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Original Article

Urine specimen validity test for drug abuse testing in workplace and court settings

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ABSTRACT

In recent decades, urine drug testing in the workplace has become common in many countries in the world. There have been several studies concerning the use of the urine specimen validity test (SVT) for drug abuse testing administered in the workplace. However, very little data exists concerning the urine SVT on drug abuse tests from court specimens, including dilute, substituted, adulterated, and invalid tests. We investigated 21,696 submitted urine drug test samples for SVT from workplace and court settings in southern Taiwan over 5 years. All immunoassay screen-positive urine specimen drug tests were confirmed by gas chromatography/mass spectrometry. We found that the mean 5-year prevalence of tampering (dilute, substituted, or invalid tests) in urine specimens from the workplace and court settings were 1.09% and 3.81%, respectively. The mean 5-year percentage of dilute, substituted, and invalid urine specimens from the workplace were 89.2%, 6.8%, and 4.1%, respectively. The mean 5-year percentage of dilute, substituted, and invalid urine specimens from the court were 94.8%, 1.4%, and 3.8%, respectively. No adulterated cases were found among the workplace or court samples. The most common drug identified from the workplace specimens was amphetamine, followed by opiates. The most common drug identified from the court specimens was ketamine, followed by amphetamine. We suggest that all urine specimens taken for drug testing from both the workplace and court settings need to be tested for validity.

1. Introduction

Drug abuse has become one of the major public health issues in the world. In Taiwan, Lee et al [1] reported that methamphetamine was the most widely used illicit drug found in urine samples collected from suspects who were arrested for possessing and/or taking illicit drugs. They also showed that the number of ketamine seizures has been rising at an alarming pace. In Southeast Asia, crystal methamphetamine is

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the most commonly used drug, including in Brunei Darussalam, Japan, the Philippines, and the Republic of Korea [2]. The abuse trend of ketamine is also on the rise in Southeast Asia. In China (including Hong Kong), Malaysia, and Vietnam, ketamine use was also perceived to increase in 2010 [2].

Over the past few decades, employee drug testing has become a common business practice in the world workplace [3–8]. Workplace drug testing laboratories certified by the U.S. Department of Health and Human Services (HHS) are processing roughly 75,000 specimens each day. The 2004 Index from Quest Diagnostics Inc. (Madison, NJ, USA) reveals that the rate of positive drug tests has declined significantly since 1998, from nearly 14% to slightly greater than 4% [3].

In urine specimens for drug abuse testing administered for the correctional service in Canada, by checking the dilution rate only, Fraser and Zamecnik [9] reported that 6.7% of 38,431 urine specimens were dilute. To the best of our knowledge, there is no previous literature concerning further urine specimen validity tests (SVTs) for urine specimens taken in a court setting, including substituted, invalid, or adulterated modalities. For workplace drug testing of urine specimens, there have been several reports concerning urine SVT for drug abuse tests [10–15]. The aim of this study was to describe our findings from urine SVTs, including the rates of dilute, substituted, adulterated, and invalid samples, for drug abuse tests from court and workplace sources in southern Taiwan over 5 years.

2. Methods

2.1. Materials

Our laboratory is one of 13 urine drug abuse-testing laboratories certified by the Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare in Taiwan. A total of 21,666 urine specimens from workplace and court settings for drug abuse testing were investigated by urine SVT during the period of April 1, 2009 to March 31, 2014. Of these urine specimens, 14,289 (65.9%) came from workplaces, and were mainly for random testing of safety security-sensitive personnel in southern Taiwan. The other 7,377 (34.1%) urine specimens came from courts, with 89.7% of these specimens coming from two juvenile courts for youths on probation in southern Taiwan. Urine specimen collection was guided by the Drug Abuse Urine Collection Guideline of the TFDA, which was implemented in August 1999. Urine donors were witnessed and placed in a room with no access to water. This study was approved by the Investigational Review Board of Kaohsiung Medical University Hospital (KMUH-IRB –EXEMPT -20140042).

2.2. Specimen validity test

For urine SVT criteria, we used a mildly modified version of the 2008 Mandatory Guidelines for Federal Workplace Drug Testing Program of the United States [10]. We used a Food and Drug Administration-cleared immunoassay test that assayed amphetamine, 3,4-methylenedioxymethamphetamine (MDMA) using Microgenics (Microgenics Corporation, Fremont, CA, USA), other opiates, phencyclidine (PCP), marijuana, and benzodiazepines using Diagnostic Reagents Inc. (DRI) reagent. Ketamine was also assayed using DRI reagent as the initial screen test on each urine specimen [10]. If the immunoassay test result was below the cutoff, the specimen was reported as negative. If the immunoassay result was positive, we further established the identity of the drug or drug metabolite definitively by using gas chromatography/mass spectrometry (GC/MS) (Agilent, 6890/5973N, Hewlett-Packard, Palo Alto, CA, USA). The cutoff levels of each drug in urine for immunoassay screening and GC/MS confirmation were guided by the TFDA (Table 1).

For every sealed urine specimen submitted for a drug abuse test from the court or workplace, the collection process was under the chain of custody principle and then the samples were sent to our laboratory. For every specimen that underwent urine SVT, we: (1) determined the creatinine concentration with a Hitachi 7170 (Diamond Diagnostics, Holliston, MA, USA) based on the colorimetric Yaffe method; (2) determined the specific gravity using a UG-alpha refractometer (Atago, Tokyo, Japan) if the urine creatinine concentration was less than 20 mg/dL; and (3) determined the pH using pH paper (Adventec; Toyo Rash Karisha, Tokyo, Japan).

We first used pH paper with the detection range of pH 5–8; if the pH was outside this range, we then used pH paper ranging from 0–14. Of all the urine specimens, >99% were in the range of pH 5–8 and none of the specimens had pH <3 or >10.

Results for specimens reported using SVT were categorized as follows [10]. (1) A urine specimen was reported as dilute when the creatinine concentration was ≥2 mg/dL but <20 mg/dL, and the specific gravity was >1.0010 but <1.0030 on a single aliquot. A dilute specimen is a urine specimen with creatinine and specific gravity values lower than expected for human urine. (2) A urine specimen was reported as substituted when the creatinine concentration was <2 mg/dL on both the initial and confirmatory creatinine test, and the specific gravity was

Table 1 – Taiwan Food and Drug Administration guidelines.

Screen items	Screen cutoff (ng/mL)	Confirmation items	Confirmation cutoff (ng/mL)
Amphetamine	500	Amphetamine	500
		Methamphetamine	500 and amphetamine > 100
		MDMA	500 or MDMA + MDA ≥ 500
		MDA	500
Opiate	300	Morphine	300
		Codeine	300
Marijuana	50	Marijuana	15
Cocaine	300	Cocaine	300
Ketamine	100	Ketamine	100 or K + NK ≥ 100
		Norketamine	100
PCP	25	PCP	25
Benzodiazepines	200	Benzodiazepines	≥ LOD

K = ketamine; LOD = limit of detection; MDMA = 3,4-methylenedioxymethamphetamine; MDA = 3,4-methylenedioxyamphetamine; NK = norketamine, PCP = phencyclidine.

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