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 GCMS

5.8.5.1 Instrument Maintenance

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

5.8.5.2 MSD Tuning

5.8.5.2.1 A Tune must be run within a week prior to analysis of casework.

5.8.5.2.2 A Tune Evaluation should be completed and parameters should be reviewed for acceptance based on the report's predefined criteria, set by the manufacturer. *Note: H_2O and N_2 values should be monitored for possible instrumentation leaks (acceptance parameters are listed in parentheses on the tune evaluation report).*

5.8.5.3 Instrument Performance Monitoring

5.8.5.3.1 Instrument performance will be monitored through evaluation of the positive and negative controls run with every extraction batch. The control requirements for an extraction are found in the applicable analytical methods. The instrument will be determined as working properly if the expected

responses are obtained for the controls evaluated.

5.8.5.3.2 Analysts may use the control data to determine if instrument maintenance is needed.

5.8.5.3.2 A test mix may be useful for troubleshooting purposes. If a problem is indicated with the test mix, the analyst will indicate the problem with a notation in the instrument's maintenance log. Appropriate troubleshooting, repairs and maintenance will take place and be documented.

5.8.5.4 Data file back up

5.8.4.1 Data files will be retained and backed up to external media at least once every two months.

5.8.6 SAMPLE PREPARATION QUALITY ASSURANCE

5.8.6.1 Qualitative Analysis

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.

5.8.6.1.1.4 Commercially-obtained controls may be utilized for qualitative analysis after the manufacturer's expiration date *provided* all method control requirements are met AND an additional in-run control that is not expired be run. This limited permission is not applicable to expired controls of a unique nature (e.g. EMIT level 0 pre-run control). It is applicable, for example, to the use of an expired commercially-obtained c-THC control when

performing AM 2.4.4; this method requires two (non-expired) spiked controls be run in addition to the commercially-obtained control.

5.8.6.1.2 Solvent Blanks

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

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

5.8.6.1.2.3 *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.

5.8.6.1.2.4 If significant contamination is present, as discussed in 5.8.6.1.2.2, 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; this includes Combo Collection Kits.

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 until they are returned to the agency.

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.
8	1/16/2013	Obsolete reference to a step that no longer exists was discovered in the method and removed numbering updated.
9	3/8/2013	Added section 5.8.4.1 requiring retention of electronic data.
10	04/22/2015	Added section 5.8.6.1.1.4 allowing use of expired, commercially-obtained controls under limited circumstances. Clarified tune requirements and added blanket interval for requiring tunes. Clarified instrument performance monitoring requirements.