



### **F39 Method Validation and Admissibility of Forensic Alcohol and Drug Tests**

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After attending this presentation, attendees will understand the legal issues that are presented in courts when analytical methods are challenged as not having been properly or fully validated prior to use.

This presentation will impact the forensic science community by advising crime laboratories of the need to perform full validation on all methods, old and new, so that courts will be able to properly determine the legal admissibility of testing results when such quandaries occur.

Recently, courts have been called upon to determine whether a crime laboratory has fully validated their testing methods for drugs and alcohol in accordance with acceptable guidelines or publications.

Non-standard or in-house analytical methods are being used to test for alcohol and drugs in biological samples in crime laboratories throughout the United States. The forensic community has promulgated standards for validation that would apply to all such methods, both new and old. But many of these laboratories have failed to take steps to validate their methods. Many attorneys now argue that results obtained from less-than-fully validated methods should be ruled inadmissible as a matter of law in court proceedings.

In the scientific community, it is widely recognized that analytical methods employed for the qualitative or quantitative determination of drugs or alcohol in biological samples must be fully validated to yield reliable results. It is also understood that each analytical technique must be so validated for each target analyte that it seeks to identify and/or quantitate (where quantitation is necessary). While there is general consensus that validation parameters should include accuracy, precision, selectivity, sensitivity, reproducibility, limit of quantification, and stability, many crime laboratories have failed to validate their methods utilizing all or many of these parameters.

There is not complete agreement in the forensic community as to how method validation should be performed in order to satisfy both the courts and the sciences. The International Organization for Standardization (ISO) 17025 includes a requirement that method validation be performed (unless the methods are found in “preferred methods published in international, regional or national standards”), but ISO 17025 fails to specify with particularity the requisite steps necessary to satisfy this standard.

The recently published Scientific Working Group for Forensic Toxicology (SWGTOX) guidelines (2013) are the best attempt yet to govern the validation of new methods used in crime laboratories. The SWGTOX guidelines also apply to methods that were validated prior to the promulgation of the SWGTOX standards, allowing for the use of historical calibration and control data to fulfill some, but not all, of the validation parameters. Of note is that compliance with SWGTOX procedures is purely voluntary and ISO 17025 has not adopted or even acknowledged them as being satisfactory for ISO purposes.

Some crime laboratories have claimed that proficiency testing, coupled with periodic calibrations, along with the use of controls and standards, are suitable substitutes for the types of method validations found in SWGTOX and other scientific publications. Still others have simply claimed that their methods pre-date all guidelines and are thus exempted from any proof of validation in court – akin to a “take my word for I” approach.

Because of the lack of uniform application of published guidelines on method validation within the forensic and legal community, and because of the lack of published court decisions regarding challenges to the lack of full-



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method validation, courts have struggled with determining whether a method has been “validated” sufficiently to be accepted in court.

In one case that will be presented, non-standard methods have been employed for decades with no evidence of them ever having been subjected to true validation testing. This presentation will include a case study of the issue(s) and the legal process that was used to challenge method validation and admissibility of the result(s).

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### **Method Validation, Guidelines, Admissibility**