IAC-203	Analysis	Data Assessment and Rework
IAC-204	Analysis	Y-STR Interpretation
IAC-205	Analysis	GeneMapper ID-X
IAC-206	Analysis	Bioinformatic Analysis for NovaSeq Data
IAC-201	Analysis	Technical and Administrative Review

Evaluation: A practical competency on a minimum of one report technical and administrative review. The review documentation and corrections will be reviewed by an authorized technical reviewer to ensure that all errors were identified, and the procedure was followed when completing the review.