Training Procedure for Immunoassays

1.0 Purpose - An Immunoassay (IA) is a biochemical test that measures the presence of an antigen or antibody. In Forensic Toxicology, IA is used to determine the presence or absence of drugs or drug classes in a biological fluid such as blood, serum or urine. An IA is generally considered a preliminary test (i.e., it lacks the specificity to be considered conclusive) and semi-quantitative (i.e., there is some correlation between the amount of substance present and test response).

2.0 Scope - This procedure applies to trainees in the Toxicology Section of the State Crime Laboratory (SCL).

3.0 Procedure

3.1 Objectives

3.1.1 Review the Enzyme Immunoassay (EIA) procedure, and be able to discuss the following:

- The assays/kits used to analyze blood.
- The assays/kits used to analyze urine.
- The daily and weekly maintenance tasks.
- The quality control samples used.
- How blood and urine sample results are evaluated.

3.1.2 Be knowledgeable of the basic theory of an IA.

3.1.3 Be knowledgeable of different types of IA.

3.1.4 Understand the limitations of an IA.

3.1.5 Exhibit proficiency operating the IA instrumentation.

3.1.6 Be knowledgeable of Toxicology Drug Screen reporting statements described in the Drug Toxicology Reporting procedure.

3.1.7 Successfully complete a practical and a written exam with a minimum score of 85 %.

3.1.8 If given IA QC data, a sample's drug concentration and cross reactivity, estimate the sample's IA results.

3.2 Study Questions

3.2.1 Explain the basic principle of IA used in Forensic Toxicology. Include the ELISA technique used in the Toxicology Section.

3.2.2 What is meant by a homogenous/heterogeneous assay?

3.2.3 Define the term cross reactivity as it applies to IA.

3.2.4 Describe at least four common IA techniques, include EMIT and ELISA.

3.2.5 How are calibrators and controls utilized in IA techniques?

3.2.6 Explain why an IA is considered semi-quantitative.

3.2.7 Can an IA be used to conclusively identify a drug or controlled substance?

3.2.8 What are the calibrator concentrations based on?

3.3 Practical/Laboratory Exercises

3.3.1 Prior to working with any new chemical, solution, or standard, read and comprehend the SDS for each chemical used in the procedure. This includes the determination of which PPE and administrative / engineering controls are required when handling each.

3.3.2 Analyze a set of known samples provided by the Toxicology Training Coordinator, using the current immunoassay procedure(s).

3.3.2.1 Review the results with the Toxicology Training Coordinator or designee.

3.3.3 Your IA results show a significantly high positive result for benzodiazepines. However, in the course of your GC/MS analysis of this same sample you see very weak TIC peaks and MS with only major ions for diazepam, nordiazepam, midazolam and alprazolam. Explain the IA results.

3.3.4 Practical Exam: Analyze a set of unknown samples provided by the Toxicology Training Coordinator using the current immunoassay procedure.

3.3.4.1 The Toxicology Training Coordinator, or designee, will evaluate the results for precision and consistency to previous results.

3.4 Required Reading

3.4.1 Toxicology Section Technical Procedures and references:

3.4.1.1 Enzyme Immunoassay (EIA) procedure

3.4.1.2 Drug Toxicology Reporting procedure

3.4.1.3 Toxicology Quality Assurance

3.4.2 Current IA kit inserts.

4.0 References

Clarke, E.G.C., ed. *Clarke's Analysis of Drugs and Poisons.* 3rd Ed. London, England: The Pharmaceutical Press, 2004.

Goldfrank, Howland, et al. *Goldfrank's Toxicological Emergencies.* 7th Ed. USA: McGraw-Hill Company, Inc., 2002.

Williams, Phillip L., et al. *Principles of Toxicology*. New York: John Wiley and Sons, 2000.

Ellenhorn, Matthew J. and Donald G Barceloux. *Medical Toxicology – Diagnosis and Treatment of Human Poisoning*. New York: Elsevier Science Publishing Co. Inc., 1988.

5.0 Safety

- This document provides an outline for training on procedures that are written in additional detail in specific Toxicology Section documents. To see safety hazards for particular procedures, refer to that specific procedure.

6.0 Records

Toxicology Drug Training Checklist

Training Section Completion Summary

Revision History		
Effective Date	Version Number	Reason
12/09/2020	5	Removed references to Drug Chemistry Section References to Toxicology Unit Replaced with Toxicology Section3.1.1, 3.1.6, 3.4.1.1, and 3.4.1.2 -Updated procedure references 3.1.5 Abbreviated 3.2.8 - New 3.3.1 New 5.0 New