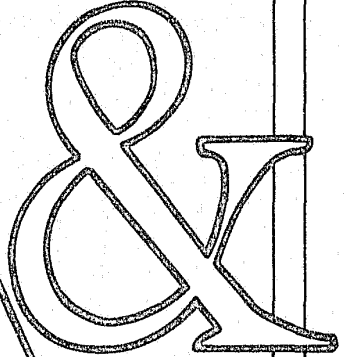


National Institute on Drug Abuse

EMPLOYEE
DRUG
SCREENING



Detection
of Drug Use
by Urinalysis

101840
078101

U.S. Department of Justice
National Institute of Justice

This document has been reproduced exactly as received from the person or organization originating it. Points of view or opinions stated in this document are those of the authors and do not necessarily represent the official position or policies of the National Institute of Justice.

Permission to reproduce this copyrighted material has been granted by

Public Domain

National Institute on Drug Abuse

to the National Criminal Justice Reference Service (NCJRS).

Further reproduction outside of the NCJRS system requires permission of the copyright owner.

* 2. *

This leaflet was written by J. Michael Walsh, Ph.D., Chief, Clinical and Behavioral Pharmacology Branch, Division of Clinical Research, and Richard L. Hawks, Ph.D., Chief, Research Technology Branch, Division of Preclinical Research, National Institute on Drug Abuse.

All material appearing in this publication is in the public domain and may be reproduced or copied without permission from the National Institute on Drug Abuse or the authors. Citation of the source is appreciated.

The United States Government does not endorse or favor any specific commercial product or commodity. Trade names or suppliers' names are used herein only because they are considered essential in the context of the subject matter of this publication.

DHHS Publication No. (ADM) 86-1442
Printed 1986

EMPLOYEE DRUG SCREENING

DETECTION OF DRUG USE BY URINALYSIS

Many companies have established employee assistance programs and health promotion programs to prevent and intervene in drug abuse in the workplace. Recently, as part of these programs, companies have begun to utilize urinalysis to screen for employee drug use. The use of these techniques has generated many inquiries regarding the various issues involved. This booklet attempts to answer the most frequently asked questions about the detection of drug use by urine screening.

Q. Why do companies use urine screening?

A. The evaluation of employees to determine fitness for duty has long been performed in industry. Within the context of occupational medicine programs, physical examinations were initially performed to ensure the selection of personnel free of medical conditions which would be likely to interfere with their ability to work safely and efficiently. In recent years, within the context of health promotion and wellness programs, an additional purpose of the medical evaluation has evolved; that is, to address risk factors that may impair employee health (e.g., poor nutrition, substance abuse, hypertension). As the incidence and prevalence of drug abuse in the United States have risen, many companies have developed preemployment and inservice drug screening programs. The primary purpose of these programs is to protect the health and safety of all employees through the early identification and referral for treatment of employees with drug- and alcohol-abuse problems. The integration of drug screening with programs of treatment, prevention,

NCJRS

¹ JUN 30 1986

ACQUISITIONS

and drug education is proving to be an effective way of managing substance-abuse problems in industry.

Q. How many companies are using preemployment screening?

A. Preemployment screening for drug use is being used widely by industry to screen job applicants. Recent reports indicate that in the last 3 years the number of Fortune 500 companies screening employees for drug use has risen from 3 percent to nearly 30 percent. Urinalysis is now being used as part of the preemployment screening process by many of the Nation's largest employers, including major corporations, manufacturers, public utilities, and transportation, and even by small businesses. In general, these companies use a blanket policy that they will not hire individuals who present positive urines indicating current use of illicit substances. However, many of these companies also counsel applicants who fail the drug screen to seek treatment and to reapply.

Q. Is urine screening for drugs legal?

A. At the present time no Federal or State constitutional provision or law directly prohibits the use of drug detection or urine screening programs. Issues of civil rights, discrimination, etc., argue strongly for a well-thought-out policy which carefully considers the need for unbiased, accurate, and legally defensible screening for the job in question. In general, employers should use common sense procedures to minimize legal challenge, i.e., develop reasonable policies, inform management, union, and employees of drug policies and the consequences of policy violations, and ensure that employees are aware that drug testing is part of their job requirements.

Q. How often should employees be screened?

A. Company policy regarding the frequency of drug screening is usually determined with consideration of risk factors associated with safety, security, and health. Over the last 2 years, a continuum of drug screening policies has evolved, ranging from postaccident evaluation to random, unannounced testing. The least intrusive is an incident-driven policy wherein screening occurs only after an accident or "incident" (e.g., a fight) or other "probable cause" event. High-risk or safety-sensitive occupations where public safety is of special concern may require routine scheduled screening. In these cases, screening is often tied to evaluation of fitness for duty or to annual physical examinations. In extremely hazardous and high-risk occupations, periodic unannounced or random testing to assure the health and safety of employees may be warranted.

Q. What about individual rights, privacy, and confidentiality?

A. How best to deal with the problems associated with employee drug use is a complex issue. Principles of public safety, efficient performance, and optimal productivity must be balanced against individuals' reasonable expectations of privacy and confidentiality. Job situations where there is a substantial risk to the public safety will surely justify greater permissible intrusions than would be acceptable where risks to the employee or community are perceived as minimal. On the one hand, an employer has the right to demand a drug-free workplace; on the other, an employee has reasonable rights to privacy and confidentiality. Since substance abuse is a diagnosable and treatable illness, policies and procedures should be written to ensure the confidentiality of employee medical records, as in any other medical or health-related condition. Urinalysis test results, which could be part of such a diagnosis, should be treated with the same confidentiality.

Q. Who should set up a drug screening program? How does one develop a policy?

A. The first priority should be to establish whether there is a need for a screening program. Is drug use present and significant? Can a drug use deterrent be established by means other than urine screening? The decision of whether or not to establish a drug-testing program will also depend to a large extent on the work setting. The initial question that management should consider is, "What is the purpose for testing?" The key concerns must be for the health and safety of all employees (i.e., early identification and referral for treatment) and to assure that any drug detection or screening procedure would be carried out with reasonable regard for the personal privacy and dignity of the worker.

The second critical question to consider is, "What will you do when employees are identified as drug users?" Once these issues are clarified, drafting a policy should be relatively easy.

Q. What level of drug in the urine indicates an individual is impaired?

A. Although urine screening technology is extremely effective in determining previous drug use, the positive results of a urine screen cannot be used to prove intoxication or impaired performance. Inert drug metabolites may appear in urine for several days, even weeks (depending upon the drug), without related impairment. However, positive urine screens do provide evidence of prior drug use.

Q. How reliable are urinalysis methods?

A. A variety of methods are available to laboratories for drug screening through urinalysis. Most of these are suitable for determining the presence or absence of a drug

in a urine sample. Accuracy and reliability of these methods must be assessed in the context of the total laboratory system. If the laboratory uses well-trained and certified personnel who follow acceptable procedures, then the accuracy of the results should be very high. Laboratories should maintain good quality control procedures, follow manufacturer's protocols, and perform a confirmation assay on all positives by a different chemical method from that used for the initial screening.

Equally important are the procedures that are followed to document how and by whom the sample is handled from the time it is taken from the individual, through the laboratory, until the final assay result is tabulated. This record is referred to as the "chain of custody" for the sample.

Q. What does laboratory quality assurance mean?

A. Quality assurance procedures are documented programs which the laboratory follows to ensure the highest possible reliability by controlling the way samples for analysis are handled and instruments are checked to be sure they are functioning correctly, and by minimizing human error. It involves the analysis of standard samples and blank samples along with the unknown samples to ensure that the total laboratory system is producing the expected results. These known samples are referred to as quality control samples.

Q. Many reports have appeared in the news media about legal cases in which experts have questioned the validity of a urine assay result. Does this indicate that the assay methods are not sufficiently reliable for broad application?

A. There is little controversy among experts in those cases where appropriate methods were used, good laboratory procedures were followed in the context of a

good quality assurance program, and adequately trained personnel carried out the analysis and interpretation.

Q. What are the primary methods being used for urine screening?

A. Two of the most widely used methods are the EMIT System, distributed by SYVA Co., and the ABUSCREEN System, distributed by Roche Diagnostics, Inc. These are both based on immunoassay techniques. Information on these assays can be obtained by contacting the companies at the following addresses:

SYVA Company
900 Arastradero Rd.
Palo Alto, CA 94304
(415) 493-2200

Roche Diagnostics, Inc.
340 Kingland St.
Nutley, NJ 07110
(201) 235-6500

Q. What are "confirmation assays"?

A. If an initial screening assay shows a sample as being positive, a second assay should be employed to confirm the initial result. Two different assays operating on different chemical principles having both given a positive result greatly decreases the possibility that a "cross reacting" substance or a methodological problem could have created the positive.

A confirmation assay usually is made by a method which is more specific (or selective) than a screening assay. Examples of commonly used confirmation methods include gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS), and high performance liquid chromatography (HPLC). These are sophisticated

instrumental methods requiring highly trained technicians to operate them. They are capable of providing highly selective assays for a variety of drugs. Such assays cost more than the screening methods, but they provide a greater margin of certainty when used in concert with the screening assay.

Q. What is the preferred method for confirmation of presumptive positives from initial urine screens?

A. Gas chromatography coupled with mass spectrometry (GC/MS) is the preferred method for confirmation of a positive urine screening test, although other methods such as GC or HPLC can provide acceptable results.

Q. What do assay "sensitivity" and assay "cutoff" mean?

A. The ability of any assay to detect low levels of drugs has an inherent limit. The concentration of drug in the urine sample below which the assay can no longer be considered reliable is the "sensitivity" limit. The "cutoff" point is the concentration limit that will actually be used to assay samples. Any sample which assays below this level is considered a negative. Manufacturers of commercial urine screening systems set cutoff limits to their assays well above the sensitivity limits of the assay to minimize the possibility of a sample which is truly negative giving a (false) positive result.

For example, although the immunoassay screens such as the EMIT and ABUSCREEN for detection of marijuana use are sufficiently sensitive to detect drug metabolites at levels below 20 ng/ml, the assays are usually used at cutoff levels of 50 or 100 ng/ml. This not only decreases the possibility of a false positive resulting from operating the assay too close to its level of sensitivity, but also significantly decreases the possibility of a positive test resulting from passive inhalation.

Q. How can false positive results occur?

A. It is theoretically possible for substances other than the drug in question to give a positive result in a screening assay. This is sometimes referred to as "cross reactivity." However, most substances which could possibly cause such cross reaction have been evaluated by the companies that developed the tests and found not to interfere. These companies can supply brochures for all their drug screens which detail the extent to which other drugs or substances cross react with the assay. Generally the screening assays available today are highly selective if they are properly used.

False positive results can also occur due to human error. This is directly dependent on the experience of the laboratory personnel conducting the test and on the laboratory quality control procedures and confirmation procedures any good laboratory imposes to catch such errors.

Q. How can false positives be eliminated?

A. Probably the two most important reasons for the occurrence of false positives are poor quality assurance (QA) procedures in the laboratory and the absence of an appropriate confirmation assay to confirm presumptive positives arising from an initial screening procedure.

A good laboratory will impose a stringent and well-documented QA system and will also use a well-validated confirmation assay for all samples that test positive in a first screen.

Q. How frequently do false positives occur?

A. While there have been some reports of the occurrence of false positives, these can usually be

traced to poor quality control procedures at the laboratory site or to the fact that appropriate confirmation procedures were not used to verify the "presumptive positive." Typically the samples which were the subject of these reports were ones which tested positive by an initial screen but could not be confirmed by the confirmation assay. Such "unconfirmed positives" should always be reported as negatives.

Q. Are rigorous and costly laboratory procedures always necessary?

A. The need to use assay systems which are based on state-of-the-art methods and rigorously controlled procedures is inherent in situations where the consequences of a positive result to the individual are great. Where reputation, livelihood, incarceration, or the right to employment is an issue, maximum accuracy and reliability of the entire detection or deterrent system is indicated. In a case where the consequences are less severe, such as a counseling situation, it might be acceptable to use less rigorous systems. For instance, pediatricians sometimes use portable screening systems in their practices to assist in the diagnosis and treatment of drug problems in adolescents. Deterrence screening programs might employ screening assays alone when warnings are the only consequence and use more rigorous procedures when other actions are to be taken.

Q. Can passive inhalation of marijuana smoke lead to a positive urine even if the person did not smoke a joint?

A. Inadvertent exposure to marijuana is frequently claimed as the basis for a positive urine. Passive inhalation of marijuana smoke does occur and can result in detectable body fluid levels of THC (tetrahydrocannabinol, the primary pharmacological component of marijuana) in blood and of its metabolites in urine. Clinical studies have shown, however, that it is highly

unlikely that a nonsmoking individual could inhale sufficient smoke by passive inhalation to result in a high enough drug concentration in urine for detection at the cutoff of currently used urinalysis methods.

Q. Can time of previous drug use be determined from analysis of urine?

A. Not specifically. Urine specimens positive for cannabinoids, for instance, signify that a person has consumed marijuana or marijuana derivatives from within 1 hour to as much as 3 weeks or more before the specimen was collected. Generally, a single smoking session by a casual user of marijuana will result in subsequently collected urine samples being positive for 2 to 5 days, depending on the screening method employed and on physiological factors which cause drug concentration to vary. Detection time increases significantly following a period of chronic use. Determination of a particular time of use is thus difficult. The same issues would hold for other drugs, although the time after use during which a positive analysis would be expected might be reduced to a few days rather than a week or more.

Q. Can the level of "intoxication" of an individual due to marijuana use be gauged by urinalysis? Can his or her "use patterns" be determined?

A. Impairment, intoxication, or time of last use cannot be predicted from a single urine test. A true-positive urine test indicates only that the person used marijuana in the recent past, which could be hours, days, or weeks depending on the specific use pattern. Repeated analyses over time will, however, allow a better understanding of the past and current use patterns. An infrequent user should be completely negative in a few days. Repeated positive analyses over a period of more than 2 weeks probably indicate either continuing use or previous heavy chronic use.

Q. How long after use can cocaine/heroin/phencyclidine be detected by urinalysis?

A. Detection times are dependent on the sensitivity of the assay. The more sensitive the assay, the longer the drug can be detected. Drug concentrations are initially highest hours after drug use and decrease to undetectable levels over time. The time it takes to reach the point of nondetectability depends on the particular drug and other factors such as an individual's metabolism. The sensitivity of urine assay methods generally available today allows detection of cocaine use for a period of 1-3 days and heroin or phencyclidine (PCP) use for 2-4 days. These detection times would be somewhat lengthened in cases of previous chronic drug use but probably to no more than double these times.

Q. How long after marijuana is used can such use be detected?

A. Metabolites of the active ingredients of marijuana may be detectable in urine for up to 10 days after a single smoking session. However, most individuals cease to excrete detectable drug concentrations in 2-5 days. Metabolites can sometimes be detected several weeks after a heavy chronic smoker (several cigarettes a day) has ceased smoking.

Q. If a urine sample is negative a day after a positive sample, does this mean the first result was wrong?

A. Not necessarily. The actual concentration of drug in urine can change considerably depending on the individual's liquid intake. The more an individual drinks, the more the drug is diluted in the urine. A negative result on a sample taken a few hours after drinking significant amounts of liquid is quite possible, even though a clearly positive sample might have been evident before the liquid intake.

For this reason, a negative result does not mean that the person has not used the drug recently. As the excretion of marijuana metabolites reaches the approximate limit of detection by a given assay, repeated samples collected over several days may alternate between positive and negative before becoming all negative.

Q. How are the results of a urine drug assay expressed?

A. Frequently the results of an assay are reported by the laboratory simply as positive or negative. If a sample is reported as positive, this means that the laboratory detected the drug in an amount exceeding the cutoff level it has set for that drug. Different laboratories using different procedures and methods may have different cutoff levels. For this reason, one laboratory could determine a sample to be positive and another determine the same sample to be negative if the actual amount of drug in the sample fell between the cutoff levels used by the two laboratories.

Analyses may also be reported quantitatively. The actual concentration of the drug is expressed as a certain amount per volume of urine. Depending on the drug or the drug metabolite that is being analyzed, urine concentrations may be expressed either as nanograms per milliliter (ng/ml) or as micrograms per milliliter (ug/ml). (There are 28,000,000 micrograms in an ounce, and 1,000 nanograms in a microgram.) Cocaine metabolites may be detected in amounts as high as several micrograms in a heavy user, but the levels of metabolites from marijuana use rarely reach one microgram per milliliter and are usually expressed in nanograms per milliliter.

Q What adverse health effects can be correlated with the presence of marijuana metabolites in urine?

A. No studies have attempted to correlate metabolites in urine with specific adverse health effects. The presence of metabolites in urine indicates previous use of marijuana, and use of marijuana, at least on a chronic basis, is likely to lead to adverse health effects. Specific effects, however, cannot be correlated with a single urine concentration of metabolite.

"HOW DO I DEVELOP A DRUG POLICY?"

This is the question about employee drug use most often asked of the National Institute on Drug Abuse. The following steps are recommended in developing a drug abuse policy:

Determine the need for such a program.

Write for further information:

National Clearinghouse for
Drug Abuse Information
P.O. Box 416
Kensington, Maryland 20795

If individual urine screening or other surveillance is to be implemented, determine what you will do when you identify employees who use illicit substances.

Identify treatment resources.

Get expert assistance to identify reliable laboratories with good quality control programs.

Develop a company policy. Get union, labor relations, legal, medical, and employee assistance program staff involved.

Educate employees regarding the changes in company policy and make sure they are aware of the consequences of drug use.

National Institute on Drug Abuse
5600 Fishers Lane
Rockville, Maryland 20850