Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	Amber Rowland	**Date**	6/30/2020

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

Drug Toxicology Reporting Section 5.1 and 5.2

B. Requested deviation:

5.1.2 Change reporting statement
From - "Immunoassay drug screening tests for the following drugs or classes of drugs were negative: {list the assays that are negative}.
To - "Immunoassay drug screening did not detect the following drugs or classes of drugs: {list the assays that were not detected}.

Insert New5.2.4 (Shift other sections down):
If analysis did not detect the presence of a requested substance(s), use the statement below:
"Analysis did not detect the presence of the following substance(s):(substance(s) requested)."

C. Necessity for the deviation:

The term negative is not the best given that Immunoassay is a screening test with set cutoffs. Confirmatory tests are more sensitive, and therefore may detect a compound that screened below the cutoff.

The new reporting statement is needed as a result of the QSCREEN method being able to detect more drugs than before and can be reported out in a similar manner as the Immunoassay results.

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

Approved	☑	Yes	☐	No	Duration	1 year
Signature	Wayne Lewallen Digitally signed by Wayne Lewallen Date: 2020.06.30 12:57:04 -04'00'				Date	6/30/2020

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	☑	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	☑	No

Restrictions/limitations:

Effective 07/06/2020.

☑	Authorized	☐	Rejected	Signature	Aaron Joncich Digitally signed by Aaron Joncich Date: 2020.06.30 14:30:43 -04'00'	Date	6/30/2020

Form approved for use by: Timothy G. Suggs Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdoj.gov, c=US Date: 2014.12.19 09:01:52 -05'00'

Drug Toxicology Reporting

1.0 Purpose - This procedure specifies the required elements for reporting drug toxicology results.

2.0 Scope – This procedure applies to all submissions to the Toxicology sections in the Raleigh, Triad, and Western locations of the State Crime Laboratory

3.0 Definitions

- **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))
- **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.

4.0 Acceptable Work Product

4.1 Acceptable work product is defined as a report that was generated from the analysis of evidence in accordance with approved Toxicology procedures.

4.2 The initial identification of a substance (drug, impairing substance, and/or metabolite) shall be confirmed by a second test.

4.3 The following are acceptable tests to make an initial identification of a substance:

- Positive indication by Immunoassay.
- Chromatographic and Mass Spectral Identification of a non-screened substance.

4.4 The following are acceptable to confirm an initial identification of a substance:

- Chromatographic and Mass Spectral Identification by a different aliquot of the same specimen.
- Case history verification of a non-immunoassay screened substance (e.g., Lidocaine identified in a base extraction in a case involving medical treatment, or a prescription log).

4.5 For an initial or confirmatory identification of a substance, the subtracted mass spectra of a substance may not contain any ions at a relative abundance equal to or greater than 50% that are not present in the reference standard.

4.6 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 aliquot if the parent drug or metabolite is identified in the case.

4.7 Acceptable work product must be derived from tests in which the controls perform according to the acceptance criteria outlined in the appropriate procedure.

5.0 Reporting Statements:

5.1 Immunoassay Drug Screen Reporting Statements:

5.1.1 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}.

5.1.1.1 Unconfirmed indicative immunoassay results shall only be reported using the statement in 5.1.3 or 5.2.4.

5.1.2 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 Cases with insufficient sample remaining to confirm an indicative immunoassay result, the following statement shall be used:

> Analysis for the presence of (Insert Assay) was inconclusive.

5.2 Drug Confirmation reporting statements

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

> No impairing substances were identified.

5.2.2 If analysis results in the confirmation 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.

5.2.3 If analysis did confirm impairing substances and/or their metabolites, use the statement below followed by the name of the substance(s).

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

5.2.4 If analysis did **not** confirm an immunoassay positive indication and/or a requested substance, use the statement below:

> Analysis did not confirm the presence of the following: {insert the assay or requested substance}

5.2.5 If a substance requested cannot be identified based on the limitations listed in **6.1**.

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

5.2.6 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.

5.3 Application of Procedure on Evidence – Insufficient or Clotted Specimens

5.3.1 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.

5.3.2 If the specimen volume is insufficient to complete the requested analysis or do any additional testing, add the following statement to the report:

Quantity of specimen submitted is insufficient for further analysis.

5.3.3 If the specimen submitted is clotted and is unable to be analyzed, add the following statement to the report:

The condition of the specimen submitted precludes analysis.

5.4 Uncertainty of Measurement – Refer to Toxicology Measurement Assurance and the Toxicology Reporting Index.

6.0 Limitations

6.1 Not all known substances, including those that cross-react with the immunoassay drug screening tests, can generally be confirmed by current State Crime Laboratory analytical procedures. Toxicology capabilities and limitations are listed in the Toxicology Reporting Index. These shall be updated as needed by the Toxicology Technical Leader.

7.0 Safety

7.1 Refer to the Laboratory Safety Manual.

7.2 Refer to the Toxicology Technical Procedures.

8.0 References

Toxicology Procedures

Toxicology 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
02/12/2016	1	Initial Version
07/07/2017	2	4.3 - insert "of a non-screened substance" 5.1.3 inserted to add inconclusive reporting statement 5.2.1 – edited to remove reference to limitation 6.2 5.2.5 – removed "non-screened" 5.3.2 – insert "or do any additional testing; change "complete" to "further" 6.2 and 6.3 - removed
02/22/2019	3	2.0 – reworded scope 4.5 – added: Full scan mass spectra of a substance may not contain any ions at a relative abundance equal to or greater than 50% that are not present in the reference standard. 5.1.1.1 - added 5.2.1 – removed 5.3 – added clotted 5.3.3 - added