Section Five
Quality Assurance

5.10 Authentication of Reference Materials - Urine and Blood Toxicology

5.10.1 BACKGROUND

The quality assurance measures applied towards analysis promote confidence in results. This analytical method was created so that the shared requirements did not have to be included in every toxicology discipline analytical method.

5.10.2 SCOPE

This analytical method addresses qualitative and quantitative authentication of reference materials. Reference materials include both standards and controls.

5.10.3 EQUIPMENT AND SUPPLIES

5.10.3.1 Refer to appropriate analytical method.

5.10.4 REAGENTS

5.10.4.1 Refer to appropriate analytical method for solution preparation instructions.

5.10.5 REFERENCE MATERIAL AUTHENTICATION

5.10.5.1 General

5.10.5.1.1 Appropriate authentication must be documented for reference materials prior to an analyst reporting a conclusion in casework in which that reference material was used. Authentication data should be stored centrally. If more than one laboratory within the ISP Forensic Services system will use the same lot of a commercial control or reference material, authentication at each individual laboratory is not required, provided personnel in each laboratory have ready access to authentication data.

5.10.5.1.2 When a reference material or control contains more than one constituent, only the compound(s) of interest need be authenticated. It should be clearly marked what compounds are authenticated.

5.10.5.1.3 Whenever possible, the source of reference material used to prepare matrix controls must differ from that used to prepare a quantitative response curve. If different vendors are not available, a different lot number should be used. As a last resort, if different lot numbers are not available, a second qualified analyst may prepare one of the working solutions.

5.10.5.1.4 Unauthenticated reference material must be stored in a designated area or clearly marked that authentication is needed.

5.10.5.1.5 It is the responsibility of each analyst to verify that each standard or control used has been properly authenticated.

5.10.5.2 Qualitative Reference Material Authentication

5.10.5.2.1 Qualitative standards will be authenticated by an instrument that provides structural information (such as GCMS or FTIR) and has been validated and approved for use in the lab. A standard will be considered authenticated when the match (Q) is at least 85%, as compared to a library search *and* the analyst confirms that the spectra matches with no significant differences. If the spectra does not have a library match of 85% or greater, the spectra may be authenticated by comparing it to a peer reviewed scientific journal, reference standard compendium or a library match that is less than 85%. For these three options, two analysts trained to use the authentication instrumentation must initial the documentation signifying that it is an appropriate match.

5.10.5.2.2 When comparison to a journal, compendium or other document is not an option, mass spectral interpretation may be used in conjunction with the COA (certificate of analysis). This would apply in cases where instrumental data for a drug metabolite is not yet published, but a structurally similar compound is available to assist with interpretation. A second trained analyst must also review and initial the printout verifying the interpretation.

5.10.5.2.3 A coversheet providing the information necessary for authentication will be prepared and placed with the MSD or FTIR data and a copy of the reference spectra. The coversheet must, at a minimum, list the lot number, vendor, date of analysis, analyst name, and mode of authentication.

5.10.5.2.4 Reference materials used for qualitative purposes do not have expiration dates; if the compound breaks down and is no longer performing as intended, the

reference material will be discarded (or clearly marked invalid for casework since it may be used for training purposes).

5.10.5.3 Quantitative Reference Materials Authentication

5.10.5.3.1 The qualitative properties of these reference materials will be evaluated using the procedures described in 5.10.5.2.

5.10.5.3.2 The quantitative values on the COA will be accepted. The COA will be centrally stored for quantitative reference materials. Quantitative reference materials will be marked or stored in a designated location to prevent those that are only authenticated for qualitative use from being inadvertently used in quantitative applications.

5.10.5.3.3 The manufacturer of reference materials used for quantitative purposes must either utilize balances calibrated with weights traceable to National Institute of Standards and Technology (NIST) standards or be 17025 certified to produce reference materials. The certificate of analysis or manufacturer's accreditation certificate(s) and scope must be consulted to verify compliance with this requirement.

5.10.5.3.4 Quantitative reference materials will be discarded or designated for qualitative use only after they expire.

5.10.5.4 Qualitative and Quantitative Matrix Control Authentication

5.10.5.4.1 Matrix controls are analyzed in parallel with casework samples to demonstrate that a procedure performed as intended.

5.10.5.4.2 Quantitative Matrix controls also serve to verify the accuracy of a response curve.

5.10.5.4.3 Matrix controls may be prepared with authenticated reference materials or obtained through a vendor. The quantitative and qualitative properties of these controls will be based on the certificate of analysis, or the in-house preparation information. In addition, controls used in qualitative analysis may be

authenticated following 5.10.5.2, if a certificate of analysis is not available.

5.10.5.4.4 The qualitative identity and quantitative values of component(s) in a commercially obtained matrix control will be based on the package insert or certificate of analysis. Certificates of Analysis (COA) and package inserts for commercially obtained matrix controls will be stored centrally in the laboratory in which they are used.

5.10.5.4.5 To authenticate the qualitative presence of components when the manufacturer does not provide a certificate of analysis or package insert, the analyst will authenticate each compound in the same way a qualitative reference material is authenticated (see 5.10.5.2). If a previous lot of that control has been authenticated with this process, the analyst may simply compare the new lot to the previously authenticated lot.

5.10.5.5 Internal Standard Authentication

5.10.5.5.1 Internal standards can be used to demonstrate the efficiency of an extraction, that the injection on the instrument worked properly, and for quantitation.

5.10.5.5.2 The qualitative identity and quantitative values of component(s) used as internal standards will be based on the package insert or certificate of analysis. Certificate of Analysis (COA) and package inserts for internal standards will be stored centrally in the laboratory in which they are used.

5.10.5.5.3 If the Certificate of Analysis is not available for an internal standard that is only used in qualitative analysis, it may be authenticated the same way a qualitative standard is authenticated (see 5.10.5.2).

5.10.6 REFERENCES

5.10.6.1 Wu Chen, N.B. Cody, J.T., Garriott, J.C., Foltz, R.L., 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.

5.10.6.2 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.

5.10.6.3 SOFT/AAFS Forensic Toxicology Laboratory Guidelines, 2002.

Revision History

Revision	Issue Date	History
0	05-24-2006	Original Issue – Split from analytical method 5.8. Clarifications of authentication process described.
1	05-07-2007	Reformat, updated QA language.
2	08-15-2011	Major revisions to authentication requirements for quantitative standards and quantitative matrix controls. Revisions to quantitative standards to mirror controlled substance authentication requirements. Changes to required authentication documentation. Major reformatting to facilitate method comprehension.
3	11-28-2012	Internal standards were included and clarification of how standards used to prepare matrix controls are authenticated.
4	04/222015	Allowed for single authentication throughout ISP lab system. Clarified RM requirements from vendors. Made provision for unavailability of second RM lot from same or different vendor. Formatting. Replaced “standard” language with “reference material.”