

Drug Testing Technologies: Sweat Patch

A recent innovation in the science of drug testing, the PharmChek Drugs of Abuse Patch - or "sweat patch" - is used to test for various illegal drugs. The sweat patch is affixed to the skin in much the same way as a band-aid, and is worn for up to 14 days. The patch is used to detect the presence of drugs as excreted through perspiration. Individuals required to wear the sweat patch are those on probation or involved in child custody cases. The federal government is currently considering use of the sweat patch in federal workplace drug testing.

The Drug Policy Alliance and DPA Network feel that the use of sweat testing in any of these settings is inappropriate, as published, peer-reviewed research has revealed serious problems with current sweat testing technology. We believe that sweat patch testing poses an unacceptably strong potential for false positive test results. False positives carry serious consequences for tested individuals - sometimes including incarceration or loss of child custody.

If you are involved in a court case where sweat patch evidence is being used, please contact us at legalaffairs@drugpolicy.org. Drug Policy Alliance tracks the use of the sweat patch, and in some cases can assist individuals in challenging the use or admission of sweat patch test results.

How does the sweat patch work?

The sweat patch consists of a gauze pad covered by a protective membrane similar to that of a band-aid. The membrane has an adhesive perimeter that sticks tightly to the test subject's skin. The sweat patch is usually worn on the subject's upper arm. Before application, the subject's arm is swabbed with an isopropyl alcohol rub.

After the patch has been worn for approximately seven to ten days, it is removed and the gauze pad is sent to the laboratory for testing. The lab

usually performs "screening tests" for several different drugs, using an immunoassay testing system. If any screening test indicates the presence of a drug, the lab performs a "confirmatory test" for that drug, using the more precise "gas chromatography / mass spectrometry" (GC/MS) testing system. If the confirmatory test finds levels of the drug above the "cutoff" the lab is using, the lab will report a positive test result.

Where is the sweat patch being used?

Many counties around the country use the sweat patch to drug test individuals who are on probation, in drug courts, or involved in child custody cases. PharmChem contracts with these counties to sell them the sweat patch testing kits, to perform the drug tests, and to help the counties defend the results in court.

The Administrative Office of the Federal Courts also has a contract with PharmChem. This contract gives individual federal court districts the option to use the sweat patch when they drug test individuals who are on probation or "supervised release" for federal crimes. Not all federal court jurisdictions use the sweat patch, but many do.

How has the sweat patch fared in court?

Each trial court has the right to make its own decision as to whether sweat patch evidence will be admitted, and how that evidence will be used. A decision by an appellate court would govern the trial courts in that appellate court's jurisdiction, but so far there are no appellate court decisions on the sweat patch from either state or federal courts.

Many trial courts have considered the sweat patch. Some courts have admitted sweat patch evidence, and relied on it in deciding to imprison probationers or terminate parental custody. Others have found the sweat patch insufficiently reliable for these purposes: at least six different

federal courts have rejected government efforts to base punitive action on sweat patch test results.

While Drug Policy Alliance tracks court decisions on the sweat patch, many of these cases are confidential, and hardly any have resulted in written court decisions. There is no exhaustive list of court rulings on the sweat patch. Only two courts have issued written decisions that discuss the science behind the sweat patch and are published in official legal case reports.

§ U.S. v. Snyder. F.Supp. 2d. 2002 WL 257381 N.D.N.Y., 2002. This recent federal court decision finds that in certain circumstances, the sweat patch can be environmentally contaminated, leading to a false positive test result. Because the defendant in this case made a plausible case that his positive test results were a product of environmental contamination, the court rejected the use of the sweat patch to revoke the defendant's supervised release.

§ U.S. v. Stumpf. 54 F. Supp. 2d 972 D. Nev. May 31, 1999. This federal court decision finds sweat patch evidence admissible, and rules that it can be used as the basis for revoking an individual's supervised release. This decision was issued prior to the release of several scientific studies that indicate problems with the sweat patch. The decision contains virtually no scientific analysis: the court simply describes the views presented by each side's expert, and then states that the court agrees with the government's expert.

What are the problems with the sweat patch?

The problems with the sweat patch are many:

False positives through environmental contamination. Scientific studies have demonstrated that environmental contamination can produce false positives in the sweat patch.

- **Naval Research Lab study.** This study by the United States Naval Research Laboratory found that the sweat patch is susceptible to environmental contamination through two scenarios:
 1. "Contamination from within": Environmental contamination may occur when a test subject has a small amount of drug residue on her skin where the patch is to be placed, and the isopropyl alcohol rub fails to remove that residue. The sweat patch will then pick up that drug residue, which becomes indistinguishable from drugs excreted through the subject's sweat, resulting in a false positive test result.
 2. "Contamination from without": Environmental contamination may occur when drugs in the environment leak through the protective membrane covering a patch that is being worn. This situation is more likely when the membrane is wet and when it is exposed to a substance with a high ("basic") pH level. This is the environmental contamination scenario that led to the rejection of sweat patch evidence in **U.S. v. Snyder** .
- PharmChem's internal studies have duplicated the results of the Naval Research Laboratory Study

in finding that "contamination from within" can occur. PharmChem has refused to release or publish the results of these studies, but the studies were described in detail in the recent court hearing in [U.S. v. Snyder](#) .

- Studies designed in consultation with PharmChem and conducted at the Center for Human Toxicology in Salt Lake City also duplicated the results of the Naval Research Laboratory Study in finding that "contamination from within" can occur.

False positives through skin storage. A recent study suggests that long-term storage of drugs in skin could lead to false positive test results. See Levisky, Bowerman, Jenkins, and Karch, "Drug Deposition in Adipose Tissue and Skin: Evidence for an Alternative Source of Positive Sweat Patch Tests," *Forensic Science International* 110 (2000) 35-46. The study indicates that chronic drug users may store drugs under the skin surface. These drugs may be released a long time after drug use so that "a sweat patch, used as a detection device, might falsely indicate that new drug use had occurred." Such false positives are a particular concern to the many individuals who have been heavy drug users, have conquered their drug habits, and are currently being tested by the sweat patch.

False positives during application and removal. Application and removal of the sweat patch are usually performed by non-medical personnel, in a non-clinical setting. Patches are often applied and removed in a probation office by probation officers who have received only a videotaped training. Any sloppiness or failure to follow proper procedures can easily result in false positives. PharmChem officials have themselves admitted that there is a risk of false positives during application and removal. Indeed, one study indicates that even when application and

removal is performed by scientists, in a laboratory setting, contamination can result in false positives. See Cone, Hillsgrove, Jenkins, Keenan, and Darwin, "Sweat Testing for Heroin, Cocaine, and Metabolites," *Journal of Analytical Toxicology* 18 (1994) 298, 304.)

No dose-response relationship. For any drug testing system, the "dose-response relationship" indicates the test result that one would normally expect to see based on ingestion of a certain amount of a particular drug. This information is central to analysis of the results of any drug test. If one does not know the dose-response relationship for a particular drug in a drug testing system, one cannot make meaningful statements about test results for that drug. And most importantly, one cannot set a "cutoff level" that will distinguish a positive test result from trace contamination of the subject, the sample or the testing system.

No one knows the dose-response relationship for sweat testing. The few attempts at controlled-dose studies have been methodologically inadequate, and have found enormous variability in test results.

In one study, a subject tested at 15 ng/ml after being given a dose of methamphetamine, while the next subject tested at 631 ng/ml, 42 times higher, after being given a smaller dose. (Compare subject # 6 with subject # 7, in unpublished "SCRI" study in PharmChem's FDA submission.) Such wide variations in response between different test subjects are typical. Subjects given 20 ng of methamphetamine, tested six days after ingestion, show results as low as 5.7 ng/ml (SCRI subject # 7) and as high as 905 ng/ml (SCRI subject # 15). These high-end results are in no way aberrational: twenty different tests in the SCRI study alone produced readings above 500 ng/ml; many readings were over 1000 ng/ml.

Substantial disparities exist even with two patches taken simultaneously from a single

individual. The SCRI study tested two patches from the lower chest of Subject # 13, nine days after a dose of methamphetamine. One patch tested "negative" at 7.1 ng/ml, while the other tested at 30 ng/ml - a "positive" four times as high. Similarly, the study tested two patches removed from the lower chest of Subject # 5, seven days after the dose of methamphetamine. One patch tested at 34 ng/ml, while the other tested at 185 - more than five times as high.

To our knowledge, neither PharmChem nor any scientist has claimed to understand the dose-response relationship for sweat testing. Nonetheless, PharmChem employs cutoff levels that it claims can distinguish actual drug use from contamination. Without an understanding of a dose-response relationship, however, PharmChem's cutoff level is unreliable.

No regulation of PharmChem's testing program. The federal government does not regulate the use of the sweat patch. PharmChem's sweat testing program is not overseen by the federal government. The federal government does not require PharmChem's sweat testing program to use any particular collection techniques, chain-of-custody procedures, quality control mechanisms, or testing procedures.

All aspects of PharmChem's sweat testing program are designed and operated by a private corporation, without any public checks and balances or quality assurances. No government entity ensures that PharmChem is spending the money necessary to make its tests as accurate as possible. When a company markets a product as a means to catch more drug users, there may in fact be a financial incentive to return positive test results, regardless of accuracy. Without government regulation of PharmChem's testing program, such a dynamic can take effect.

Patch wear problems. The adhesive membrane covering the sweat patch is supposed to bind tightly to the subject's skin, theoretically protecting the sweat patch and preventing

tampering. However, subjects routinely report that the membrane does not adhere properly, peeling or rolling up along one or more edges of the sweat patch. This appears to be particularly common when subjects perspire heavily. As far as we know, there have been no studies to determine how often the sweat patch will fail to adhere in real-life wear conditions.

When a sweat patch does not adhere properly, the subject is usually accused of having attempted to tamper with the sweat patch, and is considered as having submitted a positive drug test.

What about rumors that PharmChem has given false testimony about the sweat patch in court?

This **memorandum** was submitted as part of an ethics complaint filed with the American Academy of Forensic Sciences and the Society for Forensic Toxicologists. It recounts testimony given under oath by Neil Fortner, a vice president of PharmChem, in various court hearings regarding the reliability of the sweat patch. These hearings occurred in cases involving removal of child custody and the threat of incarceration.

The memorandum describes numerous false statements made under oath by Mr. Fortner regarding scientific research on the sweat patch. The memorandum also describes false or strongly misleading statements made under oath by Mr. Fortner regarding his academic credentials. Drug Policy Alliance possesses and can produce copies of court transcripts and other documents referenced in the memorandum.

Provided by the Drug Policy Alliance Network

http://www.drugpolicy.org/law/drugtesting/sweatpatch_/