
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 Units of the State Crime Laboratory.

3.0 Procedure

3.1 Objectives

3.1.1 Review the [Technical Procedure for ELISA Drug Screen](#), 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 used to document the verification of by the State Crime Laboratory.

3.1.6 Be knowledgeable of Toxicology Drug Screen reporting statements described in the [Procedure for Toxicology Analysis](#).

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 Unit.

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?

3.3 Practical/Laboratory Exercises

- 3.3.1 Analyze a set of known samples provided by the Toxicology Training Coordinator, using the current immunoassay procedure(s).
 - 3.3.1.1 Review the results with the Toxicology Training Coordinator or designee.
- 3.3.2 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.
- 3.3.3 Practical Exam: Analyze a set of unknown samples provided by the Toxicology Training Coordinator using the current immunoassay procedure.
 - 3.3.3.1 The Toxicology Training Coordinator, or designee, will evaluate the results for precision and consistency to previous results.

3.4 Required Reading

- 3.4.1 Drug Chemistry Section Toxicology Unit Technical Procedures and references:
 - 3.4.1.1 [Technical Procedure for ELISA Drug Screen](#)
 - 3.4.1.2 [Procedure for Toxicology Analysis](#)
 - 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 Records

Toxicology Drug Training Checklist

Training Section Completion Summary

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
05/10/2013	2	3.1.7 - inserted criteria for successful completion
11/15/2013	3	Added issuing authority to header
08/29/2014	4	2.0 - made consistent with other documents 3.1.1 – removed references to obsolete procedures, and listed expectations. 3.1.6 – listed procedure to reference. Added 3.1.8 3.2.1 – removed obsolete method Split second part of 3.2.3 to create new 3.2.7 3.2.5 – corrected typo 3.3.1 and 3.3.3 - removed references to obsolete procedures 3.3.1.1 – added “or designee” Added 3.3.3.1 3.4 and 4.0 - removed references to obsolete procedures Added 3.4.1.3