Idaho State Police
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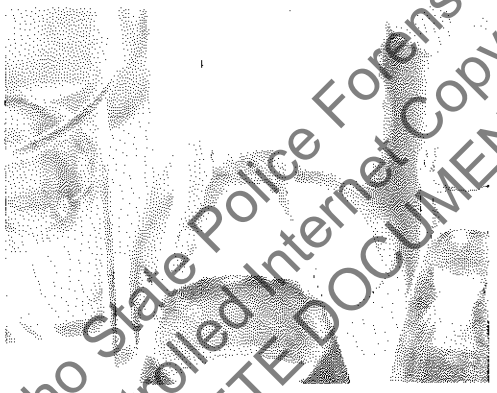


Discipline/Name of Document: Toxicology Work Instructions
2.4.1– Qualitative Confirmation of Basic and Neutral Drug Compounds in Urine
Toxi-A Tube Extraction

Revision Number: 0

Issue Date: 6/29/2007

APPROVED BY: Corinna C Ousley
Quality Manager

6/29/07
Date Signed

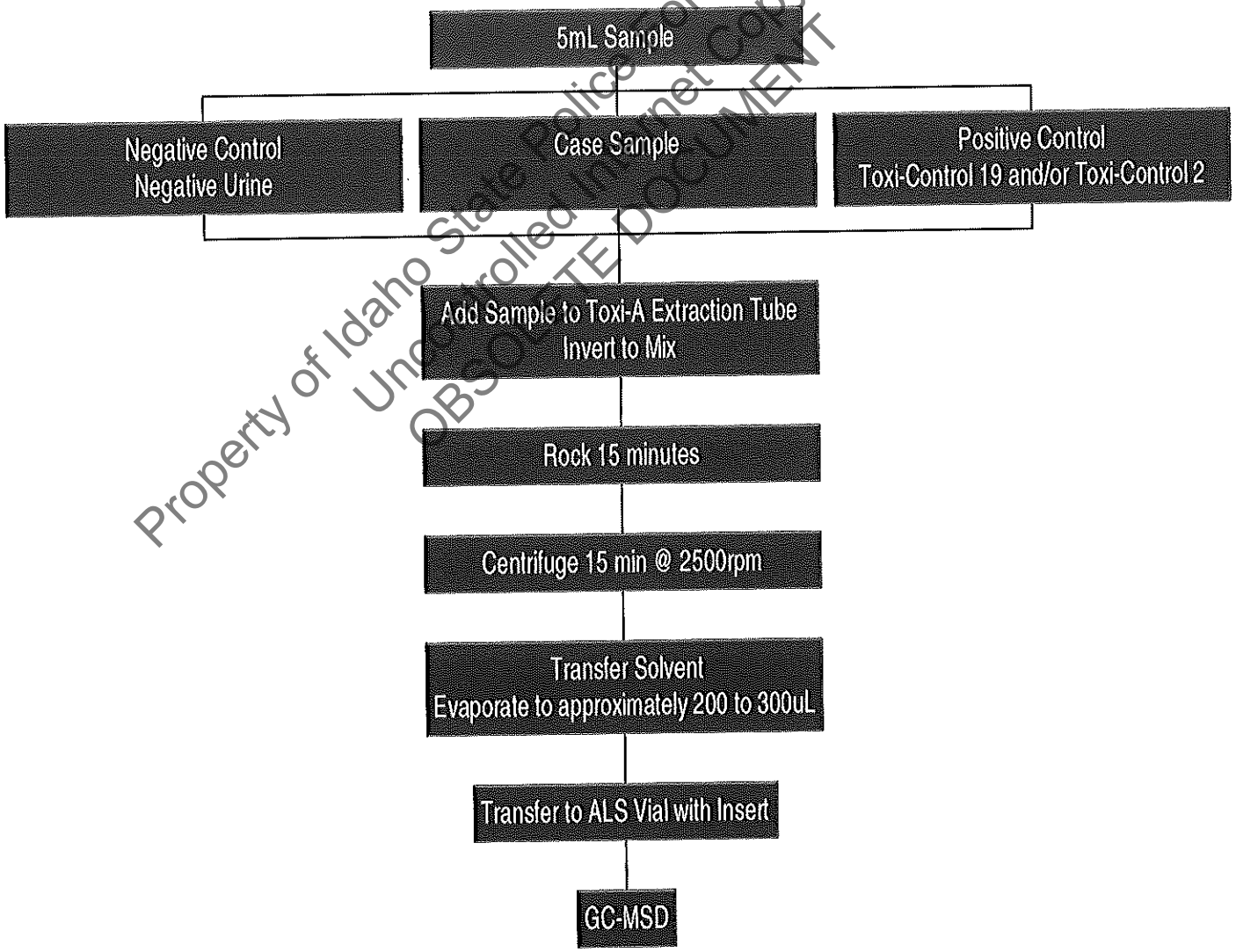
WORK INSTRUCTIONS

2.4.1 Qualitative Confirmation of Basic and Neutral Drug Compounds in Urine

Toxi-A Tube Extraction

Reagents
TOXI-TUBES A

Qualitative Controls
Toxi-Control No. 19
Toxi-Control No. 2
Negative Urine



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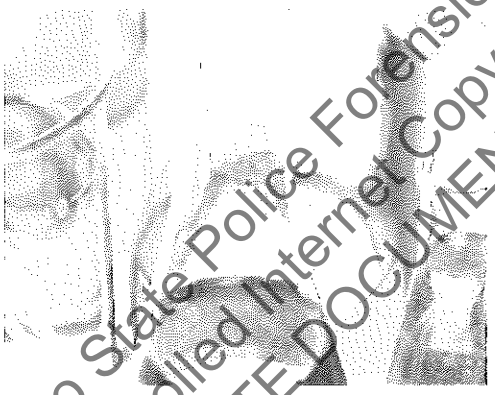

Discipline/Name of Document: Toxicology
5.13 Confidence in Data

Revision Number: 0

Issue Date: 9/7/2009

APPROVED BY: _____ 9/7/09
Quality Manager — Date Signed

Checklist Submitted and Checked _____

Section Five
Quality Assurance

5.13 Confidence in Quantitative Analytical Data

5.13.1 BACKGROUND

Any measurement, no matter how carefully obtained, must not be considered as the true value for the measurement. Whenever any quantitative measurement is performed, the value obtained is only an approximation of the true value.[1] According to JCGM 200:2008, the International vocabulary of metrology – Basic and general concepts and associated terms (VIM),[3] measurement uncertainty is defined as "*A non-negative parameter associated with the result of a measurement/quantity value (number and measurement unit used together to express the magnitude of a quantity) that characterizes the dispersion of quantity values that could reasonably be attributed to the measurand (quantity intended to be measured).*" ISO/IEC 17025:2005 clause 5.4.6.2 requires that we make a reasonable estimation of uncertainty that is based on knowledge of the performance of the method and on the measurement scope and shall make use of for example, previous experience and validation data.[2] Clause 5.4.6.2, NOTE 1 goes on to state that the degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as the existence of narrow limits on which decisions on conformity to a specification is based.[2] Paragraph 5.10.3.1 states that when applicable, the test report should include a statement on the estimated uncertainty of measurement.[2] For our purposes, it is applicable due to the uncertainty affecting the application of the test results which are compliant to a specification limit. In the analysis of forensic specimens, we do not know the true value for the specimen; hence this information is not the error associated with the analysis. Rather, it is a range of values likely to be encountered during the measurement process.[7] This information is crucial to the legal system because it impacts if and how an individual will be charged with an offense such as DUI.[4,5]

5.13.2 SCOPE

This analytical method will be applied to analytical methods which report quantitative results. The *top-down* approach to the estimation of uncertainty evaluates multiple sources of uncertainty simultaneously and does not distinguish contributions from single sources.[6] This approach to uncertainty uses the standard deviation of matrix matched controls; the uncertainty of measurement culminates in the values measured for control samples. A 95% confidence interval will be created by two standard deviations of data collected during the authentication process. To properly represent the uncertainty, this data will be expressed as the Coefficient of Variation (CV%) (relative uncertainty) on the analysis report. Authentication of blood volatiles controls is described in Analytical Method 5.14.

5.13.3 EQUIPMENT

As described in relevant analytical methods.

5.13.4 REAGENTS

As described in relevant analytical methods.

5.13.5 QUALITY ASSURANCE MATERIAL

As described in relevant analytical methods.

5.13.6 REPORTING OF QUANTITATIVE ETHANOL RESULTS

5.13.6.1 Analytical Methods

4.1 Quantitative Analysis for Ethanol and Qualitative Analysis for Other Volatiles in Blood, Vitreous Humor and Urine by Dual Column Headspace Gas Chromatography

4.2 Analysis of Solutions Containing Ethanol and Common Volatiles

5.13.6.2 Determination of Confidence Interval

5.13.6.2.1 Blood control values obtained during the authentication process are used to establish the CV% based on the standard deviation of authentication data.

5.13.6.2.2 Two standard deviations will be calculated for a 95% confidence interval.

5.13.6.2.3 The mean value as determined by the above analytical methods will be reported along with a ± CV%.

5.13.7 REFERENCES AND RECOMMENDED READING

5.13.7.1 Huber, L., Validation and Qualification in Analytical Laboratories, pp. 146 - 150, Interpharm/CRC, 1999.

5.13.7.2 International Organization of Standardization (ISO) / International Electrochemical Commission (IEC), *General requirements for the competence of testing and calibration laboratories*, 2005. (ISO/IEC 17025:2005)

5.13.7.3 Joint Committee for Guides in Metrology (JCGM), *International Vocabulary of Basic and General Terms in Metrology (VIM)*, 2008. (JCGM 200: 2008)

5.13.7.4 Idaho Code §18-8004. Persons under the influence of alcohol, drugs or any other intoxicating substances.

5.13.7.5 Idaho Code §18-8004C. Excessive Alcohol Concentration – Penalties.

5.13.7.6 ISO/IEC 17025:2005: Section 5.4.6: Estimation of Uncertainty of Measurement Workshop, Presented by J.P. Bono and E.A. Mishalanie, AAFS 61st Annual Meeting, Denver, Colorado, 2009.

5.13.7.7 Mason, F., Uncertain About Uncertainty, Quality Digest, Inside Metrology Column, 06-12-2008.

Revision History

Section Five
Quality Assurance

5.13 Confidence in Quantitative Analytical Data

Revision #	Issue Date	Revisions
0	09-07-2009	Original issue Analytical Methods 4.1 and 4.2 addressed for quantitative ethanol results.