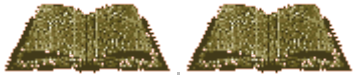
ANIL AGGRAWAL'S
Internet Journal of
Forensic Medicine and Toxicology
The world's first online journal devoted entirely to forensic medicine and toxicology · Published 1 January and 1 July

VOL. 3, NO. 1
Downloaded from www.anilaggrawal.com · ISSN 0972-8074 (Online) · https://www.anilaggrawal.com/ij/vol_003_no_001/reviews/tb/page010.html

Book Reviews: Technical Books Section



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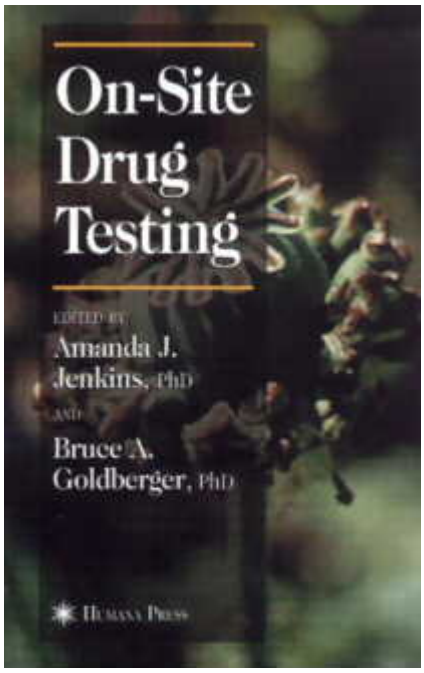
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TESTING FOR DRUGS

On-Site Drug Testing, 1st Edition, *Edited by* Amanda J. Jenkins and Bruce A. Goldberger. Hard Bound, 6" x 9".
(A Book from *Forensic Science and Medicine* Series by Humana Press)
Humana Press Inc., 999 Riverview Drive, Suite 208, Totowa, New Jersey 07512; xxii + 276 pages: ISBN 0-896-03870-X (alk. Paper). Publication Date 01/29/2002: Price, $89.50

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The testing of body fluids by physicians may have existed as long as the time of Hippocrates when he and other physicians of the Aesculapian School brought some rationality to medicine. It is felt that the determination of the presence of glycosuria, or sugar in the urine was an indication of a wasting disease which was to become called diabetes by later writers. The testing done is reported to have been either the attraction of flies to the collected container of urine, or even the tasting of the urine by the physician and noting whether the urine was sweet. The sensitivity and specificity of this testing seems not to have been recorded.

Interest in psychoactive drugs of abuse was also well developed by this time some two thousand years ago. Heraclitus of Ephesis, a philosopher and presumed influence on the Ionian writers wrote "A man when he is drunk is led by an ungrown boy, stumbling, not knowing where he is going, having a wet soul."

However, it was not until the twentieth century that the continuing interest in controlling psychoactive drugs of abuse coupled with the technology to inexpensively test for the use of these drugs. This began with the work of Widmark with alcohol and proceeded to the development of inexpensive immunologic methods for drugs of abuse other than alcohol as marketed by the Syva Corporation.

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A hallmark of this testing was that it was laboratory based. This meant that the testing encompassed a significant investment in capital for the laboratory as well as in highly trained personnel to operate the laboratory. In the United States, these laboratories were hospital based, almost entirely. Changes in the funding of hospitals, brought about in large part by the passage of the 1967 Medicare Act, created the need for laboratories outside the hospital setting, providing specialized testing for the smaller hospitals and routine and specialized testing for the medical practitioner. The Clinical Laboratory Improvement Act of 1988 (CLIA 88) made clinical testing in the physician office setting, which had grown considerably in the 1970's, less attractive due to the various requirements of quality control which are incorporated into the act. CLIA 88 specifically exempts forensic laboratories and probably therefore on site drug testing. This exemption plus the continued growth of drug of abuse testing in the United States and Western Europe, characterized by Bryan Finkle in his foreword as a "minor national industry," has prompted the development of "point-of-care" or "on-site" testing for drugs of abuse.

View this book on Amazon

On Site Drug Testing, edited by Amanda J. Jenkins and Bruce A. Goldberger collects writings from some of the foremost experts in analytic toxicology and the jurisprudence of drug testing. This collected work adequately covers the subject. It provides a source book for persons interested in what products are available to accomplish the testing, as well as a general framework for some of the issues involved in accomplishing the testing. It is also an important source of data for the attorney defending or attacking the credibility of on-site testing.

...the work...collects writings from some of the foremost experts in analytic toxicology and the jurisprudence of drug testing. It provides a source book for persons interested in what products are available to accomplish the testing, as well as a general framework for some of the issues involved in accomplishing the testing...

The work is organized into 18 chapters. Covered are testing schemes for drugs of abuse and therapeutic drugs as well as a general discussion of the jurisprudence of such testing. Discussions of use of on-site testing in DUI (Driving-under-the-influence of alcohol) cases as well as alcohol and drug testing of saliva are discussed. In both chapters dealing with saliva, specific currently available kits are discussed. Eight chapters concern the various currently available commercial tests for drugs of abuse in urine. A final chapter explores the effectiveness of commercially available kits to thwart the sensitivity of urine drug testing.

As with all compendia, this collection suffers from some lack of focus and unevenness. The chapter by Jimmie L. Valentine clearly demonstrates his interest in the psychological issues of drug testing in the clinical setting, which probably is not a major concern of most readers of this work. Further, Alan H. B. Wu's discussion of therapeutic monitoring of non-abused drugs, while rounding out the areas covered, is probably not of much interest to the bulk of the readers.

It is in dealing with the available technology for urine testing that this work excels. Generally, the issues of specificity, accuracy and precision, and sensitivity are examined for each commercial product and the strengths and weaknesses of each are explored. This is nicely summarized in chapter 17 by Robert E. Willette and Leo J. Kadehjian. Indeed, I would imagine that for most readers, Chapter 17 makes the book worth buying.

Forensic Science and Medicine Series of Humana Press

The chapter on the jurisprudence of on-site drug testing is a valuable addition to the general part of the book. Theodore F. Shults and Yale H. Caplan have combined their considerable knowledge of the ongoing development of standards for on-site drug testing which is currently generally lacking. They discuss the only currently enforced standards, that of the United States Department of Transportation (DOT). DOT was mandated to create testing methods for holders of Commercial Driver's Licenses in the United States to reduce the incidence of driving under the influence of drugs of abuse. Included in the standards are those speaking to the collection site, the person collecting and/or testing, the procedure for collecting the specimen, the effectiveness of the testing regimen, the chain of custody of the sample, including methods to prevent contamination, and the requirement for confirmatory testing of samples found to be positive.

These requirements developed by DOT have had some impact upon the development of the general field of on-site drug testing, as described by the authors, but they lack the force of law, except with testing of Commercial Drivers. The use of pre-employment testing, in particular, in the United States is generally free of any governmental regulation. This is based upon the concept in English-American Law of the "employment-at-will doctrine" which basically preserves the right of the employer to hire or fail to hire a person unless that decision is clearly based upon discrimination against a protected class. Abusers of drugs have been held repeatedly not to be a "protected class" under the various state and federal anti-discrimination statutes. The authors explore the impact of the Americans with Disabilities Act (ADA) in regard to drug testing. The ADA requires the covered employers to employ the services of a Medical Review Officer (MRO). Impliedly, this requirement of the ADA would seem to apply to any employer doing drug testing. Further, the authors explore the expanding liability of laboratory operations to employees being tested for drugs. Citing a 1999 Wyoming case, the authors explain that the various immunities which have protected laboratories in the past are collapsing with the changes in work drug testing.

The chapter by Leo J. Kadehjian and James Baer on on-site testing devices n the Criminal Justice System addresses some to the major issues of standards in this arena as well. As previously mentioned, CLIA specifically exempts the forensic science laboratories in the United States from federal standards. Part of the rationale for this exemption was that the criminal court system, though its jurisprudence would obviate the need of federal regulation. Whether this is true or not is not directly addressed by this work, but a discussion of the current jurisprudence is discussed. The different standards which apply depend in large part upon ones status. A person, who has not been convicted of crime, must be proved to have committed the crime beyond and to the exclusion of every reasonable doubt. While perhaps on-site drug testing might be used, or be attempted to be used, to prove the crime of drug use, generally the courts have not allowed such proof for various reasons. The primary use of on-site drug testing is in the monitoring of drug use by paroles and by prison inmates. For the latter, for administrative purposes of prison discipline, the "some evidence" standard is required. In revocation of parole, the civil standard of "more likely than not" is required.

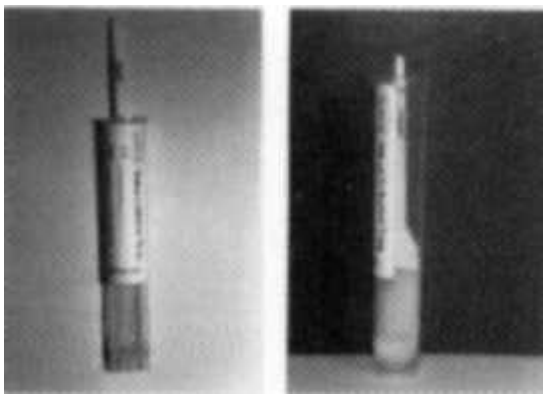
Q.E.D saliva-alcohol test device (from chapter 7, page 86)



Of course before one can reach the threshold of standard of proof, with scientific evidence the first hurdle is admissibility. Currently in the United States there are two standards of admissibility. The first is the Frye test which was established in 1923 (Frye vs U.S., 293 F. 1013 (D.C. Cir. 1923) which held that novel scientific testimony must be supported by a "consensus" of the scientific community. The court held in the Frye case that the admissibility of blood pressure readings as a "lie detector test" was not admissible. The authors point out that on-site testing has generally been held to be admissible under the Frye test. However, 1993 the United States Supreme Court decided the Daubert case and introduced a new standard of admissibility (Daubert vs. Merrell Dow Pharmaceuticals, Inc. (509 U.S. 579 (1993). In Daubert the court held that the issue of admissibility was the trial courts to make and while "consensus" was certainly a factor, peer reviewed publication, false positive and negative rates as well as a few other matters were to be considered by the judge in ruling upon admissibility. The Daubert standard is the law within the Federal court system and approximately 2/3's of the State Courts. However, Frye is still that standard in 1/3 of the States.

Having established the various standards for proof, and having dealt with the admissibility standards of Frye and Daubert, the authors conclude that instrumental on-site testing for drugs of abuse in urine has been accepted widely by the courts using both the Frye and Daubert standards. Indeed, in the prison discipline cases, they report that unconfirmed immunologic tests have been upheld as the basis for prison discipline. However, they go on to discuss the newer non-instrumental tests which have so far not been tested by the courts.

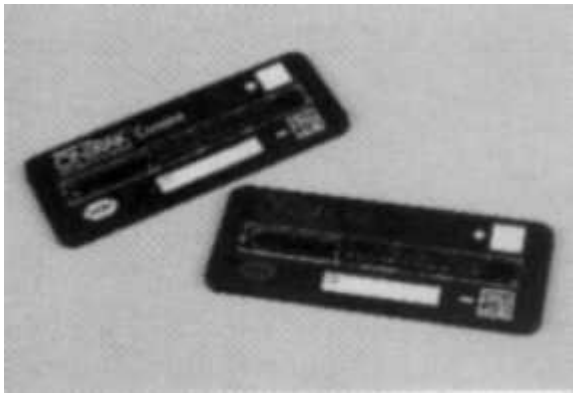
Cozart RapiScan collection pad and test tube (from chapter 8, page 102)



Kurt M. Dubowski discusses at some length the use of saliva for alcohol testing. This is one of two chapters on saliva, and again the inclusion of this subject seems to be to broaden the scope of the

work, more for the sake of broadening than for the current usefulness or use of saliva testing. Oddly, the testing of breath for alcohol, which is extremely widely used, and is certainly almost always an on-site test, is not discussed, except for being mentioned in the chapter on driving under the influence introductory chapter. Perhaps these decisions are more marketing driven than scientific, as there is a plethora of works devoted to breath testing. Whatever the general merits, or current use, Dubowski's coverage of saliva testing is thorough and complete. He discusses the three currently available saliva testing devices. He does not address comparing these devices, but does reference the technical details as being available on the internet. Unfortunately, he does not list the URL for these reference. His 36 non-internet references trace the testing of alcohol in saliva from the earliest work in 1898 through the 1997 standards. For anyone interested in alcohol testing in saliva, this is really a very definitive review.

The Abuscreen ONTRAC® assays manufactured by Roche Diagnostics Systems (from chapter 12, page 155)

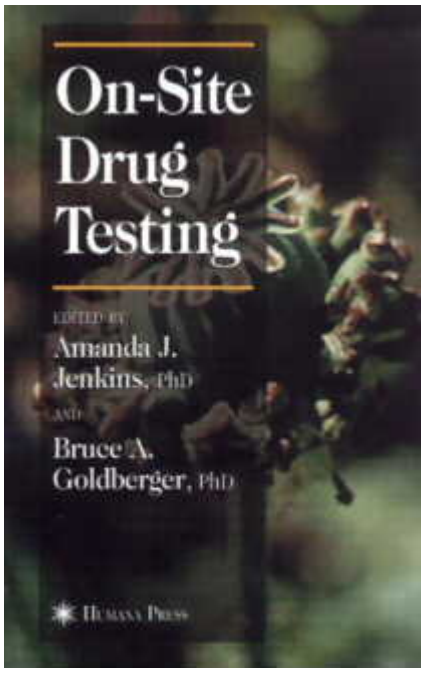


The chapter on drugs other than alcohol testing in saliva by Vina Spiehler, Dene Baldwin and Christopher Hand, is rather short, but does introduce the concepts involved in saliva testing for drugs. The important consideration is coefficient of concentration between blood and saliva. For some drugs, such as benzodiazepine, there is very little of the drug present in the saliva due to very unfavorable saliva to plasma ratio, making detection of this drug very difficult. Other drugs, such as cannabinoids, cocaine and opiates are easily detected in saliva. The authors point out the calculating the plasma concentration from saliva is not possible without knowing the instantaneous salivary pH. In practice, salivary testing, like urine testing, is more a binary proposition. If it is positive the person has consumed the drug and that is the end of the discussion. This difference of approach between alcohol and non-alcohol drugs of abuse is interesting. With salivary alcohol testing, the saliva blood coefficient has been widely measured and reported. Thus alcohol blood concentration can be estimated from the salivary concentration just as it may from the breath concentration. The interest in such estimations reflects the acceptance of alcohol in Western society as a legally consumed drug, which we control by prohibiting excessive use while operating motor vehicles. The other psycho active drugs of abuse we control by complete prohibition at all times, and particularly while operating motor vehicles.

The authors of the chapter on drugs in saliva go on to discuss the apparently only available commercial testing device, the Cozart RapiScan. Their conclusions are that in the setting of drug dependency clinics and prisons that the results are valid.

QUICK NOTES

Some major highlights of *On-Site Drug Testing* at a glance:

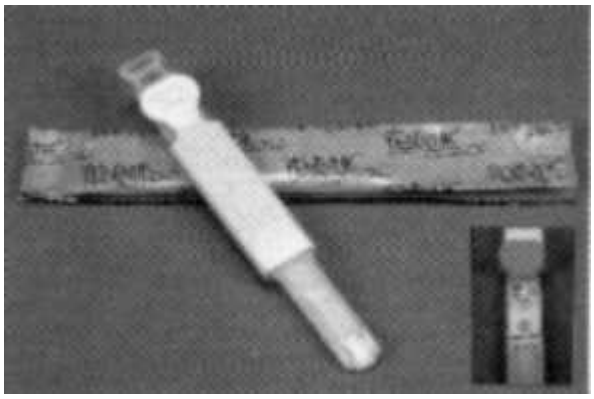


& In-depth review of current on-site drug testing devices in easty-to-read chapters
& Assessment of advantages, disadvantages, uses, and potential uses
& Written by hands-on experts familiar with the subject and the devices
& Coverage of on-site drug testing devices currently marketed in the US and Europe

The bulk of the work concerns the testing of urine for psychoactive drugs of abuse. This subject encompasses a total of ten chapters, eight pertaining to individual commercial products, one excellent summary chapter and a chapter on adulteration and its effect on on-site testing of urine. It is appropriate to devote the bulk of this book to urine testing, as urine testing makes up the vast majority of tests for drugs.

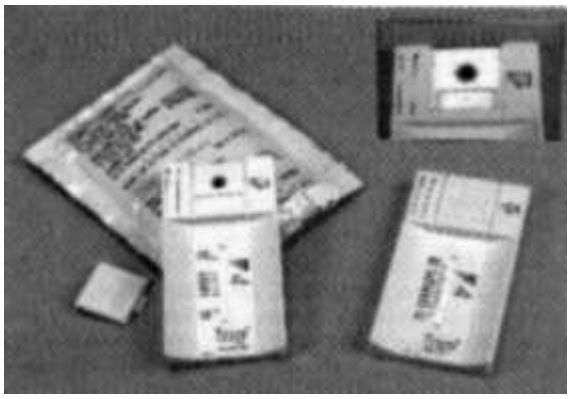
Interestingly, the ONTRAK system, made by Roche Diagnostics is given three of the eight chapters dealing with commercial products. The rationale for this is that there are really three distinct products available from Roche and marketed as ONTRAK. The original ONTRAK is mentioned prominently in the jurisprudence literature, because it was the most popular and the earliest or one of the earliest products on the market for on-site testing. The original kit was introduced in the spring of 1989 and was marketed for $385.00 for 100 tests. The principle is immunologic, relying upon competition for antibody binding sites between drug in the urine and latex-drug conjugate reagent supplied in the kits. If drug is not present in the urine, agglutination of the latex-drug conjugate occurs. The chapter on ONTRAK cites various sources which show that the correlation between untrained personnel using the kit and trained laboratory technicians was 98.6%. However, variation in sensitivity was experienced with different urine sample sizes. Although a precision pipette was included with the kit, the lack of training of the operators appears to have resulted in variation of sensitivity. The original ONTRAK was withdrawn from the market in June 1999. It is appropriate to include this discussion of this widely used product because of its prominent place in the history of the on-site testing and the references to this product in the jurisprudential literature.

OnTrak TesTstik device with packaging (from chapter 14, page 186)



ONTRAK TesTcup was introduced in 1995 and is the first second generation on-site urine drug testing kit. The kit involves no mixing of reagents or transferring of urine. The kit comes with a collection cup which is merely tilted to wet an absorbent pad. The urine migrates from the pad to the testing area where the immuno-chemical reactions take place. At the end of 5 minutes, the results are visually read. For each drug tested there is a separate area where for each drug tested there is an indication whether the drug test was valid or invalid, a variation on the theme of a quality control method. As originally marketed the test kit analyzed for cocaine metabolites, opiates as morphine and marijuana metabolite (THC-COOH). Subsequently, additional products were introduced which added amphetamines and phencyclidine.

Triage drugs-of-abuse devices (from chapter 15, page 200)



An interesting feature of this kit is that the original urine sample, ostensibly not contaminated by the person doing the test, is available for retesting or confirmatory testing. The testing is again immunologic, but is based upon immobilized drug conjugate imbedded in the test strip. If drug was present in the urine at or above the cut off concentration, the antibody-microparticle complex interacts with the drug conjugate producing a blue band in the detection window. If there was no drug or drug below the cut off, then there is no reaction and hence no-color. The authors discuss the reliability testing of this product in some detail and deal with the issues of cross reactivity which is always an important issue with immunologic drug testing.

ONTRAK TesTstik gets another chapter, although the technology appears to be identical to TesTcup, except that with TesTstik there is no cup, the test is performed by actually wetting the end of the strip with the urine. The results of the TesTstik, as one would imagine, is comparable to the TesTcup and this is discussed at length by the authors. Interestingly, the only typographic error which I found in the entire work is located in this chapter.

The other currently available testing products are reviewed, with ample references to support the conclusions drawn.

On site testing has come quite a long way since the time of Hippocrates, when on-site testing was all that was available. This book is a nice addition to the library of anyone involved of this minor national industry of drug testing.

-Ronald Wright



-Ronald Wright
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