## E9 Cutoff Concentration of Ketamine and Metabolite in Urine Was Set in Taiwan for Certified Laboratories

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Taiwan is the first country of the world to set the cutoff concentrations of ketamine and its metabolite in urine for certified laboratories. Ketamine, which is a non-barbiturate, rapid-acting disassociative anesthetic is used in pediatric burn cases, in dentistry and is used experimentally in psychotherapy. It is a Schedule III controlled drug, whose abuse as a "club drug" or party drug has been rising rapidly in Taiwan in recent years as documented by the amount of the drug seized by the police, the number of arrestees testing positive, the high percentage of ketamine use in recre- ational places, and the increased use reported from psychiatric hospitals case report statistics. This presentation will call attention to the forensic community of the growing abuse of ketamine and establishes a workable cutoff concentration in order to test for the drug and its metabolites.

In a study conducted from January to April 2003 there were 51 positive urinary ketamine analysis specimens collected in the laboratory. From January to April, 2004, there were 413 positive specimens collected, which represented an increase of more than a 700% in just one year. As a result of this increased use of ketamine, the Department of Health of Taiwan sought an accurate standard to measure for the presence of ket- amine in urine and added ketamine to the list of drugs to be analyzed by accredited drug analysis laboratories.

Five research projects were conducted from 2002 to 2003 on different methodologies to measure for the presence of ketamine. The National Bureau of Controlled Drugs, Department of Health, had established the cutoff limits for the detection of ketamine and its metabolites, norketamine and dehydronorketamine by the use of GC/MS, LC/MS, GC-NPD and CE methods. At the same time testing laboratories around Taiwan accepted requests to conduct analyses of ketamine, but used their own methods and cutoffs for urine analysis. One laboratory used 200 ng/mL for ketamine or norketamine as the cutoff, while another was used 100 ng/mL for ketamine, norketamine and dehydronorketamine as their cutoff limit.

Accurate confirmation of the presence of any drug in a urine specimen requires two testing methods utilizing a different methodology for each test. Immunoassay coupled with GC/MS methods have been 'the gold standard" for urine drug testing laboratories in Taiwan. However, Taiwan has revised its "Statute for Narcotics Hazard Control" to include ketamine, and the Department of Health promulgated on December 24, 2003, revised "Regulations Governing Drug Abuse Urine Testing Operations" and the "Regulations Governing Certification and Management of Drug Abuse Urine Testing and Medical Institutions" which took effect on January 9, 2004. These new regulations establish a ketamine analysis standard.

Since there are few commercial immunoassay methods available at this time in Taiwan, for the screening test of ketamine and metabolite, it was decided that any proper chromatographic methods coupled with a suitable detector would be allowed and the cutoff was set at 100 ng/mL for either ketamine, its metabolite- norketamine or the sum of the concentra- tions of the two compounds. For the confirmation test, the GC/MS method should be used for the analysis of ketamine and norketamine, the cutoff concentration is 100 ng/mL for either of the two compounds or both of them combined.

The National Bureau of Controlled Drugs proposed the new standards in an amendment to the regulation, which was approved by the Institution Certification Review Committee of the department of Health on June 28th 2004. The amendment of the regulations is expected to take effect as soon as possible after it is enacted by the legislature.

**Ketamine, Taiwan, Cutoff Concentration**

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