Instant Drug Testing Kits: Let the buyer beware!

The following is being sent in response to your questions about "instant testing kits". I have attached the June-July 2002 Newsletter from the Drug & Alcohol Testing Industry Association, in which the following article appeared. I know Attorney Tom Eden and he is considered a national expert on drug testing law.

Because the article may be somewhat technical in its discussion of specific laws and regulations, I've added some information and links at the end of this message.

I would like to stress the importance of Mr. Eden's advice on *Risk Reduction Strategy*:

"As part of their due diligence efforts, employers and all Service Agents need to ensure that the laboratories and device manufactures they are utilizing meet the FDA regulatory requirements. Write a letter today to your lab, device manufacturer or Service Agent, pose that very question, and mention 21 CFR§ 864.3260 or 21 CFR§ 809.40. If you do not get the right answer, my advice is to find someone else."

Ask the manufacturer (not the salesperson) for a copy of the FDA clearance letter and to confirm in writing on company letterhead, that this device has been approved for workplace or employment drug testing and that it has been approved for your staff (who are probably not medical professionals) to perform the tests per 21 CFR 801.109.

Many of the distributors of the so called "instant tests" attempt to get past the risk issue by telling you that you should confirm all positive results at a certified laboratory using conventional testing methods. But, they are only talking about the risk of having an employee or applicant bring a law suit because of a *false positive*. An even higher risk is hiring drug users who passed the instant test because of a *false negative*. (Note that the 510(K) for these devices state that “a more specific alternate chemical method *must* be used to obtain a confirmed result, e.g. gas chromatography/mass spectrometry (GC/MS)”. This refers to all results, not just positive results.)
In addition, at the very end of the 510(K) Summary you will find the box checked for “Prescription Use - Per 21 CFR 801.109”.

Almost all of the instant testing scenarios omit the lengthy list of quality controls and safeguards that are used in conventional testing, e.g. integrity testing (dilution, adulterants, creatinine, pH, specific gravity), blind specimen quality control, certifying scientist review, laboratory instrument readouts and records, ability to retest contested specimens, etc. Without integrity testing, it becomes very easy for a drug user to “fool” the instant test. Some distributors have come up with ‘instant’ integrity testing kits (dipsticks), however these also have 510(K)’s and those that I have checked out are also only for use by *licensed medical professionals*.

If you are a service provider (collection site, TPA, mobile testing) using these devices you will also want to confirm that your liability insurance will still cover you even if you are not following the manufacturer’s written instructions.

If you are an employer, collection site, or third-party-administrator using these so-called instant drug tests, here is the scenario you are trying to avoid:

- An applicant passes a pre-employment (or random) *instant* drug test and is allowed to start or continue work. He then causes a serious accident in which someone is killed or seriously disabled. It is determined during the accident investigation that he had illegal drugs in his system -- and of course the employer gets sued for negligent hiring or negligent retention - and whoever performed the instant drug test and reported that the worker “passed” gets sued also.
- The employer’s defense is that “he passed the drug test”. They put you on the witness stand and confront you with the 510(K) and/or the testing device’s package insert. Here are the questions they are going to ask you:
    - “Does it say anywhere that this device has been approved for workplace or employment purposes?
    - Are you a licensed medical professional per 21 CFR §801.109?
    - Did you confirm the preliminary analytical test result using a more specific alternate chemical method as required by the manufacturer of the test?
    - Did you perform any of the standard integrity tests to confirm that the specimen was not adulterated, diluted, or tampered with?
    - Do you have any laboratory or testing device documents to prove that he really did pass the instant test?
    - Since the FDA approved this device as a *Prescription* device, which doctor wrote the prescription for the use of this device or supervised its use?
    - Was this device always shipped and stored within the manufacturer’s temperature range?
    - If the manufacturer’s insert states “All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.” did you dispose of the urine according to biohazard waste procedures, or did you just flush it?

I think you will agree that you, or the third-party administrator or collection site you used to perform "instant drug" testing for you cannot satisfactorily answer these questions, so you will probably attempt to settle the case. So you might want to send this information to your attorney right now – ask him or her about this risk.

June-July 2002 Newsletter from the Drug & Alcohol Testing Industry Association

It's The Law: FDA's Regulation of Workplace Drug Testing: Risk Reduction Strategy

By Tom Eden & Michael Jackson of Wallace, Jordan, Ratliff & Brandt, L.L.C.

On June 8, 2001, amendments to the Food and Drug Act became effective that increased the Food and Drug Administration's (FDA) role in the regulation of workplace drug testing. Under the amended rules (21 CFR§ 864.3260) specimens such as hair, urine, sweat or saliva used outside the medical setting and not on order of a healthcare professional, such as in the home, insurance, sports or workplace setting, are considered over-the-counter (OTC) test sample collection systems by the FDA rule.

These OTC test sample collection systems for testing drugs of abuse are now restricted devices and under the new regulations must be "… performed in a laboratory using screening tests that have been approved, cleared, or otherwise recognized by the Food and Drug Administration as accurate and reliable for the testing of such specimens for identifying drugs of abuse or their metabolites."

Additionally, under this regulation, the laboratory performing the test must be recognized as having adequate capability to reliably perform the screening and confirmation tests (i.e., the laboratory must be certified or licensed by a recognized agency), and the tests need to be appropriately labeled.

Before these amendments, manufacturers of screening tests for commercial workplace use that wanted to sell those tests to laboratories through interstate commerce needed to have their drug-screening assays submitted to the FDA for review. This review is generally conducted by comparing one cleared device to an earlier cleared or recognized device. (Urine tests that were on the market before the enactment of the initial medical device amendments in 1976 were simply recognized by the FDA and did not need to go through a review process. Subsequent urine tests brought to the commercial market to be sold to laboratories had to demonstrate under this comparison process that they were "substantially equivalent" to products already cleared or recognized.)

To conduct workplace testing, laboratories could either purchase these cleared screening tests from a manufacturer or they could create their own screening tests for internal in-house use that did not have to be cleared through the FDA, the so called "home brew" exception. The FDA has cleared more than 200 drugs-of-abuse testing devices.

The distinction between an in-house test and a test sold over the counter to laboratories has been eliminated with the newer regulations and essentially all testing (there are still exceptions for law enforcement, research and medical purposes) must be approved, cleared or otherwise recognized by the FDA as accurate and reliable. The greatest impact of this regulation will be on newer matrices (e.g., hair, saliva, and sweat) and, to some extent, point of collection (on-site) urine screening through another set of regulations. Currently, there is only one laboratory provider in each of the newer

matrix areas that has FDA clearance on its screening tests. To learn more about laboratory providers, visit the FDA website at http://www.fda.gov/.

"Point of collection" (POC) or "on-site" testing follows a slightly different set of FDA rules because these tests are performed outside of a laboratory and interpreted usually by a non-laboratory person. For these devices there are additional FDA rules requiring that the average person be able to easily understand the labeling and the tests results. 21 CFR§ 809.40. On November 14, 2000, the FDA issued the "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Pre-market Notifications" position paper which recently has been the subject of much controversy. You should also anticipate more governmental guidance from the Department of Health and Human Services regarding the use of POC devices.

Risk Reduction Strategy

As part of their due diligence efforts, employers and all Service Agents need to ensure that the laboratories and device manufactures they are utilizing meet the FDA regulatory requirements. Write a letter today to your lab, device manufacturer or Service Agent, pose that very question, and mention 21 CFR§ 864.3260 or 21 CFR§ 809.40. If you do not get the right answer, my advice is to find someone else.

While generally the impact of an FDA regulation falls on the supplier or manufacturer, 21 CFR§ 809.40 sets forth restrictions on the "sale, distribution, and use of OTC test sample collection systems for drugs of abuse testing." When it comes to lawsuits," the "defendant" is not a sought after designation. Drug-testing professionals do not want to put themselves in a position to incur liability for testing in violation of federal law, and they should not put their clients in harm's way or they may become what the law calls a "third-party defendant."

FDA enforcement aside, in any litigation scenario arising from a wrongful discharge action or union challenge, the issue of regulatory noncompliance would be nearly impossible to overcome in a courtroom, the ultimate drug-testing landmine!

Ask Delta Airlines and LabOne, who last summer ended up on the wrong end of a six-figure verdict in a wrongful-discharge action by a flight attendant based on regulatory noncompliance by the lab in its adulterant testing (since corrected). Imagine hearing the words from the plaintiff's attorney: "Your Honor, my client was discharged (or not hired) based upon the results of a drug test the federal government has not identified as accurate and reliable."

It is a simple matter to inquire of the laboratory or on-site device manufacturer to ask for a copy of their FDA clearance letter as part of your due diligence. This is especially important when using alternate matrices, on-site testing, or laboratory urine testing outside the normal five drug screen panel (e.g., testing for oxycontin or ecstasy where clearances may not have been obtained).

Disclaimer & Acknowledgements: The above should not be construed as legal advice or legal opinion as to any specific

facts or circumstances. The contents are intended for general information only, and you are urged to consult your attorney concerning your own situation and any specific legal questions you may have. Tom Eden and Mike Jackson are management labor attorneys with the law firm of Wallace, Jordan, Ratliff & Brandt, L.L.C. who advise collection sites, TPAs, employers, workers' compensation administrators, and MROs on a variety of drug and alcohol testing issues, policy development, and risk-reduction programs.

Tom Eden and Mike Jackson may be reached by telephone at (205) 870-0555 or by e-mail at te@wallacejordan.com or mlj@wallacejordan.com. Please visit our web site at http://www.wallacejordan.com/ (which contains federal drug-testing regulations and other drug-free workplace resources at www.wallacejordan.com/drugfree.htm).

To determine if a particular instant test kit has been approved and "what for" go to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm , or, if you don't find it there, to the CLIA section at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm where you can search by manufacture or device name. (Note: Many of these devices are "rebranded" by the manufacturer, so you may have to do some research to find the original manufacturer). Once you have found the device in question and retrieved the 501(K) info, click on the "Summary" to see the actual FDA approval letter. If you scroll to the end of the letter, you will see two check boxes, i.e. "Prescription Use (Per 21 CFR 801.109)" or "Over the Counter Use". If the "summary" info is not available on this web page, you will want to obtain a copy of the FDA 510(K) decision letter from the manufacturer or distributor to verify if it is for use by licensed medical professionals only, or approved for "over the counter use".

Look closely at the 510(K) information. I have reviewed dozens of these devices and I have never seen the words "employment", "employee", "workplace", mentioned anywhere in the associated documentation – they are approved "For in vitro diagnostic use only."

The regulations mentioned in Eden's article can be found on the FDA search page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

21 CFR 801.109
A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by

law to direct the use of such device, and hence for which ``adequate directions for use'' cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement ``Caution: Federal law restricts this device to sale by or on the order of a --------'', the blank to be filled with the word ``physician'', ``dentist'', ``veterinarian'', or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented:

Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder--piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)
PART 809--IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE--Table of Contents
Subpart C--Requirements for Manufacturers and Producers
Sec. 809.40 Restrictions on the sale, distribution, and use of OTC test sample collection systems for drugs of abuse testing.

(a) Over-the-counter (OTC) test sample collection systems for drugs of abuse testing (Sec. 864.3260 of this chapter) are restricted devices under section 520(e) of the Act subject to the restrictions set forth in this section.

(b) Sample testing shall be performed in a laboratory using screening tests that have been approved, cleared, or otherwise recognized by the Food and Drug Administration as accurate and reliable for the testing of such specimens for identifying drugs of abuse or their metabolites.

(c) The laboratory performing the test(s) shall have, and shall be recognized as having, adequate capability to reliably perform the necessary screening and confirmatory tests, including adequate capability to perform integrity checks of the biological specimens for possible adulteration.

(d) All OTC test sample collection systems for drugs of abuse testing shall be labeled in accordance with Sec. 809.10(f) and shall provide an adequate system to communicate the proper interpretation of test results from the laboratory to the lay purchaser.
[65 FR 18234, Apr. 7, 2000]

Sec. 864.3260 OTC test sample collection systems for drugs of abuse testing.

(a) Identification. An over-the-counter (OTC) test sample collection system for drugs of abuse testing is a device intended to: Collect biological specimens (such as hair, urine, sweat, or saliva), outside of a medical setting and not on order of a health care professional (e.g., in the home, insurance, sports, or workplace setting); maintain the integrity of such specimens during storage and transport in order that the matter contained therein can be tested in a laboratory for the presence of drugs of abuse or their metabolites; and provide access to test results and counseling. This section does not apply to collection, transport, or laboratory testing of biological specimens for the presence of drugs of abuse or their metabolites that is performed to develop evidence for law enforcement purposes.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter subject to the limitations in Sec. 864.9 if it is sold, distributed, and used in accordance with the restrictions set forth in Sec. 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of Sec. 820.198 of this chapter with respect to complaint files.
[65 FR 18234, Apr. 7, 2000]

NOTICE: Every employer should have a drug and alcohol policy. The responsibility to provide a safe workplace and the potential liability from negligent hiring and retention require that employers be aware of and take steps to control work-related substance abuse.

The components of a drug-free workplace program, especially drug testing of employees, may raise legal issues with a risk of legal liability if conducted improperly or in violation of federal, state or local laws.