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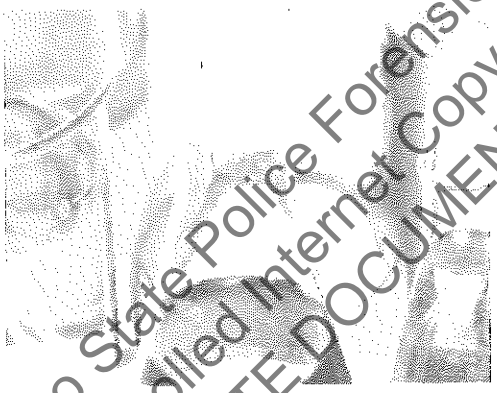

Discipline/Name of Document: Toxicology
5.8 Quality Assurance Measures – Urine and Blood Toxicology

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Quality Manager

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Date Signed

Section Five
Quality Assurance

5.8 Quality Assurance Measures - Urine and Blood Toxicology

5.8.1 BACKGROUND

The quality assurance measures applied towards analysis of toxicological samples promote confidence in results.

5.8.2 SCOPE

This analytical method addresses general acceptance requirements for qualitative and quantitative analysis data obtained through analysis by gas chromatography equipped with a nitrogen phosphorus (NPD) or a mass selective detective (MSD). Requirements for analysis with other instrumentation are addressed in relevant analytical methods.

5.8.3 EQUIPMENT AND SUPPLIES

Refer to specific analytical method.

5.8.4 REAGENTS

Refer to appropriate analytical method as well as manual section 5.12 for solution preparation instructions.

5.8.5 INSTRUMENT QUALITY ASSURANCE

5.8.5.1 Instrument Maintenance

5.8.5.1.1 Replacement parts and cleaning supplies required for GC-MSD and GC-NPD maintenance should be stocked to reduce the time that an instrument is off-line. Refer to manufacturer's hardcopy or electronic instrument manuals and/or hardcopy or on-line catalog for ordering information.

5.8.5.1.2 Refer to manufacturer's hardcopy or electronic instrument manuals for maintenance indicators and instructions.

5.8.5.2 MSD Tuning

An Autotune must be performed on a weekly basis. All parameters for the Autotune must fall within ranges defined by the manufacturer.

5.8.5.3 Instrument Performance Monitoring

5.8.5.3.1 A test mix to monitor instrument performance must be analyzed a minimum of once a month.

5.8.5.3.2 The TIC and the MS data for each compound purported to be present in test mix must be printed to demonstrate the presence of acceptable instrument performance.

5.8.5.3.3 To monitor deterioration in instrument performance, compare the data for the test mix for a newly installed column and/or cleaned source with subsequent runs.

5.8.5.3.4 Examine data to verify that all compounds are detected with consistent retention time, resolution, peak shape symmetry and signal abundance.

5.8.5.3.5 Use data to determine when instrument maintenance must be performed.

5.8.5.3.6 If the test mix is used for *Operation Verification* as described in 5.8.5.4, an additional test mix need not be analyzed as long as the monthly requirement is met.

5.8.5.3.7 Data for test mix must be centrally stored.

5.8.5.4 Operation Verification

5.8.5.4.1 At the beginning of an analysis sequence the analyst must run a sample that verifies the instrument's performance.

5.8.5.4.2 The sample may be a test mix or analysis control. The data must be evaluated as indicated in 5.8.5.3.

5.8.5.3.3 The TIC and the MS data for each compound purported to be present in test mix or analysis control must be printed to demonstrate the presence of acceptable instrument performance.

5.8.5.4.4 The data from this verification sample must be centrally stored.

5.8.6 SAMPLE PREPARATION QUALITY ASSURANCE

5.8.6.1 Qualitative Analysis

5.8.6.1.1 Non-extracted Reference Material

5.8.6.1.1.1 Reference material must be prepared

and analyzed as designated in appropriate analytical method.

5.8.6.1.1.2 Acquired data must be comparable to authentication data. No significant differences in GC-MS data must be apparent.

5.8.6.1.2 Matrix Controls

5.8.6.1.2.1 Quality controls are to be prepared and analyzed as designated in the appropriate analytical method.

5.8.6.1.2.2 Positive controls should exhibit proper retention time and mass spectral characteristics for compounds of interest.

5.8.6.1.2.3 Negative controls should be examined for compound(s) of interest and interfering substances.

5.8.5.1.3 Solvent Blanks

5.8.5.1.3.1 An appropriate solvent blank should be run between sample extracts.

5.8.5.1.3.2 If the solvent blank contains a reportable analyte of interest, the corrected area of the analyte peak must be a minimum of 10 times stronger than the corresponding peak in the blank preceding it. Ideally, no contamination should be apparent.

5.8.5.1.3.3 Reportable is defined as a complete fragmentation pattern at the appropriate retention time. Analytes of interest include, but are not limited to, analytes routinely reported.

5.8.5.1.3.4 If significant contamination is present, as discussed in 5.8.5.1.3.2, evaluate the analysis of a newly obtained solvent blank and the sample extract in question. If the

contamination is still apparent, troubleshoot the instrument to determine the source of contamination. In addition, the sample in question should be re-extracted prior to reanalysis on rectified instrument.

5.8.6.2 Quantitative Analysis

Quality measures are optimized for the analytes in question and are addressed in each individual quantitative analytical method.

5.8.6.3 Distribution of Quality Data

5.8.6.3.1 Original data for matrix controls will be stored in a designated central location in the laboratory where the analysis was performed.

5.8.6.3.2 Copies of all quality assurance control data need not be placed in each case file except those required under 5.8.6.3.3.

5.8.6.3.3 Copies of analytical reference material used to substantiate the identification of each drug compound must be included in each case file if not otherwise indicated in the relevant analytical method.

5.8.7 REFERENCES

5.8.7.1 Wu Chen, N.B. Cody, J.T., Garriott, J.C., Foltz, R.L., and et al., Report of the Ad hoc *Committee on Forensic GC/MS: Recommended guidelines for forensic GC/MS procedures in toxicology laboratory associated with offices of medical examiners and/or coroners*, J. Foren. Sci, 236 (35): 236-242, 1990.

5.8.7.2 Goldberger, B.A., Huestis, M.A., Wilkins, D.G., *Commonly practiced quality control and quality assurance procedures for gas chromatograph/mass spectrometry analysis in forensic urine drug-testing laboratories*, For Sci Review, 9(2): 60-79, 1997.

5.8.7.3 SOFT/AAFS Forensic Toxicology Laboratory Guidelines, 2002

Revision History

Section Five
Quality Assurance

5.8 Quality Assurance Measures – Urine and Blood Toxicology

Revision #	Issue Date	History
0	10-18-2002	Original Issue
1	04-16-2003	Clarifications, Updated.
2	07-23-2003	Clarification of authentication process.
3	03-09-2005	Reformatted, scope broadened.
4	05-24-2006	Clarifications, authentication process moved to SOP 5.10.
5	05-07-2007	Updated QA measures and reformatting. Weekly tuning introduced.