

Idaho State Police Forensic Services

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Quality Manager

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**Idaho State Police
Forensic Services**

Toxicology Discipline Training Plan

Section Three – Technique/Instrument Update

Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine

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Trainee: _____
Forensic Scientist _____

Trainer: _____
Forensic Scientist _____

Trainer: _____
Forensic Scientist _____

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Section Three – Technique/Instrument Update

Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine

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Section Three – Technique/Instrument Update**Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine****3.1 TRAINING OBJECTIVES**3.1.1 Introduction

This section of the Idaho State Police Forensic Services (ISP-FS) toxicology training plan is designed as a guide to provide a previously trained ISP-FS Analyst with the background necessary to screen urine specimens to detect drugs-of-abuse compounds with the EMIT principle utilizing Analytical Method 1.1.

3.1.2 Approach to Training

3.1.2.1 In order to address the training plan questions, The *Required Reading* cited, or equivalent, must be consulted if the Trainee is not familiar with the subject matter. Both the education and work experience of the Trainee must be considered, however, at least a verbal review of material for the trainer must be done to the satisfaction of the Trainer.

3.1.2.2 Answers to training plan questions may be provided verbally and/or in written form. This choice is at the discretion of the trainer.

3.1.3 Hands-on Analysis During Training Defined

3.1.3.1 As part of the training process, the Trainee will perform hands-on analysis on only urine control samples and “old” urine proficiency tests.

3.1.3.2 Due to the nature of the analysis of biological fluids to detect drug and drug metabolites, no “hands of the trainer” casework will be pursued during the training process.

3.1.3.3 The trainee will observe the trainer performing casework and can assist the trainer with preparation for analysis, solution and reference material preparation as well as data analysis print-out (non-interpretive) but until the Trainee has successfully completed all relevant training, the required competency test and signed off by the quality manager, no supervised case work will be performed.

Section Three – Technique/Instrument Update**Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine****3.2 IMMUNOASSAY**

- 3.2.1 Describe the competitive binding process as it applies to immunoassay.
- 3.2.2 The trainee must define and discuss the following terms as they related to Enzyme Immunoassay (EIA):
- 3.2.2.1 *Enzyme*
 - 3.2.2.2 *Antigen*
 - 3.2.2.3 *Antibody*
 - 3.2.2.4 *Hapten*
 - 3.2.2.5 *Cross-reactivity/analytical specificity*
 - 3.2.2.6 *Antigenic Determinant*
 - 3.2.2.7 *Cut-off*
- 3.2.3 Discuss specificity versus sensitivity as it applies to EIA.
- 3.2.4 Discuss the major differences between homogeneous and heterogeneous enzyme immunoassays.
- 3.2.5 The trainee must demonstrate a working knowledge of theory and application of enzyme-multiplied immunoassay technique (EMIT).
- 3.1.5.1 Describe the basic EMIT process.
 - 3.1.5.2 Discuss the attributes and limitations of EMIT.
- 3.2.6 Required Reading
1. Thompson, S.G., *Principles for Competitive Binding Assays*. pp. 246 – 264. *in: Clinical Chemistry: Theory, Analysis, Correlation*. Mosby, 2003.
 2. Sections Covering *Immunoassay and EMIT*. pp. 34-35, 119-139, 212, 234-235, 249, 268-269, 271, 288-292, *in: Principles of Forensic Toxicology*. Second Edition, Levine, B. ed., AACC, 2006.
 3. Spiehler, V. *Immunoassays in Toxicology*. pp. 55-98, *in: California Association of Toxicologists (CAT) Manual for Analytical Toxicology*, 1994.
 4. Liu, R.H. *Evaluation of Commercial Immunoassay Kits for Effective Workplace Drug Testing*. pp.67-130, *in: Handbook of workplace Drug Testing*. Liu, R.H. and Goldberger, B.A. eds., Washington D.C.: AACC Press, 1995.
 5. Hearn, W.L. and Walls, H.C. *Common Methods in Post-Mortem Toxicology*. pp. 995-998, *in: Drug Abuse Handbook*. Second Edition, Karch, S.B. ed., Boca Raton: CRC Press, 2007.

3.3 VIVA AUTOMATIC CHEMISTRY ANALYZER OPERATION AND MAINTENANCE

- 3.3.1 The Trainee must demonstrate their ability to apply the Viva system software to operate the analyzer.
- 3.3.2 The Trainee must demonstrate a thorough understanding of the required periodic and as needed maintenance for the Viva analyzer.
- 3.3.3 The Trainee must demonstrate a thorough understanding of troubleshooting techniques for the Viva analyzer.
- 3.3.4 Background Reading: Viva Junior™ Operation and Maintenance:
1. Viva-Jr™ Operator's Manual, Article No.: 6002-940-410, Version number: 01/04-06.
 2. Viva-Jr™ System Operations Guide, T268, 6/25/07, D01373.
- 3.3.5 Background Reading: Viva-E™ Operation and Maintenance
1. Viva-E™ Operator's Manual, Article No.: 6002-380-410-01, Version number: 1.0/08-04.
 2. Viva-E™ System Operations Guide, T216, 6/4/07, D01320.

3.4 QUALITY ASSURANCE PACKET AND CASEFILE PREPARATION

- 3.4.1 The Trainee must describe what EMIT instrument printout is required to be included in analysis casefile.
- 3.4.2 The Trainee must describe the QA data that must be compiled in centrally stored files.

3.5 ANALYSIS OF CONTROLS AND "OLD" PROFICIENCY TESTS

To develop their expertise in using Analytical Method 1.1, the Trainee will apply it to the analysis of control samples, and/or old proficiency test samples.

3.6 ANALYTICAL METHOD SIGN-OFF

- 3.6.1 The trainee must fully describe the steps involved in Analytical Method 1.1: Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine.
- 3.6.2 Trainee must describe the quality assurance requirements described in Analytical Method 1.1.
- 3.6.3 Trainee must describe the acceptance criteria for an EMIT analysis run.

- 3.6.4 Trainee must describe how quality assurance data is monitored and where it must be stored.
- 3.6.5 Required Reading
1. Analytical Method 1.1 Enzyme Immunoassay Screening for Drugs of Abuse in Urine.

3.7 **COMPETENCY TESTING FOR EMIT URINE SCREEN**

Upon the completion of this training plan update, the trainee must complete a competency test consisting of ≥ 6 specimens. The specimens will contain compounds commonly encountered in EMIT analysis.

3.8 **PERFORMANCE OF ANALYSIS ON CASE MATERIAL**

- 3.8.1 Upon successful completion of urine toxicology competency testing and the Quality Manager has reviewed and approved the training documentation, the Trainee will be responsible for the analysis casework under close supervision.
- 3.8.2 For supervised analysis, EMIT instrument data will be signed by the trainer.
- 3.8.3 Upon completion of required number of case samples and associated paperwork, the trainee can begin unsupervised casework.
- 3.8.4 Supervised Analysis Case Sample Requirements for Training Update
- 3.8.4.1 **Urine Drug Toxicology**
A minimum of 25 case samples.

Section Three – Technique/Instrument Update

Enzyme Immunoassay Screening for Drugs-of-Abuse in Urine

3.9 TRAINING PLAN TOPIC COMPLETION SIGN-OFF

3.1 TRAINING OBJECTIVES

Date of Completion

Trainee

Trainer

3.2 ENZYME IMMUNOASSAY

Date of Completion

Trainee

Trainer

3.3 VIVA CHEMISTRY ANALYZER OPERATION AND MAINTENANCE

Date of Completion

Trainee

Trainer

3.4 CASEFILE PREPARATION

Date of Completion

Trainee

Trainer

3.5 ANALYSIS OF CONTROLS AND "OLD" PROFICIENCY TESTS

Date of Completion

Trainee

Trainer

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3.9 TRAINING PLAN TOPIC COMPLETION SIGN-OFF

3.6 ANALYTICAL METHOD SIGN-OFF

Date of Completion

Trainee

Trainer

3.7 COMPETENCY TESTING - URINE

Date of Completion

Trainee

Trainer

3.8 SUPERVISED EMIT ANALYSIS OF CASE MATERIAL - URINE

Date of Completion

Trainee

Trainer

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