Toxicology Analysis

1.0 Purpose - This procedure specifies the required elements for analyzing toxicology submissions and reporting drug testing results.

2.0 Scope – This procedure applies to all submissions to the Toxicology Units of the State Crime Laboratory.

3.0 Definitions

- **Blood Drug Testing –** Use of the Toxicology Unit ELISA Drug Screen procedure followed by the Toxicology Unit Solid Phase Extraction of Acidic, Neutral and Basic Drugs for GC-MS Analysis procedure, and/or Toxicology Unit Technical Procedure for Blood Cannabinoid Liquid-Liquid Extraction (BCLLE) for Analysis by LC-MS/MS procedure, and/or Technical Procedure for Phenethylamine Liquid-Liquid Extraction, (PHEALLE) for Analysis by GC-MS Analysis followed by the Toxicology Unit Toxicology Gas Chromatography-Mass Spectrometry (GC-MS) and/or Toxicology Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) procedure.
- **Drug** – "a. substances recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; b. substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; c. substances (other than food) intended to affect the structure or any function of the body of man or other animals; and d. substances intended for use as a component of any article specified in a, b, or c of this subdivision; but does not include devices or their components, parts, or accessories." (NCGS 90-87 (12))
- **Immunoassay Blood Drug Screen Testing**- Amphetamine, Barbiturates, Benzodiazepines, Carisoprodol, Cocaine Metabolite (Benzoylecgonine-BE), Cannabinoids (THCA/CTHC), Methadone, Methamphetamine, Opiates, Oxycodone / Oxymorphone, Tramadol, and Zolpidem Direct ELISA Assay Kits used in the Toxicology Unit ELISA Drug Screen procedure. The Carisoprodol Direct ELISA kit as titled by the manufacturer, Immunalysis, is equally capable of detecting the presence of meprobamate; therefore, the immunoassay drug screen report statement also reflects Meprobamate as part of the screening test. The Amphetamine Direct ELISA kit as titled by the manufacturer, Immunalysis, is equally capable of detecting the presence of 3,4-methylenedioxyamphetamine (MDA); therefore, the immunoassay drug screen report statement also reflects MDA as part of the screening test. The Methamphetamine Direct ELISA kit as titled by the manufacturer, Immunalysis, is equally capable of detecting the presence of 3,4-methylenedioxymethamphetamine (MDMA); therefore, the immunoassay drug screen report statement also reflects MDMA as part of the screening test.
- **Immunoassay Urine Drug Screen Testing**– Barbiturates, Benzodiazepines, Cocaine metabolite (Benzoylecgonine-BE), Methadone, Methamphetamine and Opiates assay kits used in the Toxicology Unit ELISA Drug Screen procedure. The selection of assays was based on the prevalence of use in the population and to help determine analytical direction. The Methamphetamine Direct ELISA kit as titled by the manufacturer, Immunalysis, is equally capable of detecting the presence of 3,4-methylenedioxymethamphetamine (MDMA); therefore, the immunoassay drug screen report statement also reflects MDMA as part of the screening test.
- **Impairing Substance** – Alcohol, controlled substance under Chapter 90 of the General Statutes, any other drug or psychoactive substance capable of impairing a person's physical or mental faculties, or any combination of these substances. (NCGS 20-4.01 (14a))
- **Metabolite** – A product of a biotransformation action on the drug.
- **Urine Drug Testing** – The use of the Toxicology Unit ELISA Drug Screen procedure in the analysis followed by the Toxicology Unit Solid Phase Extraction of Acidic, Neutral and Basic Drugs for GC-MS Analysis procedure and/or Technical Procedure for Phenethylamine Liquid-Liquid Extraction, (PHEALLE) for Analysis by GC-MS Analysis followed by the Toxicology Unit Toxicology Gas

Chromatography-Mass Spectrometry (GC-MS) procedure. Cannabinoids Immunoassay Drug Screen Testing shall not be performed in urine drug testing.

4.0 Equipment, Materials and Reagents – N/A

5.0 Procedure

5.1 Analysis and Reporting of Blood/Urine Drug Testing:

5.1.1 Use the Toxicology Unit ELISA Drug Screen procedure.

5.1.2 Immunoassay (ELISA) results shall meet the requirements listed in the Toxicology Unit ELISA Drug Screen procedure.

5.1.3 Immunoassay drug screen reporting statements:

5.1.3.1 If there are indicative immunoassay results, the following results statement shall be used:

Immunoassay drug screening tests for the following drugs or classes of drugs gave a positive indication: {list the assays that are positive}.

5.1.3.2 If there are negative immunoassay results, the following results statement shall be used:

Immunoassay drug screening tests for the following drugs or classes of drugs were negative: {list the assays that are negative}.

5.1.3.2.1 If the submission does not contain any drug specific request(s) and all drug screening tests are negative, no additional analysis will be conducted except as defined in 6.2 and the following results statement shall be added:

Confirmatory analysis was not performed.

5.1.4 Use the appropriate Toxicology Unit extraction procedures under the following circumstances:

5.1.4.1 The immunoassay results give a positive indication.

5.1.4.2 The submission contains other drug specific request(s).

5.1.5 Reporting criteria:

5.1.5.1 Substances for which there is an Immunoassay Drug Screen shall be evaluated as positive by that screen. In addition, the substance shall be identified by a mass spectrum comparison and a relative retention time comparison.

5.1.5.2 Substances for which there is not an Immunoassay Drug Screen that are identified in one aliquot may be reported if the case history verifies the

identification (e.g., Promethazine identified in a base extraction in a case involving medical treatment, a prescription log).

5.1.5.3 Substances which do not have an Immunoassay Drug Screen and do not meet the criteria in **5.1.5.2** shall be identified by a mass spectrum comparison and a relative retention time comparison in each of a minimum of two samplings. Substances that are either the parent drug or metabolite of a substance that does have an Immunoassay Drug Screen may be identified from only one sampling if the parent drug or metabolite is identified in the case.

5.1.5.4 Tetrahydrocannabinol (THC), 11-hydroxy-Δ9-tetrahydrocannabinol (11-OH-THC), and 11-nor-*delta*-9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH) shall meet the identification requirements listed in the Toxicology Unit Procedure for Blood Cannabinoid Liquid-Liquid Extraction (BCLLE) for Analysis by LC-MS/MS.

5.1.5.5 Phenethylamines shall meet the identification requirements listed in the Toxicology Unit Procedure for Phenethylamine Liquid-Liquid (PHEALLE) for Analysis by GC-MS Analysis. The Technical Leader may approve an exception for this requirement when a phenethylamine has been previously identified in the analysis involving the Procedure for Solid Phase Extraction of Acidic, Neutral Basic Drugs for GC-MS Analysis, and the quantity of specimen remaining is insufficient for analysis by the PHEALLE Procedure.

5.1.6 Blood/Urine Drug Testing reporting statements:

5.1.6.1 If the analysis did not identify any drugs and/or their metabolites, use the following statement:

No impairing substances were identified.

5.1.6.2 If analysis results in the detection of alcohol and/or other volatiles, but no drugs and/or their metabolites were identified, and both results will be listed on the report, use the following statement:

No other impairing substances were identified.

5.1.6.3 If the analysis did identify impairing substances and/or their metabolites, use the statement below followed by the identity of the substance(s) identified.

Analysis confirmed the presence of the following substances: {insert the substances identified}

5.1.6.4 If a positive immunoassay drug screen assay(s) was not confirmed and/or an analysis for a specifically requested non-immunoassay screened substance(s) was not confirmed, use the following statement(s) as applicable (**refer to Limitations 6.4, 6.5, 6.6)**.

5.1.6.4.1 Confirmatory testing for (insert assay(s) and/or specifically requested non-immunoassay screened substance(s)) was performed, but was/were not identified.

5.1.6.4.2 (List the specifically requested substance(s)) generally cannot be identified by current State Crime Laboratory analytical procedures.

5.1.6.5 Reporting statements not included above may be needed to convey the analysis results. These reporting statements shall be approved by the Toxicology Technical Leader or designee and the approval shall be documented in the case record.

5.2 Application of Procedure on Evidence - Insufficient Specimen

5.2.1 If a specimen is submitted with insufficient volume for analysis, add the following statement to the report:

Quantity of specimen submitted is insufficient for analysis.

5.2.2 If the specimen volume is insufficient to complete the requested analysis, add the following statement to the report:

Quantity of specimen submitted is insufficient for complete analysis.

5.3 Disposition Statement on Laboratory Reports

5.3.1 The following disposition statement will be used for DWI and Non-DWI Toxicology Laboratory reports that are not returned via First Class Mail or Retained for Pickup:

5.3.1.1 The evidence will be retained until otherwise authorized.

5.3.2 The following disposition statement will be used for DWI and Non-DWI Toxicology Laboratory reports where subsequent analysis will be performed.

5.3.2.1 The evidence will be retained for further analysis.

5.4 Standards and Controls – N/A

5.5 Calibrations – N/A

5.6 Maintenance – N/A

5.7 Sampling – N/A

5.8 Calculations – See Drug Chemistry-Toxicology Unit technical procedures.

5.9 Uncertainty of Measurement – Refer to the individual technical procedures and the Drug Chemistry Section Technical Procedure for Measurement Assurance.

6.0 Limitations

6.1 Toxicology reporting capabilities are based upon the techniques used and reference standards available. These shall be updated by the Toxicology Technical Leader as needed.

6.2 No further analysis shall be performed for DWI submissions with a blood alcohol concentration at or greater than 0.08 g/100 mL of whole blood, unless the case involves a death or personal injury to someone other than the driver, or the Forensic Scientist Manager approves a request from the District Attorney's office. The request must be received subsequent to the alcohol results being conveyed to the District Attorney's office, and the approval shall be documented in the case record.

6.3 In the event that additional analysis is performed on the same evidence after a report has been released (i.e., drug analysis is requested after a blood alcohol, volatiles and /or drug screen only report has been issued), the subsequent report shall contain only the results of the additional analysis.

6.4 When the Oxycodone / Oxymorphone immunoassay drug screen result gives a positive indication and neither the oxycodone nor the oxymorphone were confirmed, the reporting statement 5.1.6.4.2 will be used to report the limitation for the oxymorphone confirmation.

6.5 Not all known substances that cross-react with the immunoassay drug screening tests can generally be confirmed by current State Crime Laboratory analytical procedures. When a substance of this type is specifically requested and is not confirmed, the reporting statement 5.1.6.4.2 will be used to report the limitation.

6.6 Substances that generally cannot be identified by current State Crime Laboratory analytical procedures are listed in the ***Toxicology GCMS Reporting Index***.

7.0 Safety

7.1 Refer to the Laboratory Safety Manual.

7.2 Refer to the Toxicology Unit Technical Procedures.

8.0 References

Toxicology Unit Technical Procedures:

ELISA Drug Screen

Solid Phase Extraction of Acidic, Neutral and Basic Drugs for GC-MS Analysis

Technical Procedure for Phenethylamine Liquid-Liquid Extraction, (PHEALLE) for Analysis by GC-MS Analysis

Technical Procedure for Blood Cannabinoid Liquid-Liquid Extraction (BCLLE) for Analysis by LC-MS/MS

Toxicology GCMS Reporting Index

Williams, Philip L., et al. *Principles of Toxicology Environmental and Industrial Applications*, 2nd edition. A Wiley Interscience Publication John Wiley & Sons, Inc, © 2000: 5.

Forensic Toxicology Laboratory Guidelines, 2006 version; SOFT / AAFS.

9.0 Records

- Case Record

10.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	2008-DCS-05 Toxicology Criteria for Identification of Analytes revision and conversion to ISO format
10/26/2012	2	3.0 - Removed redundant definition, clarified wording for consistency throughout procedure, updated name of ELISA procedure, alphabetized; 5.2.4 - consolidated small volume statement with unusual observations; 5.2.7 - clarified requirement to be consistent with lab-wide procedures; 5.3.1.2.3 - removed redundant wording; 5.3.2.1, 5.3.2.5.1, 5.4.1.2, 5.4.2.3,5.4.3.2, and 8.0 - updated name of ELISA procedure; 5.6 - removed reference to poison testing, changed to include reporting statements for insufficient specimen volumes
02/15/2013	3	2.0 Modified Scope (and Document) to include Triad Laboratory 3.0: Removed redundant definitions Removed previous sections 5.1 and 5.2 and placed in new procedure and renumbered subsequent sections 5.1: Title changed 5.1.1: Removed and adjusted indention of subsequent sections 5.1.2.7: Reworded Previous 5.3.2 now 5.2: Title changed to consolidate previous 5.4.1.6, 5.4.1.7, 5.4.2, and 5.4.3 5.2.5.2: inserted new reporting criteria 5.2.5.3: inserted language to address criteria in 5.2.5.2 Subsequent sections reorganized for structure and better flow. Previous 5.3.3 Removed - redundant Previous 5.4 now 5.3: Title changed Previous 5.5 now 5.4: Title changed 6.1: Reworded 6.3: Reworded for consistency with change in 5.1.2.7
05/10/2013	4	5.10 and 5.11 - changed "N/A" to refer to technical procedures
06/14/2013	5	1.0 – Amended purpose to reflect changes throughout procedure 3.0 - Removed alcohol related definitions Removed alcohol related reporting statements and added to Technical procedure for Headspace Gas Chromatography to Quantitate and Identify Volatiles in Liquids (previous sections 5.1, 5.3, and 5.4)

11/15/2013	6	Added issuing authority to header
03/14/2014	7	Definitions - Replaced references to the solid phase extraction procedure with the liquid-liquid extraction procedure 5.1.5.4 – added 11-OH-THC to list of analytes, and replaced references to the solid phase extraction procedure with the liquid-liquid extraction procedure 8.0 – replaced procedure reference
05/09/2014	8	3.0 – Removed references to GHB procedure and added reference to Phenethylamine Extraction procedure. 5.1.5.3 – Updated reference and added criteria regarding Immunoassay Screens 5.1.5.5 – Removed reference to GHB and replaced section with Phenethylamine Extraction. 5.1.6.5 – Modified wording 6.5 – Removed reference to GHB. 8.0 – Removed reference to GHB and alcohol procedures added reference to Phenethylamine Extraction 5.1.6.2 - grammar
08/29/2014	9	3.0 – Updated the definition for the Immunoassay Blood Drug Screen Testing to include the Amphetamine and Oxycodone / Oxymorphone assay kits. 5.1.3.2.1 – Removed due to the elimination of using elevated immunoassay results and replaced with a new reporting statement covering the conclusion for all negative immunoassay results. 5.1.4.1 – Removed reference to elevated results. 5.1.4.2 – Removed and now covered in 5.1.3.3. 5.1.4.3 – Added “drug” and “(s)” to the end of the word “results” for clarification. 5.1.5.1 – Removed reference to elevated results. 5.1.6.4 – Removed reference to elevated results. 5.3 – Inserted information explaining the Disposition Statement used on reports. 6.2 – Removed due to the elimination of using elevated immunoassay results.
03/20/2015	10	3.0 - Updated the definition for the Immunoassay Blood Drug Screen Testing to include Meprobamate use on the report. Updated wording for clarity. Added clarification for the Methamphetamine Direct ELISA kit reporting for Urine 5.1.3.2.1 - Added criteria for clarification of the application of the reporting statement 5.1.4.1 and 5.1.4.2 - removed redundant language 5.1.6.2 - Added criteria for clarification of the application of the reporting statement 5.1.6.5 - Replaced with new reporting criteria, and 5.1.6.4: Reworded to incorporate an updated reporting application and statements. 5.3.2 -Added to incorporate additional disposition statement 6.4, 6.5, and 6.6 - New limitations added 8.0 - New reference added