Idaho State Police Forensic Services

Toxicology Discipline Training Plan

Section Four – Technique/Instrument Update

Enzyme-Linked Immunosorbent Screening for Drugs-of-Abuse

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Section Three – Technique/Instrument Update

Immunoassay Screening for Drugs-of-Abuse in Blood and Urine

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Issuing Authority: Quality Manager Rev. 0, Issued: 4/10/2012

Section Three – Technique/Instrument Update

Immunoassay Screening for Drugs-of-Abuse in Blood and Urine

4.1 TRAINING OBJECTIVES

4.1.1 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 blood or urine specimens to detect drugs-of abuse

- aress the training plan questions availent, must be consulted if the Trainee per matter. Both the education and work experence be considered, however, at least a verbal review aniner must be done to the satisfaction of the Trainer.

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

Issuing Authority: Quality Manager Rev. 0, Issued: 4/10/2012 SECTION 4- Tox training plan – ELISA ONLY

Section Three – Technique/Instrument Update

Immunoassay Screening for Drugs-of-Abuse in Blood and Urine

4.2 IMMUNOASSAY

- 4.2.1 The trainee must demonstrate a working knowledge of theory and application of enzyme-linked immunosorbent assay (ELISA) technique.
 - 4.2.2.1 Describe the basic ELISA process.
 - 4.2.2.2 Discuss the attributes and limitations of ELISA.

3.3 DSX Chemistry ANALYZER OPERATION AND MAINTENANCE

- 4.3.1 The Trainee must demonstrate their ability to apply the DSX system software to operate the analyzer.
- 4.3.2 The Trainee must demonstrate a thorough understanding of the required periodic and as needed maintenance for the DSX analyzer.
- 4.3.3 The Trainee must demonstrate a thorough understanding of troubleshooting techniques for the DSX analyzer.

4.3.4 <u>Background Reading:</u>

- 4.3.4.1 Butler, J.E. **Enzyme-Linked Immunosorbent Assay**. pp. 759-803 *In*: "Immunochemistry". Van Oss, C.J.; van Regenmortel, M.H.V., eds., Marcel Dekker, inc. New York, NY: 1994.
- 4.3.4.2 Sections Covering *Immunoassay and ELISA*. Refer to index for pages, *inte* Principles of Forensic Toxicology, Second Edition, Levine, B. ed., ACC 2003 or prore recent version.
- 4.3 → 3 DSX Automated ELISA System™ User's Manual, REV.04-20-05, 2005.
- 4.3.4.4 OraSure Technologies DSX™ Startup Procedure and Setup of a Worklist.
 - 4.3.4.5 OraSure Technologies Package Inserts for Serum Microplate EIA.

4.4 OUALITY ASSURANCE PACKET AND CASEFILE PREPARATION

- 4.4.1 The Trainee must describe how ELISA-generated data is to be included in analysis casefile.
- 4.4.2 The Trainee must describe the QA data that must be compiled in centrally stored files.

4.5 ANALYTICAL METHOD SIGN-OFF

- 4.5.1 The trainee must fully describe the steps involved in Analytical Method 1.0: Enzyme-Linked Immunosorbent Screening for Drugs-of-Abuse in Blood and Urine.
- 4.5.2 Trainee must describe the quality assurance requirements described in Analytical Method 1.0.
- 4.5.3 Trainee must describe the acceptance criteria for an ELISA analogis run.
- 4.5.4 Trainee must describe how quality assurance data is monitored and where it must be stored.

4.5.5 Required Reading

1. Analytical Method 1.0 Enzyme-Linked Immunosorbent Assay Screening for Drugs of Abuse in Blood and Urine.

4.6 COMPETENCY TESTING FOR ELISA 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 ELISA analysis or participate in the validation of the instrument and demonstrate competency by testing controls and case samples in parallel with another screening method.

4.7 COMPETENCY TESTING FOR ELISA BLOOD 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 of participate in the validation of the instrument and demonstrate competency by testing controls and case samples in parallel with another screening method.

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Toxicology Discipline Training Plan

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Revision History

Section Three – Technique/Instrument Update

Immunoassay Screening for Drugs-of-Abuse in Blood and Urine

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