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 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 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 analyst will review the MS data for each compound, annotate the TIC, label each compound, and print it out. The analyst will initial the printout

indicating that they reviewed the data and it was acceptable. If a problem is indicated with the test sample, the analyst will print out the TIC or the MS that indicates the problem and place a note on the printout indicating what the problem is. Appropriate troubleshooting repairs and maintenance will take place and be documented.

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.

5.8.6 SAMPLE PREPARATION QUALITY ASSURANCE

5.8.6.1 Qualitative Analysis

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5.8.6.1.1 Matrix Controls

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

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

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

5.8.5.1.2 Solvent Blanks

5.8.5.1.2.1 An appropriate solvent blank will be run before case sample extracts.

5.8.5.1.2.2 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.

5.8.5.1.2.3 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.

5.8.5.1.2.4 If significant contamination is present, as discussed in 5.8.5.1.2.2, rerun the solvent blank that was used in that analysis and the sample extract in question. If the contamination is still apparent, or the original samples are no longer available, troubleshoot the instrument to determine the source of contamination. In addition, the sample in question must be re-extracted prior to reanalysis on the 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 SAMPLE STORAGE

5.8.7.1 Blood samples will be stored under refrigeration.

5.8.7.2 Urine samples will be stored under refrigeration or frozen. If samples are going to be stored longer than two weeks prior to analysis, they should be frozen. Once analysis is complete, samples will be frozen for long term storage.

5.8.8 REFERENCES

5.8.8.1 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.

5.8.8.2 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.

5.8.8.3 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.
6	08/16/2007	Changed wording of 5.8.5.4.1 to “during an analysis sequence”
7	11-11-2011	Removed reference to NPD in Scope, removed recommendation to keep instrument parts on hand. Revised documentation process and review for GCMS test mix. Removed section on operation verification. Clarified when blanks are to be run, revised procedure when blank shows contamination. Added section on sample storage.