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Roche Diagnostic Systems
A Member of the Roche Group

Roche Diagnostic Systems, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Direct Dial
Fax

July 9, 1996

DOCKET NUMBER
PROPOSED RULE PR 26
(61FR 21105)

Mr. Loren L. Bush
Office of Nuclear Reactor Regulation
US Nuclear Regulatory Commission
Washington, DC 20555

RE: Comments Relative to Non-Instrument, On-Site Drug Testing

Dear Mr. Bush:

Roche Diagnostic Systems, Inc. ("RDS"), a subsidiary of Hoffmann-La Roche Inc., ("Roche") is a company dedicated to improving human health care by developing, manufacturing and marketing diagnostic test kits, reagents, and analytical instrumentation in a number of diagnostic fields. The field of toxicology and specifically drug abuse testing is a specialty in which RDS has over twenty years' experience. Both Hoffmann-La Roche and RDS are strong proponents of a drug-free workplace and believe drug testing plays a vital role in the responsible management of the problem of drug abuse in the work setting.

Roche offers a number of drug testing products based on various technologies, as well as laboratory services for the detection of illicit drug use. Among our product lines is Abuscreen OnTrak which is specifically designed to meet the needs of the on-site market, whether it be criminal justice or workplace. These tests are based upon latex agglutination inhibition, used on a non-instrument dependent self contained, single test "slide"; a simple, yet proven technology similar to many urine pregnancy tests. OnTrak provides a highly accurate qualitative assessment of whether the testing subject has ingested any of eight illicit drugs with a simple "yes" or "no" (positive or negative) result and requires minimal operator skills and interpretative judgment. RDS is proud of the quality and caliber of the OnTrak product line because it meets a strong market need in an efficient and simple system. RDS recently introduced the OnTrak TESTCUP which is also a non-instrument test which incorporates the collection device and test mechanism into one integrated unit. The TESTCUP allows for simultaneous detection of multiple drugs in as little as 5 minutes with no reagent mixing or urine handling. Furthermore, it has always been RDS' policy, even before the mandate from the Food and Drug Administration, to recommend that all positive OnTrak screening results be confirmed by an alternate methodology, preferably GC/MS.

On behalf of some of our colleagues in the non-instrument, on-site drug testing business, its imperative you review the facts and issues below which clearly

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demonstrates the utility of an onsite drug test and more importantly the superior accuracy and reliability of these tests. We have some concern that the preliminary comments depict non-instrument, on-site drug tests as not being accurate. This is absolutely not true and in some instances, the non-instrument test is more reliable than the instrument based test.

1. The **purpose** of drug abuse testing in the workplace is to identify behavior that unquestionably is illegal and clearly constitutes a danger to the work force collectively and its individual members. Likewise, the **purpose** of drug abuse testing in the correctional setting is not diagnosis or treatment, but rather to monitor and control a prisoner's or probationer's illegal and dangerous **behavior**.

2. Drug abuse testing is of critical importance to the identification of illegal, dangerous behavior in the workplace and correctional settings, and provides a unique aid to alcohol and drug rehabilitation counseling. When performed in the management of probation, parole, prison, drug and alcohol rehabilitation or management of workplace policies, drug abuse screening provides detection of drug or alcohol use; it does not assess disease, immediate impairment or other health-related diagnosis requiring medical judgment or treatment. Drug abuse testing is also qualitatively different from testing for purposes of treatment or diagnosis. This is because the patient being tested is fully aware of what the outcome of the test should be. The principles of diagnosis are then irrelevant for this type of testing.

3. Businesses which have an acute need to hire casual, short-term labor while ensuring a safe workplace for all employees can benefit greatly from on-site drug abuse testing. There were 6,101,924 small businesses (1 to 999 employees) in the Unites States in the last available census of 1989. Of these, 1,494,820 were engaged in retail trade, 546,848 were engaged in construction, 28,248 in textiles, 6,864 in the maritime industry, 8,893 in security services, and 12,381 were in the temporary help industry. These small businesses are examples of facilities unlikely to include occupational health laboratories and which must typically hire casual labor immediately, often for a shorter time period than the turn-around-time necessary for laboratory results. Those businesses which utilize employees in "safety sensitive" type positions, such as nuclear powerplants benefit tremendously from on-site testing, since the test is immediate those individuals testing negative can be put to work and those that test positive can be further evaluated.

4. On-site drug abuse testing is also performed on a "random" basis to ensure not only the safety of the community and corrections settings, but also to ensure a safe workplace by providing a means to immediately identify high risk individuals and to immediately return safe individuals to their ongoing activities. It is interesting to note that a recent American Management Association survey on Workplace Drug Testing showed that nearly 28% of companies said they used periodic or "random" testing, an increase of 435% compared to 1989. "Random" testing is especially important not only to the workplace but also to the management of offenders and

rehabilitation clients. In these settings, on-site drug testing unquestionably deters drug use.

5. On-site "for cause" drug abuse testing provides protection to the community and the workplace by allowing immediate assessment where drug abuse is suspected in cases of unsafe behavior or accidents. Individuals under the influence of illegal substances can be identified and prevented from operating machinery or vehicles immediately, thus eliminating exposure and risk to others. This would be of particular relevance in non-DOT regulated, intrastate transportation settings, such as school bus drivers, or in other areas where heavy equipment is in use, such as forestry, manufacturing, construction and maritime settings.

6. On-site drug abuse testing provides the most effective means of uncovering illegal and unsafe behavior because the testing takes place in the presence of the individual being tested. This minimizes denial, provides immediate feedback, and eliminates the cost, delay and "chain-of-custody" problems that accompany referral of all urine samples to off-site laboratories. In short, effective drug abuse testing and management should and does begin in places where no laboratory typically exists.

Non-Instrument, On-Site Drug Tests

- Non-instrument, on-site drug tests such as OnTrak are cleared by the US Food and Drug Administration for commercial distribution as a medical device for in vitro diagnostic use. The FDA 510 (k) notification supports the product as being safe and effective. The Roche OnTrak test was subject to the identical FDA review process that an instrument test must go through. There is no abbreviated process, nor are there lower standards for a non-instrument, on-site drug test.

- The Roche OnTrak tests (where applicable) are optimized at the current established and legally defensible SAMHSA (formerly NIDA) cutoff detection levels. This is consistent with the Federal Guidelines mandated by former President Ronald Reagan in the late 1980's. The cutoff detection levels for the OnTrak tests are identical to those cutoffs utilized in an instrument based test system.

- OnTrak test results have been upheld in court, in fact OnTrak test results have been upheld in several Federal Courts.

- OnTrak tests utilize immunoassay technology to provide clear cut, easy to read results with a high degree of accuracy.

- OnTrak and TESTCUP incorporate a quality control to verify the integrity and performance of the reagent system.

- In many instances, a non-instrument test such as OnTrak has been compared extensively against instrument based testing and also against the gold standard,

"GC/MS" confirmation. The results of these comparative studies clearly demonstrate the reliability and accuracy on a non-instrument test such as OnTrak.

- Roche maintains a client list of approximately 5,000 customers that utilize a non-instrument, on-site drug test. The applications for these tests vary from criminal justice, workplace, drug treatment and clinical testing programs.

- Non-instrument, on-site drug tests are simple and easy to use and require far less training than an instrument operator. This aspect greatly reduces the operational issues surrounding a legal since there are no questions regarding instrument calibration, maintenance and reliability. The non-instrument test is used once and simply discarded if the sample is negative or in the case of OnTrak, a positive result can be photocopied for evidence.

- Non-instrument, on-site drug test reagents are not subject to dilution/extension/enhancement processes like the instrument based reagents. In some instances those labs that utilize an EIA drug test modify the FDA cleared test by adding extender reagents to simply obtain more tests from a single test kit. For example, a typical 300 test EIA kit can be diluted to yield 1,500 or more tests. This practice is not supported by the manufacturer of the kit and is used outside the intended use of the product.

In conclusion Mr. Bush, I hope this information is useful and can be utilized once all the comments are collected. I have enclosed some product literature for your review. If you would like to discuss this further or if you have any questions, please feel free to contact me at 908-253-7720.

Sincerely,

Robert L. Aromando, Jr.
International Marketing Manager
Drug Abuse Testing Business Unit

Selected ONTRAK Court Challenges

* **Commonwealth of Pennsylvania vs. Twyman. Numbers 2557-87, 2695-89, 3179-87. Court of Common Pleas of the County of Chester, Pa.**

  Sanctions were imposed on defendant due to a positive ONTRAK cocaine result. The officer was able to testify successfully to the training received, the test procedure and principles as well as the reliability of ONTRAK. The positive ONTRAK test result was upheld as evidence to establish the defendant was in violation of his probation and parole.

* **State of Arkansas vs. Gary Chandler. Pulaski County Court, Floyd J. Lofton; Circuit Judge.**

  The defendant tested positive for cocaine using the ONTRAK immunoassay. The defendant subsequently admitted he had used cocaine. The Judge ruled the defendant was in violation of his suspended sentence.

* **People vs. Joe Weccele. Numbers 87-CF16, 87-CF 17, 90-CM 121, 2nd Judicial Circuit Court, Wayne County, Illinois.**

  The defendant tested positive for amphetamines using the ONTRAK immunoassay. The specimen was subsequently rescreened and confirmed positive at a certified reference laboratory. The toxicologist testified that the ONTRAK immunoassay was equivalent to the EMIT screening test utilized by the lab. The court upheld the ONTRAK result.

* **Kimball vs. Stotts, et al. Case Number 92-3413-DES, United States District Court for the District of Kansas.**

  Kimball challenged the accuracy of the prison drug testing procedure. He also contended that the initial ONTRAK THC positive immunoassay result should have been confirmed. The Judge ruled that similar urinalysis test results in prison drug surveillance have consistently found the test results sufficiently accurate.

* **State of Georgia vs. Boykin Cobb. Superior Court of Newton County, State of Georgia, Probation Revocation, December 13, 1994.**

  The defendant contested the validity of two OnTrak cocaine positive results conducted on two separate occasions. Dr. Sal Salamone of Roche Diagnostic Systems provided testimony regarding the scientific principles of the ONTRAK test. Both test results were deemed acceptable by the court.

* **United States of America vs. Diana Ceasar-Gonzalez. Criminal Action Number 93-10020-Z, United States District Court for the District of Massachusetts, October 21, 1993.**

  During pre-trial supervision, the defendant was tested for cocaine use and subsequently determined to be positive by the ONTRAK immunoassay. The officer that performed the test had testified to validate the procedure, the training and the interpretation of the result. The ONTRAK result was upheld.

* **Knight vs. Roberts. Case Number 90-C-094, District Court of Leavenworth County Kansas.**

  The defendant took issue with the lack of any sort of confirmation test conducted by the defendant's agents after subsequently testing positive for THC by the ONTRAK immunoassay. The ONTRAK THC result was upheld.

* **United States of America vs. Keith Nicholas Marchezak. Criminal Number 92-108, United States District Court for the Western District of Pennsylvania, May 23, 1994.**

  During probation the defendant tested positive for cocaine on four subsequent occasions by the ONTRAK immunoassay. Additional testing on other occasions by a certified laboratory established a consistent trend of drug abuse. The court ruled that all the drug tests performed were upheld.

ABSTRACT

EVALUATION OF ABUSCREEN ONTRAK™ ASSAYS: CORRELATION WITH RIA AND GC/MS

Derek P. Baker*, D.C. Gulntu, D.A. Mendoza, M.E. Calderone,
P.F. Shepp, M.S. Murphy, M. Greene
Damon Reference Laboratories, Newbury Park, California 91320

The Abuscreen **ONTRAK™** Assay is a self-contained, single test unit employing a sensitive latex agglutination system. The assay provides a rapid test system that gives qualitative results with urine samples within 3 to 4 minutes, without need for instrumentation. **ONTRAK™** Assays for Amphetamines, Barbiturates, Cocaine, Morphine, and THC (Cannabinoids) were evaluated in this study.

Qualitative drug screening results obtained by testing with **ONTRAK™** were compared to quantitative results obtained by Abuscreen RIA methodology. All positive **ONTRAK™** and/or RIA results were confirmed by GC/MS.

Patient urine samples (n=635) were assayed for each of the five drugs to evaluate sensitivity and specificity. Sensitivity was evaluated by comparison of **ONTRAK™** results with those obtained by GC/MS: Amphetamines 88.2% (82/93), Barbiturates 100% (90/90), Cocaine 100% (129/129), Opiates 99.2% (113/114), and THC 98.6% (142/144). The specificity of the **ONTRAK™** Assay was 100% when results were compared to those obtained by RIA: Amphetamines (418/418), Barbiturates (417/417), Cocaine (375/375), Opiates (392/392), and THC (334/334). **There was 100% agreement between the ONTRAK™ positive samples confirmed by GC/MS.**

These results show the Abuscreen ONTRAK™ Assays for Amphetamine, Barbiturates, Cocaine, Morphine, and THC can provide reliable screening results with urine.

ABSTRACT

EVALUATION OF ABUSCREEN ONTRAK™ ASSAYS: CORRELATION BETWEEN CLINICALLY TRAINED PERSONNEL AND NON-CLINICAL PERSONNEL IN THE FIELD

Derek P. Baker*, D.C. Gulntu, D.A. Mendoza, M.E. Calderone,
P.F. Shepp, M.S. Murphy, M. Greene
Damon Reference Laboratories, Newbury Park, California 91320

The Abuscreen **ONTRAK™** Assay is a self-contained, single test unit employing a sensitive latex agglutination system. The assay provides a rapid test system that gives qualitative results with urine samples within 3 to 4 minutes, without need for instrumentation. **ONTRAK™** Assays for Amphetamines, Barbiturates, Cocaine, Morphine, and THC (Cannabinoids) were evaluated in this study.

Qualitative drug screening results obtained by testing with ONTRAK™ at non-clinical off-site facilities by non-clinical personnel were compared to those obtained by technically trained personnel using **ONTRAK™** and Abuscreen RIA methodology. All positive **ONTRAK™** and/or RIA results were confirmed by GC/MS.

Aliquots of previously screened urine samples (n=6945) were assayed at non-clinical sites (n=3) by **ONTRAK™** for each of the five (5) drug classes. Specificity was evaluated by comparison of **ONTRAK™** results with those obtained by RIA: Amphetamines 99.7% (1160/1163), Barbiturates 99.6% (1105/1109), Cocaine 98.7% (1088/1102), Opiates 99.8% (1142/1143), and THC 98.2% (747/761). The sensitivity of **ONTRAK™** was evaluated by comparison of results obtained by GC/MS: Amphetamines 87.6% (247/282), Barbiturates 98.8% (415/418), Cocaine 97.6% (378/387), Opiates 98.8% (335/339), and THC 99.3% (415/418). **There was 98.6% (6850/6945) agreement between the ONTRAK™ Assay results obtained in the field and results obtained by technically trained personnel in a clinical laboratory.**

These results show the Abuscreen ONTRAK™ can provide reliable screening results in a non-technical setting by non-technical personnel.

ONTRAK Technical review

Screening for Drugs of Abuse with the Roche ONTRAK Assays

(Armbruster, D.A. and Krolak, J.M., Journal of Analytical Toxicology, 16, pp. 172-175, May/June 1994.)

- In this study, ONTRAK for cocaine and THC were extensively compared to RIA, which is considered the gold standard in drug testing by the U.S. Department of Defense, and the Abbott TDx fluorescent polarization (FPIA) system.

- The ONTRAK assays exhibited excellent correlation to both RIA and GC/MS. Table III in the paper documents 100% specificity and predictive value for a positive test among the three technologies.

- FPIA and ONTRAK results agreed in all cases for both cocaine and THC assays.

- ONTRAK for amphetamines, barbiturates and morphine assays were studied on fewer samples and compared favorably to FPIA.

- This study attests to the high quality of ONTRAK, a qualitative, on-site, non-instrument testing system. The excellent correlation of results with instrument-based technologies which are considered to be highly accurate demonstrates the confidence ONTRAK users should have in their test results.

"We conclude that the ONTRAK assays produce results that usually agree with typical automated immunoassays and GC/MS confirmatory procedures."

ONTRAK TESTCUP Technical review

ONTRAK TESTCUP: A Novel, On-Site, Multi-Analyte Screen for the Detection of Abused Drugs

(International Drug Monitoring Business Unit, Roche Diagnostic Systems, Inc., 1080 U.S. Highway 202, Somerville, NJ 08876, Journal of Analytical Toxicology, Vol. 19, pp. 504-510, October 1995.)

- In this study, the correlation's of clinical sample results using TESTCUP versus results by GC/MS and the ONTRAK and ONLINE assays were assessed.
- There was 100% agreement between samples prescreened positive by GC/MS and positive by TESTCUP for all three assays.
- There was 100% agreement between TESTCUP and ONTRAK results and between TESTCUP and ONLINE results when testing clinical samples positive and negative for cocaine (benzoylecgonine) or THC.
- Greater than 99% agreement was observed between TESTCUP and ONTRAK results and between TESTCUP and ONLINE results when testing samples positive and negative for morphine
- This study attests to the high correlation of TESTCUP results, a qualitative, on-site, non-instrument testing system to other well established and highly accurate drug testing technology. TESTCUP permits simultaneous detection of THC, cocaine and morphine directly within the collection device.

"The ONTRAK TESTCUP assay system is an easy-to-use and reliable method for the detection of cocaine, opiates, and THC in urine. When compared with other ROCHE immunological assays for drugs of abuse, whether they be instrument or non-instrument based, there is good agreement between clinical results."

Drug Detection Cut-off Levels

Substance Abuse and Mental Health Services Administration (formerly NIDA), Mandatory Guidelines for Federal Workplace Drug Testing Programs

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(e) Initial Test. (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

• Marijuana metabolites	50 ng/mL
• Cocaine metabolites	300 ng/mL
• Opiate metabolites	300 ng/mL
• Phencyclidine	25 ng/mL
• Amphetamines	1,000 ng/mL

(Federal Register, Part V, Thursday, June 9, 1994)

Roche

Helping solve the problems of drug abuse

WARNING: THE STATE OF THE ART OF DRUG TESTING HAS CHANGED FOREVER...

...WITH ONTRAK TESTCUP!

The new ONTRAK TESTCUP™ from Roche Diagnostic Systems offers...

- Simultaneous detection of cocaine, morphine, and THC
- Integrated collection *and* testing device for every sample
- Room temperature storage
- No urine or reagent handling
- Results in under 5 minutes *without* timing
- Clear positive/negative results

For more information on the *new* state of the art in drug testing, call the Roche Response Center® at 1-800-526-1247.

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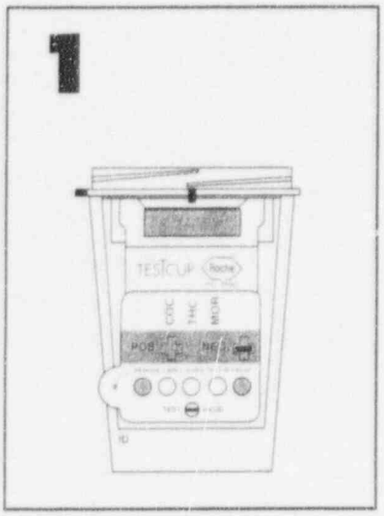
*The **only** drug test endorsed by The National Association of Temporary and Staffing Services.*

ONTRAK
TESTCUP™
Collection / Urinalysis Panel

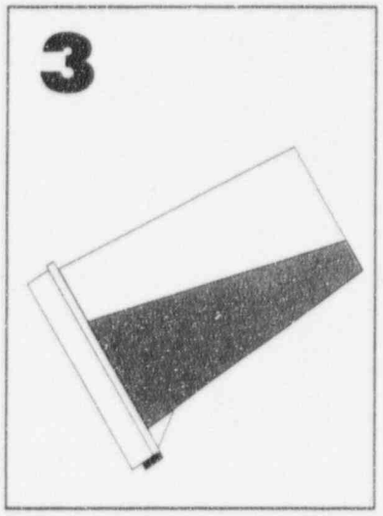
Roche

Helping solve the problems of drug abuse

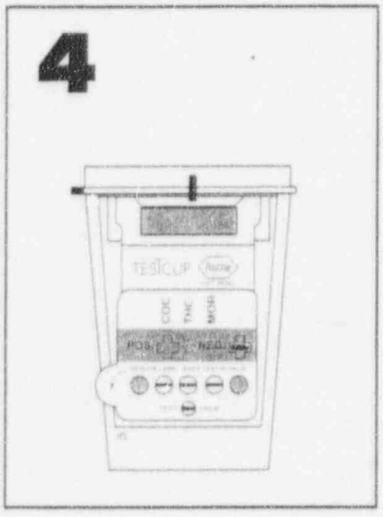


1. Add specimen to cup. Minimum 30 mL recommended.

2. Close lid by turning to "test" position.

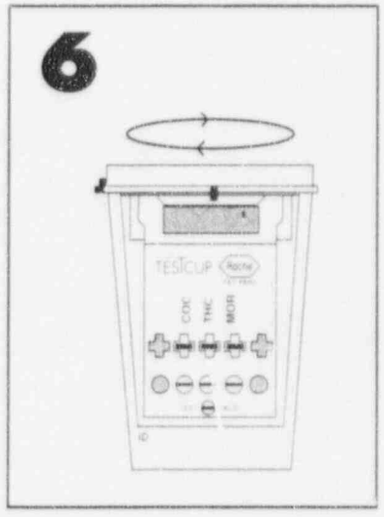


3. Tilt cup forward for 10 seconds. *Do not invert cup.*



4. Wait for "test valid" bands to appear. Timing is not required.

5. Peel off label and read each result.



6. Close lid by turning to "stop" position for storage.

Ordering Information

To order the *new* state of the art in drug testing, call the Roche Response Center at 1-800-526-1247.

	Package Size	Order Number	Art. No.
OnTrak TesTcup	25 cups	47226	07 5561 3

Roche Diagnostic Systems
A Member of the Roche Group

Roche Diagnostic Systems, Inc
Branchburg Township
1080 US Highway 202
Somerville, NJ 08876-3771
1-800-526-1247; in Canada 1-800-268-0482

Plandex 12255-0396R

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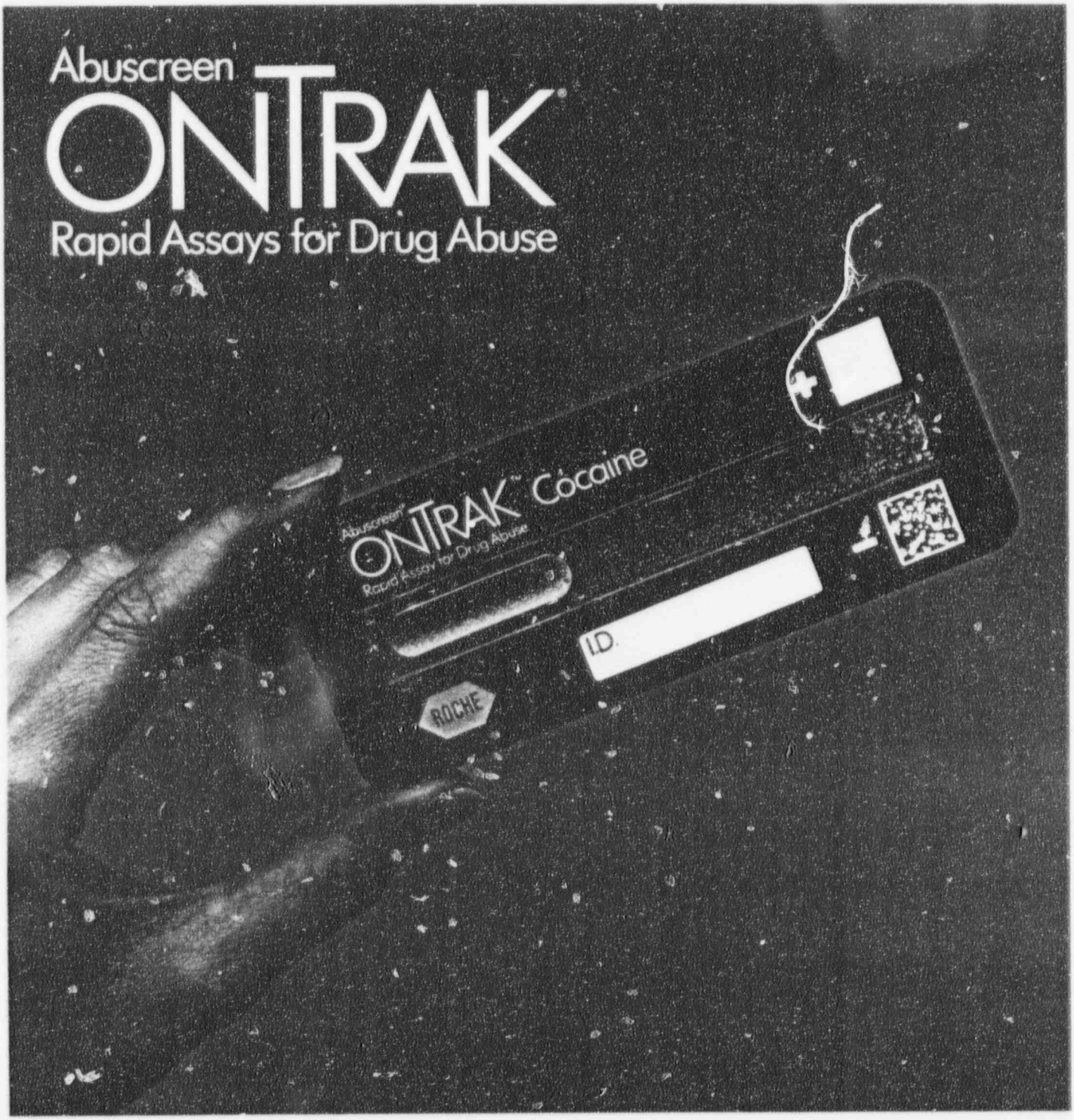
Helping solve the problems of drug abuse

REVOLUTIONIZE YOUR DRUG TESTING. SIMPLY AND ECONOMICALLY. ON SITE. IN SIGHT. ON TIME. ANYTIME.



THE ASSAY DESIGNED TO DRAMATICALLY CHANGE YOUR DRUG TESTING CAPABILITIES...

Fast setup with results in approximately three minutes.

Convenient to perform on the spot, at any location.

Simple procedure—anyone on your professional staff can perform the test in just four simple steps.

Economical testing with no special equipment—a test kit and pipette are all you need.

Clear, objective, easy-to-read "yes" or "no" results—negative results form particles (agglutination occurs); positive results have a smooth, milky appearance.

Reliable—proven in clinical studies.

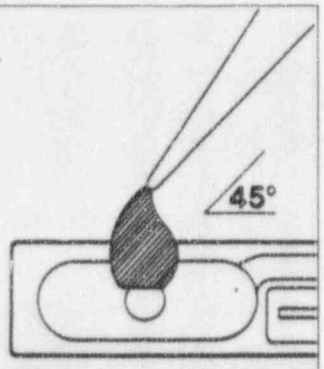
Abuscreen ONTRAK kits are designed to reliably detect cocaine, THC, morphine, amphetamines, barbiturates, PCP and benzodiazepines—accurately providing professionals with an objective "yes" or "no" response in approximately three minutes, with no special equipment.

As a fast, simple-to-use, self-contained source of patient drug-status information, ONTRAK can provide professionals with results on site, in hospital emergency rooms and STAT laboratories. ONTRAK is also invaluable for use in rehabilitative monitoring, intake screening, crisis intervention, prenatal screening, delivery room evaluation—any situation in which immediate drug-status information can make a critical difference.

Abuscreen ONTRAK®
Rapid Assays for Drug Abuse

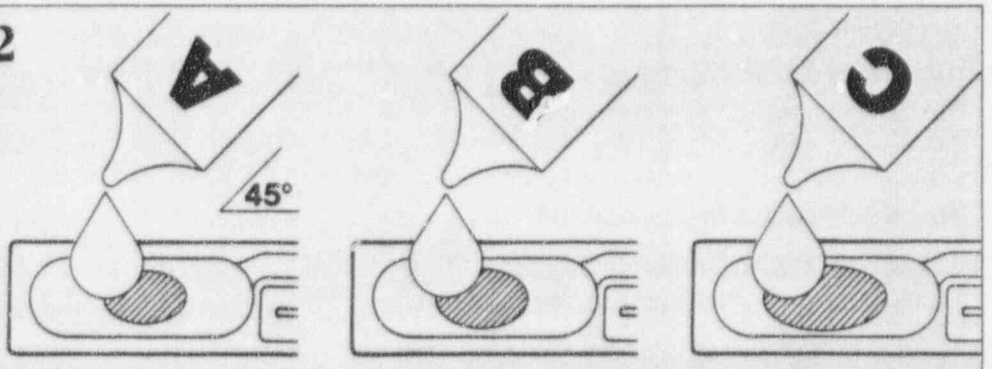
THIS SIMPLY...

1



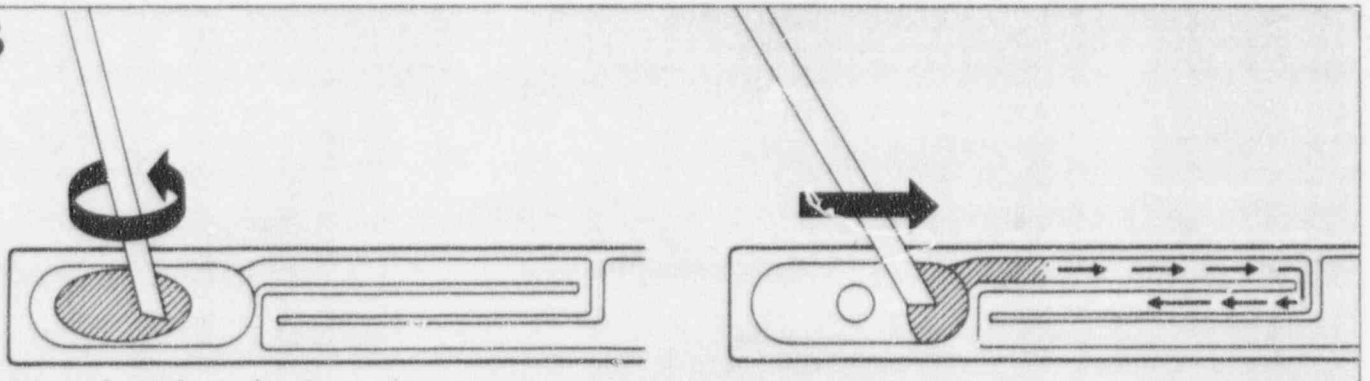
Place urine specimen in mixing well.

2



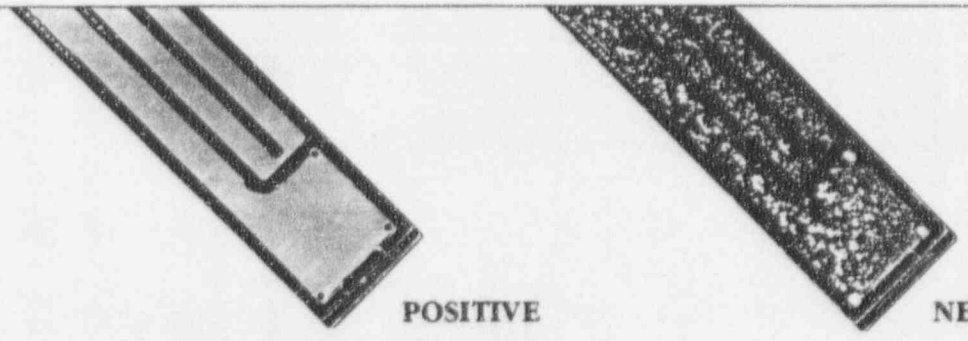
Add one drop each of reagents A, B and C.

3



Stir and gently push mixture into track opening.

4



POSITIVE NEGATIVE

Read results in viewing chamber.

Roche

Helping solve the problems of drug abuse

THE EASY-TO-PERFORM, COST-EFFECTIVE DRUG ABUSE TEST.

From the leader in drug abuse testing.

Developed by Roche Diagnostic Systems, Abuscreen ONTRAK consolidates the expertise gained through years of service to clinical, forensic and military laboratories. Today, the Roche name is your assurance of unequaled quality, service and technical support.

Ordering Information

Product	US Order No.	Article No.
Abuscreen ONTRAK Pipette	42208	0727938

The ONTRAK pipette is required for testing and should be ordered with your first kit.

Abuscreen ONTRAK Kits

	50-test		100-test	
	US Order No.	Article No.	US Order No.	Article No.
Amphetamines	42200	0738204	42216	0727911
Barbiturates	42201	0738212	42217	0727903
Benzodiazepines	42205	0738220	42221	0735515
Cocaine	42202	0738190	42218	0727865
Morphine	42204	0738247	42220	0727881
PCP	42206	0738239	42222	0735019
THC (100ng/mL)	42203	0738255	42219	0727873
THC (50ng/mL)	42330	0738263	42331	0727849

Abuscreen ONTRAK Kits include:

Reagents A, B and C	Simple Instructions
Negative Control	Stirrers
Pipette Tips	Test Slides

Positive Reference Controls

	US Order No.	Article No.
Amphetamines	43372	0730998
Barbiturates	43373	0733253
Benzodiazepines	43390	0735525
Cocaine	43374	0733261
Morphine	43387	0733288
PCP	43389	0738239
THC	43388	0733296

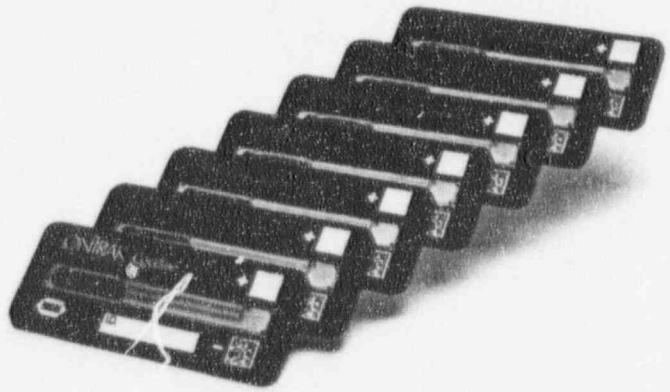
Optional Items Available

Product	Quantity	US Order No.	Article No.
Carrying case	1	42224	0730947
Disposable gloves	100	42210	0729841
Evidence tape	50	42212	0730904
Extra pipette tips	400	42214	0730912
Extra stirrers	400	42215	0730920
Pipette tip disposal bottle	1	42209	0729833
Urine sample cups	50	42211	0729868

Let Abuscreen ONTRAK help you solve the problems of drug abuse.

For more information, for technical assistance or to order, call the Roche Response Center℠ at 1-800-526-1247 (in the U.S.) or call your local Roche representative.

Abuscreen assays provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result (see package inserts).



Abuscreen ONTRAK®

Rapid Assays for Drug Abuse

Roche

Roche Diagnostic Systems

a subsidiary of Hoffmann-La Roche Inc.

Roche Diagnostic Systems, Inc.
1080 US Highway 202
Branchburg, NJ 08876-1760
1-800-526-1247
In Canada 1-800-268-0482

Roche Diagnostic Systems
a division of F. Hoffmann-La Roche Ltd
CH-4002 Basel, Switzerland

Plandex 1220SR 5/92

SUMMARY—RECENT EVALUATION OF ON-SITE DRUG TESTS

On-site drug screening tests are being widely used in a variety of ways to help solve the problems of drug abuse, both in the workplace and the criminal justice sector. On-site testing provides immediate results in a manner less likely to be challenged either by the person being tested or the courts with respect to chain of custody issues. Roche Diagnostic Systems introduced the Abuscreen ONTRAK® Rapid Assays for Drug Abuse in 1989 to the criminal justice market. Since that time, Abuscreen ONTRAK has become the test of choice throughout the criminal justice system by consistently proving its value with superior quality and accuracy.

Recently, a number of other diagnostic companies have entered the market with their versions of non-instrument, on-site test kits. Two of these companies, Editek (formerly EDI) and Drug Screening Systems, Inc. (DSSI) are promoting their kits. As a result of these newer entries into the market, it has become increasingly difficult for a criminal justice agency or a corporation to take the time to evaluate all the available assays and select a vendor for their needs. One criminal justice agency, the Florida Department of Corrections (DOC), recently commissioned a study that enabled them to purchase a drug testing system that met rigorous performance specifications.

The study was performed by a NIDA (National Institute on Drug Abuse) certified laboratory on a panel of 100 well-characterized urine samples that were tested for both THC and cocaine. The samples were defined and categorized as, 20 negatives, 20 at – 50% of cutoff (0.5 × cutoff), 20 positives at +20% of cutoff (1.2 × cutoff), 20 positives at +50% of cutoff (1.5 × cutoff), and 20 additional "random" positives for THC and cocaine. Each of three vendors (Roche Diagnostic Systems, Editek, and DSSI) were asked to provide sufficient Cocaine and THC kits to complete the test panel studies. Roche provided the Abuscreen ONTRAK System, Editek provided the EZ-Screen System, and DSSI provided the MicroLINE System (also marketed under the Mach IV label by Wells Fargo). None of the vendors assisted or participated directly in the evaluation.

On April 21, 1993, the results of the Florida DOC study were made public. Abuscreen ONTRAK was the only product to score 100% on all samples, thereby reinforcing the leading position that ONTRAK has established in the on-site drug abuse testing marketplace.

continued...

Roche Diagnostic Systems will provide a copy of the Florida DOC study in its entirety on request. The following is a summary of the results of their analyses:

Assay	# False Positives	# False Negatives	# "No Results"	# Expected Results
ONTRAK (RDS)				
Cocaine	0	0	0	100
THC	0	0	0	100
EZ Screen (Editek)				
Cocaine	2*	0	0	98
THC	20†	0	0	80
MicroLINE (DSSI)				
Cocaine	21‡	0	2	77
THC	4§	4	3	89

*Includes 2 "positives" at 0.5 × cutoff.
†Includes 20 "positives" at 0.5 × cutoff.
‡Includes 1 "positive" on negative urine plus 20 "positives" at 0.5 × cutoff.
§Includes 4 "positives" at 0.5 × cutoff.

And an excerpt from the study summary:

"The Roche ONTRAK provided the highest analytical accuracy of the three vendor kits tested for both cocaine metabolite and carboxy-THC, the Environmental Diagnostics EZ-Screen was second in accuracy, however, the kits were also the most difficult to use with several critical steps required for testing. The MicroLINE was found to be the easiest procedure to follow with only one step in the application of the urine specimen to the plate. The MicroLINE was susceptible to false positive results, however."

If your agency isn't using Abuscreen ONTRAK, the results of this study present valid reasons for you to re-examine your drug testing program. Although a simple option, you could select your vendor on price alone and perhaps not recognize the additional costs of retests, unconfirmed positives by GC/MS, and possible court challenges. However, a good drug test is designed to keep you out of court and to provide you with test results that give you a high level of confidence. This study demonstrates that not all drug tests are alike, and while some may seem more attractive due to a low direct cost per kit, overall reliability may represent a far-greater value both economically and in the quality of your results. Furthermore, the study substantiates the performance claims in the ONTRAK package inserts as they relate to the established NIDA cutoffs. To request a complete copy of the Florida DOC report, for more product information, or to order Abuscreen ONTRAK, please call the Roche Response Center℠ at 1-800-526-1247.

Roche Diagnostic Systems
a subsidiary of Hoffmann-La Roche Inc.

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Another ONTRAK success story!

"An Incredible Deterrent"

Drug Detection Test Saves Time and Money

By Lea Brooks

Some California counties are using technology that allows them to determine in about three minutes whether adults and juveniles on probation are using illegal drugs. Based on the same technology as a home pregnancy test, the ONTRAK system uses a urine sample to detect marijuana, amphetamine, cocaine, morphine and other drugs. Probation officials in five counties told California County editor Lea Brooks that the system is an effective deterrent, convenient to use and saves money.

TEENAGERS INCARCERATED IN SAN Bernardino County's juvenile hall know the Regional Youth Educational Facility as the last chance program. "If you fail here, you end up in the California Youth Authority," explained Joe Rodriguez, a facility group counselor.

The facility offers 29 components ranging from drug education to vocational training designed to help the 40 young men ordered there by the court to turn their lives around. Clients, who range from 16 to 18 years old, are allowed off site to work.

Drug testing is a major part of the five-level program, which lasts six to nine months. "An initial screening process makes sure the kids are clean when they arrive and determines if individuals have a substance abuse problem," Rodriguez said. "Whenever an individual leaves our facility and returns, he is drug tested. There is also random drug testing."

The facility's drug testing efforts were transformed when it began using ONTRAK a year and a half ago, according to Rodriguez. Previously, urine samples were mailed to a laboratory. The time lapse for results — about a week — was too long for effective intervention.

"ONTRAK is an incredible deterrent here, especially when the kids know we can ask for a urine sample at any minute," he said. "Our positive drug tests have decreased by at least 50 percent. We found out the kids are more apt to admit they are using when they're confronted with the results right in front of them."

Individuals who test positive lose free time and are demoted a level. They are also placed in a more extensive drug education program.

Immediate Results

Budget cuts prompted San Luis Obispo, Santa Barbara and San Benito counties to include ONTRAK in their probation drug testing programs. When an ONTRAK test is positive, the urine sample is sent to a laboratory for confirmation. Judges generally don't accept ONTRAK test results unless the defendant admits to using drugs.

In San Luis Obispo County, the cost for a laboratory test is $17.50, compared with $2 to $3 for an ONTRAK test. The county conducts more than 3,000 drug detection tests a year.

"We went to ONTRAK as a pre-screening tool for cost savings," said county Probation Division Manager Tom Nielsen. "Less than a third of all tests are positive. We were paying full laboratory fees for negative tests. Because of the cost savings, we're able to maintain a testing level staff thinks is appropriate."

In Santa Barbara County, a laboratory test is $7.50. Of the 530 tests done in the county's Santa Maria probation office in February, 44 were positive. "We had 486 tests we didn't have to do anything else with — we dumped them in the toilet," said Bill Pucciarelli, deputy probation officer in Santa Maria. "That's where the value comes in."

There are other benefits as well.

"The system is entirely portable," Nielsen noted. "The officers like it because the client gets to stand around and watch the test. The real beauty of it is that you can have a frank discussion about drug use on the spot, and that really aids in communication. If the test is negative you can give an 'attaboy' on the spot, too. A lot of the things probation does are of an encouraging nature."

San Diego County follows the American Probation and Parole Association's drug testing guidelines. Its program was developed based on recommendations from a U.S. Department of Justice consultant.

Most of the county's annual drug testing budget is spent on laboratory tests — $215,000 compared with $25,000 on ONTRAK tests.

"Financially, we want to get the best and the most testing we can for our dollars," said Probation Director Jone Poe. "That's why we use a combination of systems. We also need confirmation on anything we refer to court."

She called ONTRAK a "good deterrent in a constitutional setting. It's a good tool to break down denial because you have the results immediately. The results lose some of their impact when you have to wait a week."

Poe is always on the lookout for even easier-to-use and less expensive drug testing systems.

"Our positive drug tests have decreased by at least 50 percent. We found out the kids are more apt to admit they are using when they're confronted with the results right in front of them."

"These products are improving all the time — not just tests for probationers," she said. "Private-sector companies are testing their employees for drugs. All these tools are marketable because of the drug problem in this country."

Pucciarelli concurred that drug testing technology will continue to advance. He believes hair will be analyzed to detect substance abuse in the not-so-distant future. "Anything you secrete in urine is also secreted through hair follicles," he said. "By analyzing a half inch of hair, you could determine which drugs your client used in the previous month."

ONTRAK was developed by New Jersey-based Roche Diagnostic Systems Inc. The system is also used by California State Parole, the California Youth Authority, drug treatment and rehabilitation facilities, emergency rooms, neonatal wards and industry, according to company representative Rod Sprague. ▪

DRUG TESTING

A Standard Business Practice

By J. Michael Walsh

Over the last 15 years, employee drug testing has become common business practice in the American workplace. Since 1987, the date of the American Management Association initial survey, company drug testing in the United States has increased by more than 300 percent. Currently, workplace drug testing laboratories certified by the U.S. Department of Health and Human Services are processing about 60,000 specimens each day, and many employers who conduct employee testing programs use other labs or onsite test procedures. Based on this information, I estimate more than 30 million American workers will be tested for illicit drug use this year.

This phenomenon of workplace drug testing has not occurred overnight, but rather has developed slowly over more than a decade. During that time, policies, procedures and technology have evolved. In 1995, most organizations use drug testing as the foundation for a comprehensive programmatic approach to substance abuse. In fact, the American Management Association survey indicates that "testing is rarely a stand-alone policy." Only 10 percent of respondent companies rely on testing alone to deal with employee substance abuse.

Consensus Development

The basic philosophy of why to test and what to do with the results of testing has changed dramatically over the last 10 years. In the early years, the rationale for testing was to identify drug users and fire them without addressing the problem. Since then, a more positive "helping hand" philosophy has evolved. The primary purpose of today's model policy is to get the substance abusing employee into treatment, provide the opportunity to get help and to get the individual back on the job.

This change in philosophy did not come about easily. At the midpoint in the decade of the 1980's, emotions ran high as to whether testing was legal, whether the procedures were scientifically sound, whether laboratories had the skills to perform the assays required and whether the procedures were so intrusive as to make the process unconstitutional. At that time (1985-1986), the legal uncertainty of whether testing would be upheld legally and so programs could go forward and expand, or be found unconstitutional and therefore stopped, created a great deal of confusion for policy-makers, as well as for employees, employers and unions.

Many of the critical issues were resolved through a series of "Consensus Development" meetings and conferences conducted through the leadership of the National Institute on Drug Abuse. These meetings brought together government, labor and management policy-makers to discuss the issues and determine what standards were appropriate, what policies were fair, what research data were available and what research needed to be done. The outcome of these meetings eventually set the standards for all government mandated programs and has significantly influenced private sector efforts in a very positive way. The presence of the labor movement in these benchmark discussions, including the leadership of the Teamsters, Oil, Chemical and Atomic Workers, Operating Engineers, Auto Workers, Sheet Metal Workers, and others in the building trades, also positively shaped the standards and programs currently in practice.

Five Basic Elements

Today's corporate program typically consists of a comprehensive effort including five basic elements: written and communicated policy; training for supervisors; employee education; employee assistance resource and drug testing.

The written policy typically prohibits the use of alcohol on the job and illegal drug use is generally prohibited at all times—on or off the job. The training for supervisors generally covers the key aspects of the company policy, what constitutes a policy violation and the consequences of policy violation. Companies now recognize that it is also important for supervisors to be trained in the procedures for referring a problem employee to the EAP resource. Education for employees is an important element of the program and is generally viewed as a continuous ongoing effort. In reality, the drug testing component is only a small part of the overall effort, but it is critical and it is complicated. Within the testing component there is a continuum of testing policy options available to management which include:

- Applicant (pre-employment) testing. (See sidebar on proposed changes.)
- Reasonable cause/suspicion testing.
- Accident or incident-driven testing.
- Treatment or follow-up testing.
- Routine medical/scheduled testing.
- Random testing of safety/security-sensitive personnel in designated positions.
- Universal testing of all personnel on a random selection basis.

While most company programs use a combination of these policy options; the specific options adopted by an organization will depend to a great extent on the nature of the work and the characteristics of the workforce. Companies with a high degree of safety or security-sensitive work may adopt a very aggressive program with "universal" testing, while another company without such risks may adopt the "reasonable cause" option.

The Modest Approach

Although the new expanded DOT regulations require some options listed above for regulated industries (airlines, railroads, mass transit, maritime, trucking, pipeline etc.) including the random testing of nearly 7.4 million transportation workers, many companies that are not safety-sensitive have opted for a more modest approach. From a national perspective, the most common workplace testing policy we see includes a two-pronged approach:

1) Applicant testing—where any job applicant who tests positive will not be hired, and
2) Reasonable cause testing—where current employees are subject to testing only when there is cause to believe the individual is using drugs.

The actual number of companies with

Reprinted from *Employee Assistance*, June 1995

"Drug Free Workplace" programs requiring pre-employment testing is difficult to document, but the practice is becoming more evident as employers begin to advertise their policy in newspaper "want-ads."

For example, a Sprint ad reads, "We maintain a smoke-free, drug-free workplace and perform pre-employment substance abuse testing." A Boeing ad reads, "We support a drug-free workplace and require pre-employment screening." And a Wendy's ad reads, "Applicant must pass pre-employment drug screen." Even though there are changes made to the DOT regs on alcohol testing in this area, employers retain the right to require a pre-employment test.

Union Involvement

Around the country, local unions have been involved in the development of union-run drug-testing programs. Typically, these efforts are integrated with their member-assistance programs. In a tough labor market, such programs provide assurances to contractors that union labor is drug free and can serve as an important marketing edge in getting union workers on the job. Some unions (notably, the Operating Engineers and the Sheet Metal Workers) have programs that require apprentices to undergo random testing during a stipulated probationary period. These kinds of labor-managed drug-testing programs are evolving and becoming more sophisticated. From my discussions with union leaders, there appears to be good membership support for union-run drug-testing programs.

The technology of drug testing also continues to evolve at a rapid pace. New assays with higher sensitivity (ability to detect use at lower thresholds) and increased specificity (ability to discriminate between similar compounds) are now being used by most labs. New onsite testing kits are also being broadly marketed for use in the workplace as the screening test. Some of these assays are highly accurate and reliable, but employers should be cautioned that any positive screen must be sent on to a laboratory for a confirmation test (as recommended in manufacturers' packaging inserts).

Testing Growth

As the demand for testing continues to grow both in the workplace and in the criminal justice system, more and more research is being conducted to develop better testing devices. A number of the diagnostic manufacturers currently have new products in the pipeline that will make testing much easier and less expensive in the very near future.

The overall growth of workplace testing has exceeded the expectations of most experts in the field, including me. When we initiated the military program in 1981, there appeared to be a logical extension for the use of this new technology in the business community, but I do not believe anyone involved at that stage had a vision of 1995 where employers would be openly advertising that applicants would have to pass a drug test to get a job.

It is important to evaluate the effectiveness of what it is we are doing, and to take a hard look at the forecast for the future. Although substance abuse and EAP professionals have witnessed an extraordinary change in the willingness of employers to focus on the issue of substance abuse and although the technology, procedures and lab standards for the use of drug testing became integrated into comprehensive substance abuse programs from 1986 to the present, considerable resources have been expended on these efforts with some sense of success, but relatively few companies have documented the effectiveness of their programs.

EAP Involvement

From a national perspective, we have seen a significant decline in the use of drugs by "employed" individuals. Data from the National Household Survey on Drug Abuse [Conducted by NIDA and more recently, by the Substance Abuse and Mental Health Services Administration (SAMHSA)] indicates that the number of full-time workers that are current users of illegal drugs has dropped by more than 6 million over the last eight years.

Data from the railroad industry indicate that nationwide accidents in their field have been reduced by 28 percent since 1987 when the railroads initiated their drug-testing programs. But more specifically, in 1987, about 21 percent of the nation's rail accidents involved workers who tested positive for drug use; that number declined to 5.5 percent by 1993. Transportation, however, is the only industry required to maintain and report data on their drug programs.

I believe that "drug-free" workplace programs work, and that as a result of these programs, we have made significant progress in preventing and treating drug and alcohol abuse. Unfortunately, we haven't done a very good job in reporting these success stories. Recently, the National Academy of Sciences issued a report "Under the Influence: Drugs and the American Workforce" (1994) where the major finding was that there was little or no data in the scientific literature to demonstrate the effectiveness of such programs in stopping abuse.

It is critical to evaluate and publicize the effectiveness of these programs both in the scientific literature and the popular press to maintain confidence and public support. As budgets become tighter and managers look for ways to cut corners, workplace drug and alcohol programs will erode unless "cost-effectiveness" is demonstrated. It is essential that EA professionals get involved in encouraging such evaluations, and participate in designing and conducting the studies.

State-Controlled Testing

With regard to testing, I suspect the use of drug testing will grow and expand significantly as a function of welfare reform. As the Congress transfers responsibility for welfare programs to the states, it is unlikely there will be sufficient funds to maintain state benefit programs on a par with those experienced with federally administered programs. State governors will be forced to find ways to limit eligibility to program benefits. The U.S. Chamber of Commerce has taken the position that since being "drug-free" is a condition of employment in most American workplaces, states should make eligibility for welfare benefits contingent on being drug-free as a critical first step in getting people prepared for business-sponsored "welfare-to-work" programs. Governor Pataki in New York State, as well as Mayor Guiliani in New York City, have proposed testing for welfare recipients, and similar proposals have been proffered in a number of states. If such programs do develop, it will present a unprecedented challenge to the treatment community.

J. Michael Walsh, PhD, is president of The Walsh Group, P.A., a consulting firm on substance abuse policy, research and technology in Bethesda, MD. Formerly, he was executive director of the President's Drug Advisory Council (1989-1993) and director of the Division of Applied Research at the National Institute on Drug Abuse.

TESTING AND TECHNOLOGY STAY FLEXIBLE

The DOT final rule due out in January, but delayed until May by DOT Secretary Frederico Pena, responded to concerns passed on during the comment period on a number of aspects of the testing mandates. The most momentous change, suspension of the pre-employment alcohol screening mandate for DOT-designated transportation workers, will involve action by Congress, but was announced on May 8 as "in effect until further notice."

An April 5 decision by the Fourth U.S. Circuit Court of Appeals added fuel to Pena's earlier declaration that he would make DOT regulatory reforms responsive to customers' needs. The three-judge panel sided with the plaintiffs, the American Trucking Association (ATA). Their arguments attacked the latitude that the DOT had "erroneously" taken in defining "pre-employment"—any time up to the first performance of a safety-sensitive job function—and said the tests failed to improve highway safety in any appreciable measure. The court vacated that section of the final rule, declaring it "rife with ambiguity" and "based on an interpretation that is clearly unreasonable." The court directed the DOT and other affected agencies to reinterpret final rules consistent with the court's decision.

Although some parts of the testing industry do not welcome Pena's views on pre-employment testing because it may reduce the market, drug testing is still a burgeoning industry. There are four other mandated categories that require testing and a growing recognition of it as an adjunct to treatment. Also, the DOT continues to review and give approval to more drug screening and related products for mandated testing. The evidential breath tests (EBTs) may still be used for the initial screen for alcohol and for confirmation of positives. They won DOT approval, in part, for being less costly, less invasive and easier to use than other choices. The Conforming Products List has recently added four non-evidential screening devices and one quantitative saliva testing device. The EBT must still be used for confirmation.

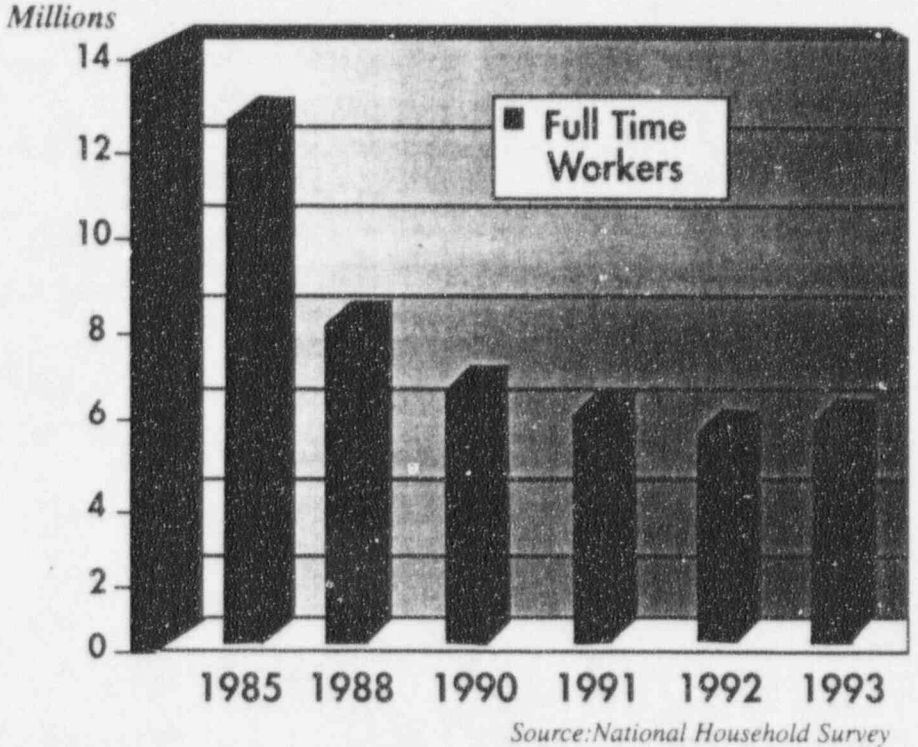
The April 20 Federal Register, Subpart D—Non-Evidential Alcohol Screening Tests details the fine points of the rule on authorization, screening test technicians, quality assurance plans, location of screening devices, testing forms, test procedures, invalid tests, refusals and inability to adequately complete tests, and maintenance of disclosure forms. They basically follow the requirements set for EBTs. Because legal liability and errors associated with chain of custody or false positives continue to be considered the biggest headaches involved in testing, the industry continues to develop devices that improve testing accuracy, guard against loopholes in custody procedures or, that all-time favorite, reduce costs.

The DOT has decided on another move toward flexibility—to extend the time between screening and confirmation from 20 minutes to 30 minutes. It ruled that "data show that an individual whose alcohol concentration at the time of a screening test was .05 would still, on average, test at .04 or above after a 30-minute interval...Consequently, increasing the interval...is unlikely to have a marked adverse effect on ...the regulation's objectives."

—Carole K. McMichael

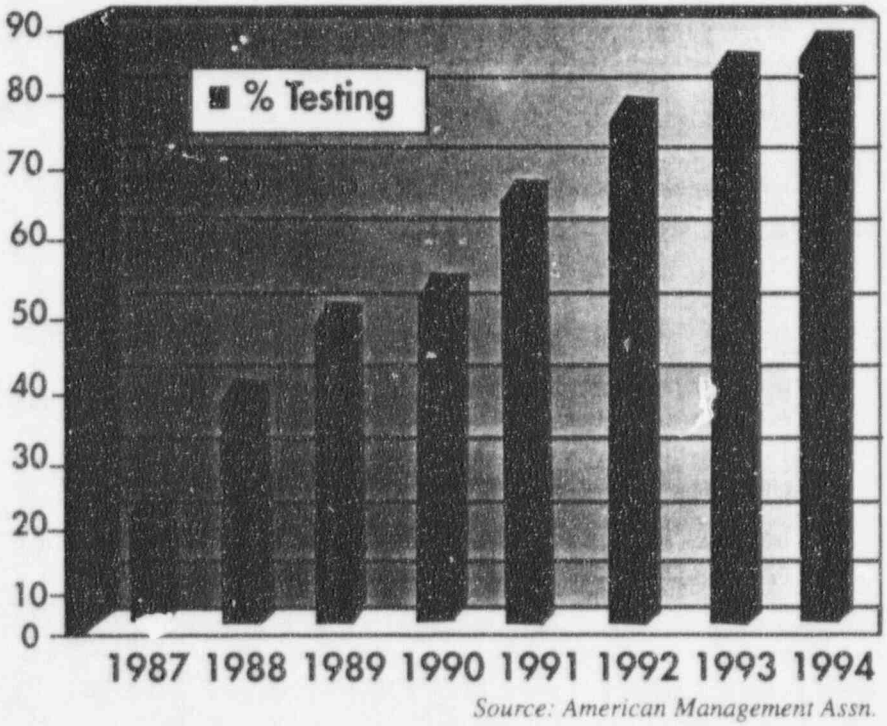
SIGNS OF SUCCESS:

Decrease in Current Drug Use Among Full Time Workers



Source:National Household Survey

PERCENTAGE OF US COMPANIES CONDUCTING EMPLOYEE DRUG TESTS



Source: American Management Assn.

Chain-of-Custody Errors Can Quickly Undermine the Case in Court

Non-instrument, on-site tests are the latest tool in the war against drugs in the workplace

Drug testing is being used to help provide a drug-free workplace, as a treatment tool, and to monitor criminal offenders. The constitutional battle over drug testing has been decided in favor of drug testing.[1] The opponents of drug testing are already turning their attention to attacking flaws in the procedural aspects of drug testing.

The most vulnerable aspect of any drug test is the chain of custody of the specimen. Chain of custody is the documentation of the transportation and handling of the specimen from the time of collection until the specimen is analyzed in a laboratory. A non-instrument, on-site drug test reduces the extent of the need for proof of the chain of custody. A non-instrument test produces rapid, documentable results using simple procedures that do not require sending a specimen to a laboratory. Non-instrument tests produce an immediacy of results; this eliminates uncertainty and substantially reduces the administrative burden posed by chain of custody. Non-instrument testing has been used extensively in the criminal justice system and has proven its value.[2]

The benefits of non-instrument testing are more clearly understood by looking at the vulnerabilities of chain-of-custody requirements.

Why is proof of a chain of custody necessary? In order to admit a drug test into court, a proper evidentiary foundation must be established by the party wishing to introduce the drug test.[3] The foundation consists of four building blocks:

1. The chain of custody of the drug test must be proven.
2. The court must recognize and/or be taught about the scientific theory and method equipment involved.
3. The circumstances of the specimen collection and analysis must be described.
4. The test result must be interpreted for the court.

A chain of custody must be proved when a specimen is liable to be altered by tampering or contamination and its condition at collection is important to the case. Urine specimens are in this class.[4]

By David G. Evans Esq.

BURDEN OF PROOF. When trying to prove the chain, the proponent has the burden of proving the identity and status of the specimen from collection until it reaches court as evidence.

A chain of custody is made of "links," i.e., persons who had significant opportunity to tamper with the specimen and/or who had custody of the specimen at some point.[5] A link could be a specimen collector or specimen transporter. In addition, the laboratory staff completing the analysis are all links.

The proponent must prove for each link:[6]

1. receipt of the specimen;
2. the specimen's ultimate destination, i.e., shipment, destruction or retention;
3. protection and proper handling between receipt and ultimate destination.

As the case requires, a court may or may not be strict in requiring proof of the chain.

The cases requiring a strict standard of proof are:[7]

1. when there is a strong chance that the specimen has been confused with other similar specimens;
2. when the specimen is easily alterable or liable to undetected contamination;
3. in a criminal case, where the establishment of a chain requires proof "beyond a reasonable doubt." This has been compared to a certitude of truth better than 95 percent. In a civil case, there must be a "preponderance of the evidence," which has been compared to a better than 50 percent certainty of proof.[8]

Chain-of-custody procedures are vulnerable to human error in a variety of ways. In establishing a chain of custody, the proponent risks having a chain that is too short, leaving out links in the chain or failing to account for time periods. The chain must be established from the time of collection to the time of analysis.[9] Some courts have required that the chain be established up to trial.[10]

Some courts require that the analysis is admissible only after each link is proved.[11] A person becomes a link not only by having access to the specimen, but by personally handling the specimen.[12]

How does one prove a link?

First, establish who handled the specimen. This is often difficult and imposes a burden that a non-instrument test does not impose.

To establish the chain with an instrument-based laboratory test, chain-of-custody forms need to be used. The drug-test form of the National Institute on Drug Abuse (NIDA) is an example. Each person handling the specimen before the result is obtained must record the handling and could be liable to be called into court.[13] The use of a chain-of-custody form raises issues which can be used to attack the admissibility of the drug test in two ways: first, it may list a link who did not appear in court; second, the form may not be properly completed, thus "breaking" the chain. In such a case, oral testimony must prove the link.

MORE PROBLEMS. Oral testimony to establish a link presents additional problems. For example, the person who is testifying may have left the room without locking the room or securing the specimen. The specimen may have been turned over to a subordinate for safeguarding. This "temporary entrustment" causes problems; the person who receives the specimen now becomes a link who may not be accounted for on the form. In addition, the parties can be questioned as to the length of time of the entrustment and the condition of the specimen. If this cannot be adequately shown in court, the chain may collapse.

If the person who was entrusted with the specimen is not present for trial, further problems arise. If the person was not originally listed as a witness, it may be a violation of a court rule to call the person.

It is also possible that a link may be an attorney who handled the specimen as part of preparing for the trial without the normal custodian of the specimen being present. This presents problems because the attorney may not be able to testify in a case in which he or she is involved.[14]

Was the specimen properly handled?

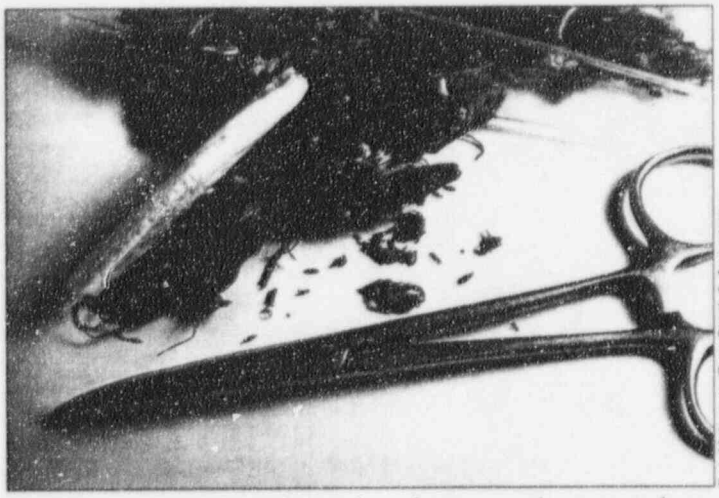
Once the links in the chain have been established, the next question raised is that of proper handling.

How is proper handling to be gauged?

Reprinted from *Occupational Health & Safety* April 1992

It must be shown that the person properly safeguarded the specimen before the test result was obtained. In criminal cases, the courts may require a "clear preponderance" of proof of proper handling.[15] In other situations, there must be a "reasonable likelihood" of proper handling.[16]

If the seal on the specimen container is broken, this may imply that the specimen was contaminated or was tampered with before it was tested.[17] Questions concerning proper handling would also arise if the specimen was not secured or refrigerated.[18] Was there free access to the specimen location, or was the specimen left alone for a period of time? Questions also can be raised about the standard operating procedures of the collection site or the laboratory. Any violation of these procedures could lead to a question about proper handling. The procedures may require that the specimen never be left unattended before it is tested. These questions can be more successfully raised with a large, high-volume laboratory where there is staff turnover. New staff may not be properly trained.



Bob McKeever from Stock & Associates

Non-instrument tests can be used to detect several common drugs, including marijuana and cocaine.

SPECIMEN IDENTITY. The collection of the initial sample also creates evidentiary problems. The placing of the specimen label is crucial to establishing the identity of the specimen. The proper sealing of the specimen must occur to avoid tampering or contamination.[19] There may also be storage requirements, depending on the jurisdiction.

Chain-of-custody problems are also raised by laboratory security requirements. For example, the NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs require that laboratories be secure at all times and that no unauthorized persons can gain access.[20] All visitors and maintenance and service personnel must be escorted at all times. Documentation of persons accessing the testing areas, dates and time of entry, and purpose of entry must be maintained. Laboratories must account for the specimen from receipt through completion of testing, reporting of results, and continuing until final disposition of the specimen.

Documentation must be provided as to the date and purpose each time the specimen is handled; each link must be identified. Upon receipt of the specimen at the laboratories, if there is evidence of tampering or damage to the package, it must be noted. Such damage could possibly invalidate a test result. In addition, refrigerated storage at a certain temperature is required if the test is not performed within seven days. If any of the above procedures or standards are not documented, or are not followed, the chain of custody may be indefensible.

Non-instrument drug tests eliminate the majority of administrative and chain-of-custody problems.

Many tested specimens yield negative results. Yet, in the absence of a non-instrument testing capability, they all must be sent to a laboratory. All the specimens must be accompanied by chain-of-custody forms and be in specially sealed tamper-proof containers or reliable tamper-evident collection devices. Non-instrument drug tests, when used with observed specimen collection, provide an initial screen which eliminates the negative test results. Although chain of custody is performed on all specimen collections, with non-instrument testing only the positive test results must be sent to the laboratory for confirmation. Paper work and staff time are then substantially reduced.

Another incentive for non-instrument testing is that, in some circumstances, positive results can be confirmed by another non-instrument test. Case law holds this as a perfectly acceptable procedure in a criminal-justice context. The criminal courts do not require the same level of proof required in employment cases. Indeed, convicted offenders have diminished rights when balanced against the right of the public to be protected.[21] For example, a single immunoassay or a double immunoassay may be all that is required.[22]

PROACTIVE TOOL. Non-instrument testing has other advantages. It is a proactive case-management tool. It is flexible as to where testing is done and increases the deterrent effect because it decreases the time between results and consequences.

Non-instrument testing provides an opportunity to promptly and positively reinforce drug-free behavior. If an employee or offender tests negative, the result is immediate and the person can be complimented on being drug-free — and encouraged to remain so.

A good non-instrument drug test is one that keeps you out of court. Such a test is one that meets rigorous scientific standards, such as demonstration of substantial equivalence to proven reference methods and pre-market clearance from the federal Food and Drug Administration.[23] The test should also, at a minimum, meet the NIDA cutoff levels for drug detection, since this has become a national standard.[24] The test should be documentable and easy to use as well as having undergone an independent scientific clinical evaluation performed by a NIDA-certified laboratory or the equivalent.[26] A reasonable cost per test is also a factor to be considered.

One test that meets all these criteria is the Abuscreen ONTRAK,® manufactured by Roche Diagnostics.[25] ONTRAK, an immunoassay, is based on the principles of latex agglutination-inhibition which relies on the competition for binding to an antibody between a latex drug compound and the drug that may be present in the specimen. The test can be used to detect marijuana, cocaine, opiates, amphetamines and PCP.

The specimen of urine is placed on a special slide in a mixing well with a buffer and reagents. The mixture has a milky appearance. The mixture moves along the track of the slide by capillary action to a viewing area. If a drug is not present in the specimen, the latex drug compound forms large particles (agglutination) by binding to the antibody. The particles are easily viewed through a clear window in the slide. If there is drug present, the particles do not form and the mixture retains its smooth, milky appearance which is also easily viewed. The advantages of ONTRAK are quick results (3 minutes), an easily read endpoint, simplicity, no instrumentation, and

since the result is obtained in front of the test subject, there are increased confessions of drug use by the test subject.[26] The viewing area on the slide can be photocopied for proof purposes and a drug test-result report can be completed right after the test. This eliminates a chain of custody.

Chain of custody poses many problems in proving drug-test results. The increasing use of non-instrument tests will eliminate many of these concerns and make drug testing a more useful tool in the war against drugs.

David G. Evans Esq. serves as a consultant on drug testing and substance-abuse issues to government, corporations, law firms, unions and laboratories. He is the author of Drug Testing Law, Technology and Practice, published by Callaghan. He has also authored the Model State Drug Testing in Employment Statute and the Model Criminal Justice Drug Testing Act which have served as the basis for legislation. Evans practices law in Lawrenceville, N.J.

References

1. Skinner v. RLEA, 109 S. Ct. 1402 (1989); NTEU v. Von Raab, 109 S. Ct. 1384 (1989); see also references 4 and 22.

2. Non-instrument drug testing is approved by the American Probation and Parole Association Drug Testing Guidelines; see Section 18-2 to 18-4 of the Drug Testing Guidelines and Practices for Adult Probation and Parole Agencies, prepared by the American Probation and Parole Association in cooperation with the Council of State Governments, (Bureau of Justice Assistance, Washington, D.C., December 1990).

3. Federal Rule Evid. 901(a) 28 USCA. On the state level see: State v. Weccele, (Cir. Ct., 2nd Cir. Ill., Oct. 18, 1990) and Commonwealth v. Tuyman, (Ct. Com. Pleas, Chester Co., Pa., May 3, 1990) (Abuscreen ONTRAK, a non-instrument test, was found to be admissible).

4. Imwinkelried, Edward J., "The Identification of Original, Real Evidence," 61 Mil. L. Rev. 145, 154 (1972); U.S. v. Sears, 248 F2d 377 (7th Cir) rvd on other grounds, 355 U.S. 602 (1957); U.S. v. Martinez, 43 CMR 434 (ACMR 1970); Powell v. Com. Pa. Bd. of Probation, 513 A2d 1139 (Pa. Cmwlth 1986); Brown v. Smith, 505 NYS2d 743 (1985); Jones v. Pa. Bd. of Probation, 520 A2d 1258 (Pa. Cmwlth 1987); Frye v. U.S., 253 F. 1013 (DC Cir 1923); U.S. v. Felix, 25 MJ 509 (AFCMR 1987); U.S. v. Harper, 22 MJ 157 (CMA 1986); U.S. v. Murphy, 23 MJ 310 (CMA 1987); U.S. v. Ford, 23 MJ 331 (CMA 1987); U.S. v. Sparr, 24 MJ 508 (AFCMR 1987); U.S. v. Hagan, 24 MJ 571 (NMCMR 1987).

5. Imwinkelried, at 156-157.

6. Imwinkelried, at 159.

7. Imwinkelried, at 162-163.

8. U.S. v. Iatico, 458 F. Supp. 388 (EDNY 1978).

9. Gordon v. Commonwealth 183 SE2d 735 (1971); Imwinkelried, at 145, 155, 156.

10. Priest v. McConnel, 363 NW2d 173 (1985); See also 21 A.L.R. 2d 1216, 1236 (1952).

11. Imwinkelried, at 145, 157 (1973); U.S. v. Godoy, 528 F2d 281 (9th Cir 1975); but see U.S. v. Fletcher, 487 F2d 22 (5th Cir 1973), cert denied, 416 U.S. 958 (1974) (proof of chain of custody goes to weight not admissibility of evidence).

12. Imwinkelried, at 145, 156.

13. The NIDA form can be found at NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 Fed Reg 11970. In most cases due to the business record exception to the hearsay rule, the test report is admissible without testimony if the report has "indicia of reliability" such as being written on laboratory letterhead and signed by the laboratory director. See U.S. v. Bell, 785 F2d 640 (8th Cir 1986); Neal v. Commonwealth, 531 A2d 119 (1987); Jones v. Commonwealth, 520 A2d 1258 (1987).

14. U.S. v. Johnston, 664 F2d 152 (7 Cir 1981), rvd., 690 F2d 638 (7th Cir 1982); MacArthur v. Bank of N.Y., 524 F. Supp. 1205 (SDNY 1981).

15. Woolley v. Hafner's Wagon Wheel, 176 NE2d 757 (1961).

16. Imwinkelried, at 158-59.

17. Imwinkelried, at 159-60.

18. Stahl v. Com Pa. Bd of Probation, 525 A2d 1272 (Pa. Cmwlth 1987).

19. Lawrence v. City of Norfolk, 135 SE2d 792 (1964).

20. NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 Fed Reg 11970.

21. Morrisey v. Brewer, 408 U.S. 471 (1972).

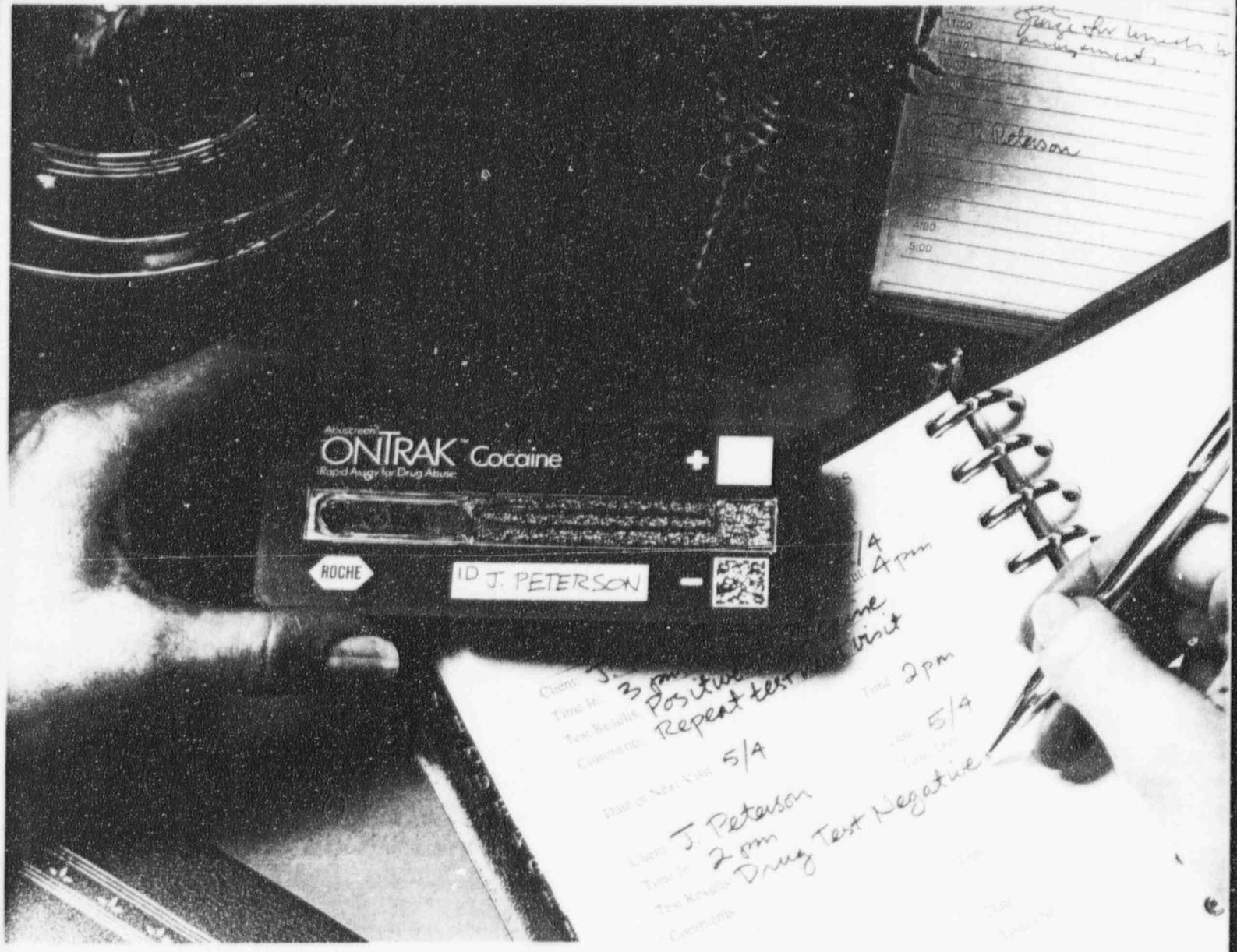
22. Jensen v. Lick, 589 F. Supp. 35 (D.N.D. 1984) (single drug test acceptable); In re Johnston, 109 Wash2d 493, 745 P2d 864 (Wash 1987) (single test sufficient evidence for prison discipline); Jones v. U.S., 548 A2d 35 (DC App. 1988) and Lahey v. Kelly, 524 NYS2d 30, 518 NE2d 924 (Ct App. 1987) (te t confirmed by same test is sufficient evidence); People v. Walker, 164 Ill. App3d 133, 517 NE 2d 679 (Ill. App. 1987) (double test reliable enough to be the only evidence of drug use in a probation revocation proceeding); Peranzo v. Coughlin, 850 F2d 125 (2d Cir 1988) (double test reliable).

23. Frye v. U.S., 293 F 1013 (DC Cir 1923).

24. NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 Fed Reg 11983.

25. ONTRAK was recently evaluated by the Damon Reference Laboratories. ONTRAK drug-detection results were evaluated in comparison to results obtained by radioimmunoassay (RAI) and gas chromatography/mass spectrometry (GC/MS). The laboratory concluded that there was 100 percent agreement when ONTRAK positive results were compared to those obtained by RIA and GC/MS. They further concluded that ONTRAK can provide reliable screening results in a non-technical setting by non-technical personnel. See Baker, Derek, P., et al, "Evaluation of Abuscreen ONTRAK Assays: Correlation Between Clinically Trained Personnel and Non-Clinical Personnel in the Field," Damon Reference Laboratories, Newbury Park, Calif.; ONTRAK meets NIDA cut-off levels, see 53 Fed Reg 11983.

26. McQueen v. State, 740 P2d 744 (OK App. 1987).



Abuscreen ONTRAK kits provide rapid results for intake screening, rehabilitative monitoring and counseling, crisis intervention—any situation in which immediate drug use status can make a critical difference in the management of your clients. Simple-to-perform ONTRAK assays require no instrumentation. Testing can be performed in the presence of your client, building trust and encouraging self-disclosure.

For a significant advantage in your drug counseling program, Abuscreen ONTRAK provides accurate, on-site "yes" or "no" results in approximately three minutes. ONTRAK can speed results cost-effectively, without compromising reliability.

Abuscreen ONTRAK was developed by Roche Diagnostic Systems and consolidates the experience gained in over fifteen years of providing quality products to drug testing laboratories.

Abuscreen ONTRAK kits are currently available for cocaine, THC, morphine, barbiturates, amphetamines and phencyclidine.

For more information or to order, call 1-800-526-1247.

Abuscreen assays provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result (see package insert).

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ONTRAK
Rapid Assays for Drug Abuse

WHY YOU SHOULD CONSIDER ON-SITE DRUG TESTING

Invalidated drug tests and wasted effort may result from careless shipping of tests to outside laboratories. Here's one way to avoid this

by David G. Evans, Esq.

Drug testing is being used to help provide a drug-free workplace, as a treatment tool, and to monitor criminal offenders. The constitutional battle over drug testing has been decided in favor of drug testing.[1] As a result, the opponents of drug testing are turning their attention to attacking flaws in its procedural aspects. These should be the focus of any treatment center using drug testing in its work.

The most vulnerable aspect of any drug test is the chain of custody for the specimen. Chain of custody is, of course, the documentation of the transportation and handling of the specimen from the time of collection until the specimen is analyzed in a laboratory. In light of this it is important to know that a non-instrument on-site drug test reduces the extent of the need for proof of the chain of custody.

An on-site test produces rapid documentable results using simple procedures that do not require sending a specimen to a laboratory. On-site tests produce an immediacy of results; this eliminates uncertainty and substantially reduces the administrative burden posed by chain of custody. On-site testing has been used extensively in the criminal justice system and has proven its value.[2]

The benefits of on-site testing are more clearly understood by looking at the vulnerabilities of chain of custody requirements.

Why is proof of a chain of custody necessary? In order to admit a drug test into court, a proper evidentiary foundation must be established by the party wishing to introduce the drug test.[3] The foundation consists of four building blocks:

1. The chain of custody of the drug test must be proven.
2. The court must recognize and/or be taught about the scientific theory, methods and equipment involved.
3. The circumstances of the specimen collection and analysis must be described.
4. The test result must be interpreted for the court.

A chain of custody must be proved when a specimen is liable to be altered by tampering or contamination and its condition at collection is important to the case. Urine specimens are in this class.[4]

When trying to prove the chain, the proponent has the burden of proving the identity and status of the specimen from collection until it reaches court as evidence.

A chain of custody is made of "links," i.e., persons who had a significant opportunity to tamper with the specimen and/or who had custody of the specimen at some point.[5] A link could be a specimen collector or a specimen transporter. In addition, the laboratory personnel completing the analysis are all links.

The proponent must prove for each link:[6]

1. receipt of the specimen;
2. the specimen's ultimate destination (i.e., shipment, destruction, or retention);
3. protection and proper handling between receipt and ultimate destination.

As the case requires, the court may or may not be strict in requiring proof of the chain.

The cases requiring a strict standard of proof are:[7]

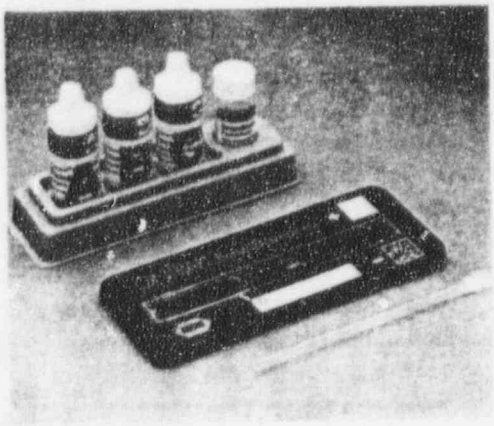
Reprinted from *ADDICTION & RECOVERY* July/August 1992 Vol. 12, No. 4

1. when there is a strong possibility that the specimen has been confused with other similar specimens;
2. when the specimen is easily alterable or liable to undetected alteration;
3. in a criminal case, where the establishment of a chain requires proof "beyond a reasonable doubt." This has been compared to a certitude of truth better than 95%. In a civil case, there must be a "preponderance of the evidence," which has been compared to a better than 50% certainty of proof.[8]

In any event, chain of custody is vulnerable to several errors (see box following references).

Advantages Of On-Site Testing

On-site drug tests eliminate the majority of administrative and chain of custody problems. As is well-known, for example, many specimens tested yield negative results. Yet, in the absence of an on-site testing capability, they all must be sent to a laboratory. All the specimens must be accompanied by chain of custody forms and be in specially sealed tamper-proof containers or reliable tamper-evident collection devices. On-site drug tests, when used with observed specimen collection, provide an initial screen which eliminates the negative test results. Although chain of custody is performed on all specimen collections, with on-site testing, only the positive test results must be sent to the laboratory for confirmation. Paperwork and staff time are then substantially reduced.



Another incentive for on-site testing is that, in some circumstances, positive results can be confirmed by another on-site test. Case law holds this as a perfectly acceptable procedure in a criminal justice context. The criminal courts do not require the same level of proof required in employment cases. Indeed, convicted offenders have diminished rights when balanced against the right of the public to be protected.[21] For example, a single immunoassay or a double immunoassay may be all that is required.[22]

On-site testing has other advantages. It is a pro-active case management tool. It is flexible as to where testing is done and increases the deterrent effect because it decreases the time between results and consequences. Since the result is obtained in front of the test subject, there are increased confessions of drug use by the subject.[23]

On-site testing provides an opportunity to promptly and positively reinforce drug-free behavior. If an employee or offender tests negative, the result is immediate and the person can be complemented on being drug free (and encouraged to remain so).

A good on-site drug test is one that keeps you out of court. Such a test is one that meets rigorous scientific standards, such as demonstration of substantial equivalence to proven reference methods and pre-market clearance from the Federal Food and Drug Administration.[24] The test should also, at a minimum meet the NIDA cut-off levels for drug detection, since this has become a national standard.[25] The test should be documentable and easy to use, as well as having undergone an independent scientific clinical evaluation performed by a NIDA-certified laboratory or the equivalent.[26] A reasonable cost per test is also a factor to be considered.

In sum, chain of custody poses many problems in proving drug test results. The increasing use of on-site tests will eliminate many of these concerns and make drug testing a more useful tool in our war against drugs.

David G. Evans, Esq., is the author of the book Drug Testing Law, Technology and Practice published by the Callaghan Publishing Company. He has also authored the Model State Drug Testing in Employment Statute and the Model Criminal Justice Drug Testing Act, both of which have served as the basis for legislation. He consults nationally on drug testing and substance abuse issues, and practices in Lawrenceville, NJ.

References

1. Skinner v. RLEA, 109 S. Ct. 1402 (1989); NTEU v. Von Raab, 109 S. Ct. 1384 (1989); see also References 4 and 22 below.
2. On-site drug testing is approved by the American Probation and Parole Association Drug Testing Guidelines; see Section 18-2 to 18-4 of the Drug Testing Guidelines and Practices for Adult Probation and Parole Agencies, prepared by the American Probation and Parole Association in cooperation with the Council of State Governments, (Bureau of Justice Assistance, Washington, DC, December, 1990).
3. Fed Rule Evid, 901(a) 28 USCA. On the state level see; State v. Weccele, (Cir. Ct. 2nd Cir. IL, October 18, 1990) and Commonwealth v. Twyman, (Ct. Com. Pleas, Chester Co., PA, May 3, 1990) (Abuscreen® ONTRAK®, an on-site test, was found to be admissible).
4. Imwinkelried, Edward J, "The Identification of Original, Real Evidence," 61 Mil. L. Rev. 145, 154 (1972); U.S. v. Sears, 248 F2d 377 (7th Cir) rvd on other grounds, 355 U.S. 602 (1957); U.S. v. Martinez, 43 CMR 434 (ACMR 1970); Powell v. Com. Pa Rd. of Probation, 513 A2d 1139 (Pa. Cmwlth 1986); Brown v. Smith, 505 NYS2d 743 (1985); Jones v. Pa. Bd. of Probation, 520 A2d 1258 (Pa. Cmwlth 1987); Frye v. U.S., 293 F. 1013 (DC Cir 1923); U.S. v. Felix, 25 MJ 509 (AFCMR 1987); U.S. v. Harper, 22 MJ 157 (CMA 1986); U.S. v. Murphy 23 MJ 310 (CMA 1987); U.S. v. Ford, 23 MJ 331 (CMA 1987); U.S. v. Sparr, 24 MJ 508 (AFCMR 1987); U.S. v. Hagan, 24 MJ 571 (NMCMR 1987).
5. Imwinkelried, at 156-157.
6. Imwinkelried, at 159.
7. Imwinkelried, at 162-163.
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9. Gordon v. Commonwealth 183 SE2d 735 (1971); Imwinkelried, at 145, 155, 156.
10. Priest v. McConnel 363 NW2d 173 (1985); See also 21 A.L.R. 2d 1216, 1236 (1952).
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12. Imwinkelried, at 145, 156.
13. The NIDA form can be found at NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 Fed Reg 11970; For cases on laboratory reports as evidence, see, U.S. v. Bell, 785 F2d 640 (8th Cir 1986); Neal v. Commonwealth, 531 A2d 119 (1987); Jones v. Commonwealth, 520 A2d 1258 (1987).
14. U.S. v. Johnston, 664 F2d 152 (7 Cir 1981), rvd. 690 F2d 638 (7th Cir 1982); Mac Arthur v. Bank of N.Y., 524 F. Supp. 1205 (SDNY 1981).

15. Woolley v. Hafner's Wagon Wheel, 176 NE2d 757 (1961).
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19. Lawrence v. City of Norfolk, 135 SE2d 792 (1964).
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23. McQueen v. State, 740 P2d 744 (OK App. 1987).
24. Frye v. U.S., 293 F 1013 (DC Cir 1923).
25. NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 Fed Reg 11983.
26. As an example see: Baker, Derek P. et al., "Evaluation of Abuscreen® ONTRAK® Assays: Correlation Between Clinically Trained Personnel and Non-Clinical Personnel in the Field," Damon Reference Laboratories, Newbury Park, CA.

Chain of Custody Vulnerabilities

Chain of custody procedures are vulnerable to human error in a variety of ways. In establishing a chain of custody, the proponent risks having a chain that is too short, leaving out links in the chain, or failing to account for time periods. The chain must be established from the time of collection to the time of analysis.[9] Some courts have required that the chain be established up to trial.[10]

Some courts require that the analysis is admissible only after each link is proven.[11] A person becomes a link not only by having access to the specimen but by personally handling the specimen.[12]

How Does One Prove A Link?

First, establish who handled the specimen. This is often difficult and imposes a burden that an on-site test does not impose.

To establish the chain with an instrument-based laboratory test, chain of custody forms need to be used. The drug test form of the National Institute on Drug Abuse (NIDA) is an example. Each person handling the specimen before the result is obtained must record its handling and could be liable to be called into court. In most cases, however, due to the business record exception to the "hearsay rule," the test report is admissible without testimony if the report has "indicia of reliability" such as being written on laboratory letterhead and signed by the laboratory director.[13]

The use of a chain of custody form raises issues which can be used to attack the admissibility of the drug test in two ways: first, it may list a link who did not appear in court; second, the form may not be properly completed, thus "breaking" the chain. In such a case, oral testimony must prove the link.

Oral testimony to establish a link presents additional problems. For example, the person who is testifying may have left the room without locking the room or securing the specimen. The specimen may have been turned over to a subordinate for safeguarding. This "temporary entrustment" causes problems; the person who receives the specimen now becomes a link who may not be accounted for on the form. In addition, the parties can be questioned as to the length of time of the entrustment and the condition of the specimen. If this cannot be adequately shown in court, the chain may collapse.

If the person who was entrusted with the specimen is not present for trial, further problems arise. If the person was not originally listed as a witness, it may be a violation of a court rule to call the person.

It is also possible that a link may be an attorney who handled the specimen as part of preparing for the trial without the normal custodian of the specimen being present. This presents problems because the attorney may not be able to testify in a case which he or she is involved.[14]

Was The Specimen Properly Handled?

Once the links in the chain have been established, the next question raised is that of proper handling. How is proper handling to be gauged? It must be shown that the person properly safeguarded the specimen before the test result is obtained. In criminal cases, the courts may require a "clear preponderance" of proof of proper handling.[15] In other situations, there must be a "reasonable likelihood" of proper handling.[16]

If the seal on the specimen container were broken, this may imply that the specimen was contaminated or was tampered with before it was tested.[17] Questions concerning proper handling would also arise if the specimen was not secured or refrigerated.[18] Was there free access to the specimen location, or was the specimen left alone for a period of time? Questions also can be raised about the standard operating procedures of the collection site or the laboratory. Any violation of these procedures could lead to a question about proper handling. The procedures may require that the specimen never be left unattended before it is tested. These questions can be more successfully raised with a large, high-volume laboratory where there is staff turnover, given the possibility that new staff may not be properly trained.

The collection of the initial sample also creates evidentiary problems. The placing of the specimen label is crucial to establishing the identity of the specimen. The proper sealing of the specimen must occur to avoid tampering or contamination.[19] There may also be storage requirements depending on the jurisdiction.

Was The Laboratory Secure?

Chain of custody problems are also raised by laboratory security requirements. For example, the NIDA Mandatory Guidelines for Federal Workplace Drug Testing Programs require that laboratories be secure at all times and that no unauthorized persons can gain access.[20] All visitors and maintenance and service personnel must be escorted at all times. Documentation of persons accessing the testing areas, dates and time of entry, and purpose of entry must be maintained. Laboratories must account for the specimen from receipt through completion of testing, reporting of results, and continuing until final disposition of the specimen. Documentation must be provided as to date and purpose of each time the specimen is handled; each link must be identified. Upon receipt of the specimen at the laboratories, if there is evidence of tampering or damage to the package, it must be noted. Such damage could possibly invalidate a test result. In addition, refrigerated storage at a certain temperature is required if the test is not performed within 7 days. If any of the above procedures or standards are not documented, or are not followed, the chain of custody may not be defensible.

David G. Evans, Esq.