Deviation Request Form

Directions: The Initiator shall complete Sections A through C. Additional continuation pages can be included if necessary.
The affected Procedure Approver (i.e., Forensic Scientist Manager) shall complete Section D. The Deputy Assistant Director shall complete Section E.

Initiator	Aaron Joncich	Date	9/24/2013

A. Requested deviation applies to (Technical Procedure- include specific section):

Drug Chemistry - Toxicology - Technical Procedure: Toxicology Analysis-06-14-2013.pdf
Sections 5.1.4.1 and 5.1.6

B. Requested deviation and duration:

In cases where a drug screen indicates the presence of cannabinoids, but confirmatory testing for cannabinoids is not necessary according to the DA's office:

- Remove the requirement of section 5.1.4.1 for cannabinoid positive immunoassays. ("5.1.4.1 If the immunoassay results give a positive indication or elevated (see 6.2) for any assay, that assay will be confirmed.")

- In section 5.1.6, allow the use of the following reporting statement: "Confirmatory testing for cannabinoids cannot be performed at this time".

C. Necessity for the deviation:

The quantitation of cannabinoids is currently not possible, and has been determined to not be necessary in some cases. There is no reporting statement listed in the referenced procedure that can be used to address this situation.

Form approved for use by: Chuck McClelland

Digitally signed by Chuck McClelland
DN: cn=Chuck McClelland, o, ou, email=cmcclelland@ncdoj.gov, c=US
Date: 2013.05.30 09:34:05 -04'00'

D. Technical review and Authorization (to be completed by the Forensic Scientist Manager or designee)					
Comments (to include merits and impacts):					
Approved	☑ Yes	☐ No	Duration of deviation: 90 days		
Sign	Timothy Suggs Digitally signed by Timothy Suggs DN: cn=Timothy Suggs, o=North Carolina State Crime Laboratory, ou=Trace Evidence Section, email=tsuggs@ncdoj.gov, c=US Date: 2013.09.25 08:22:36 -04'00'			Date	9/25/2013

E: **Quality Assurance Authorization (to be completed by Deputy Assistant Director/QM or designee):**

Acceptable within general QA guidelines and good laboratory practice?	☑ Yes	☐ No		
Significant negative impact to Crime Laboratory Quality Standards?	☐ Yes	☑ No		
Restrictions/limitations: 90 days				
☑ Authorized	☐ Rejected	Sign	Date	9/25/13

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, Toxicology Unit Solid Phase Extraction of THC and THC-COOH for GC-MS Analysis procedure, and/or Toxicology Unit Liquid-Liquid Extraction of Gamma Hydroxybutyric Acid (GHB) in Blood and Urine for GC-MS Analysis procedure, followed by the Toxicology Unit Toxicology Gas Chromatography-Mass Spectrometry (GC-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**- Barbiturate, Benzodiazepines, Carisoprodol, Cocaine Metabolite (Benzoylecgonine-BE), Cannabinoids (THCA/CTHC), Methadone, Methamphetamine, Opiates, Tramadol, and Zolpidem Direct ELISA Assay Kits used in the Toxicology Unit ELISA Drug Screen procedure. The Methamphetamine Direct ELISA kit as titled by the manufacturer, Immunalysis, is also 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**– Barbiturate, 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.
- **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 Toxicology Unit Liquid-Liquid Extraction of Gamma Hydroxybutyric Acid (GHB) in Blood and Urine for GC-MS Analysis procedure, 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.

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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}.

5.1.3.3 If there are elevated results, as defined in **6.2**, the following result statement shall be used:

Immunoassay drug screening test results required further evaluation by confirmatory testing for the following class(es) of drugs: {list the assays, as defined in **6.2**, that are elevated}. The results of confirmatory testing are listed below.

5.1.4 Use the appropriate Toxicology Unit extraction procedures applying the following criteria:

5.1.4.1 If the immunoassay results give a positive indication or elevated (see **6.2**) for any assay, that assay will be confirmed.

5.1.4.2 If the immunoassay results are negative for all assays, at minimum a base extraction using the Toxicology Unit Solid Phase Extraction of Acidic, Neutral and Basic Drugs for GC-MS Analysis procedure shall be performed.

5.1.4.3 If the submission contains any other specific requests, use the Toxicology Unit technical procedures to perform the appropriate extraction(s) and GC-MS analysis.

5.1.5 Reporting criteria:

5.1.5.1 Substances for which there is an Immunoassay Drug Screen shall be evaluated as positive or elevated by that screen. See **6.2** for elevated limitations. 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).

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5.1.5.3 Substances which do not have an Immunoassay Drug Screen and do not meet the criteria in **5.2.5.2** shall be identified by a mass spectrum comparison and a relative retention time comparison in each of a minimum of two samplings.

5.1.5.4 *delta*-9-Tetrahydrocannabinol (THC) and 11-nor-*delta*-9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH) shall meet the identification requirements listed in the Toxicology Unit Solid Phase Extraction of THC and THC-COOH for GC-MS Analysis procedure.

5.1.5.5 *gamma*-Hydroxybutyric acid (GHB) shall meet the identification requirements listed in the Toxicology Unit Liquid-Liquid Extraction of Gamma Hydroxybutyric Acid (GHB) in Blood and Urine for GC-MS Analysis procedure. See **6.5** for GHB limitations.

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, however, no drugs and/or their metabolites were identified, 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 analysis for a specific impairing substance(s) was requested and/or if an immunoassay screen was positive/elevated (see 6.2), and not confirmed/identified by the appropriate Toxicology Unit analytical procedures, add the following statement to the report:

Confirmatory Testing for (insert assay, chemical/ and/or trade name of substance(s) requested) was performed, but was/were not identified.

5.1.6.5 If analysis for an impairing substance(s) was requested which generally cannot be identified by current Toxicology Unit analytical procedures, add the following statement to the report:

Analysis for (insert chemical and/or trade name of substance(s) requested) was/were requested, but cannot be detected by the current State Crime Laboratory analytical procedures.

5.2 Application of Procedure on Evidence - Insufficient Specimen

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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 Standards and Controls – N/A

5.4 Calibrations – N/A

5.5 Maintenance – N/A

5.6 Sampling – N/A

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

5.8 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 The only elevated ELISA drug screens considered for confirmation via the Toxicology Unit Solid Phase Extraction of Acidic, Neutral and Basic Drugs for GC-MS Analysis procedure shall be the benzodiazepines and opiates assays.

6.3 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.

6.4 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 and/or other volatiles report has been issued), the subsequent report shall contain only the results of the additional analysis.

6.5 GHB analysis shall not be performed when the measured blood alcohol concentration is 0.15 g/100 ml or greater.

7.0 Safety

7.1 Refer to the Laboratory Safety Manual.

7.2 Refer to the Toxicology Unit Technical Procedures.

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8.0 References

Toxicology Unit Technical Procedures:

Headspace Gas Chromatography to Quantitate and Identify Volatiles in Liquids

ELISA Drug Screen

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

Liquid-Liquid Extraction of Gamma Hydroxybutyric Acid (GHB) in Blood and Urine for GC-MS Analysis

Solid Phase Extraction of THC and THC-COOH for GC-MS Analysis

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

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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

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