PHARMCHEK®
DRUGS OF ABUSE SWEAT PATCH

# Frequently Asked Questions

**Revised September 2023**

# Technology & History

## 1. Is the sweat patch new technology?

No. Drugs have been known and detected in sweat since the early 1970's. The principal challenge with respect to sweat testing had been how to collect and retain sweat for testing. The PharmChek® Sweat Patch was developed as a non-occlusive device that facilitates the collection of sweat. PharmChek has been used in criminal justice for over three decades.

## 2. Are the testing procedures used for the analysis of sweat considered new technology?

No. The testing procedures used for the analysis of sweat are the same well-established procedures used for the analysis of oral fluid and urine specimens. Specimens are screened using an immunoassay technique. Positive specimens are confirmed using liquid chromatography/mass spectrometry/mass spectrometry (LC-MS/MS). Both procedures utilize certified calibrator and quality control materials.

## 3. Have these procedures been submitted to and cleared by the Food and Drug Administration (FDA)?

Yes. The FDA has cleared the PharmChek® Sweat Patch as both a specimen collection device and as a scientifically valid procedure for the detection of drugs in sweat.

## 4. Has the PharmChek® Sweat Patch been accepted by the scientific community to detect drug use?

Yes. There were two court cases in Nevada where the PharmChek® Sweat Patch underwent challenges to the Daubert standards, and prevailed -- U.S. District Court, Las Vegas, NV, # CR-S-96-004-PMP, 1/15/1999 and # CR 95-023-PMP, 5/31/1999. Daubert standards state that if evidence is to be presented as scientific knowledge, the following are some of the elements to be considered:

- Proof of testing the basic underlying hypothesis upon which the techniques rests,
- Peer review and publications,
- A known or potential error rate,
- The existence of an accepted methodology, and
- General acceptance of a technique in the forensic community.

In addition, there are a number of **scientific articles** in peer-reviewed journals that have established the use of the sweat patches as a scientifically accepted tool for the detection of drug use.

## 5. Has the PharmChek® Sweat Patch been accepted by the Courts?

Yes. There have been many court cases, both at the federal and state levels, in which the results of the sweat patch have been challenged and where the sweat patch prevailed. Two cases of interest include: the U.S. Court of Appeals, 5th Circuit in June 2011 affirmed the reliability of the sweat patch to test for drugs of abuse. Also, in June of 2006, sweat patch results were upheld by U.S. Court of Appeals, which was heard by the Honorable Judge Sandra Day O'Connor (former member of the U.S. Supreme Court).

*Refer to the **Court Cases** page at **PharmChek.com** for highlighted cases from your state.*

### 6. Is the laboratory process subject to false-positive error?

False positives only apply to the immunoassay screen, not LC-MS/MS confirmation. All presumptive positive screens are sent for confirmation testing. As an additional safeguard, the laboratory utilizes blind quality assurance samples in the testing process.

All positive samples are placed in frozen storage for 12 months prior to disposal in the event a result is challenged.

## Wear Times & Application

### 7. What is the window of detection?

The PharmChek® patch is a sweat collection device designed to retain evidence of drug use for an extended period. It can detect use 24-48 hours before the application of the patch, during the wearing of the patch, or both. For example: a PharmChek® patch worn for 7 days might be positive because of drug use on Day 1 or on Day 6.

### 8. How long does it take for drugs to be excreted through sweat after a single drug use?

Clinical trial data from the administration of known amounts of drugs show that essentially all the drugs detectable with the patch are **excreted over a period of about 2 - 3 days**. This is similar to the elimination period for drugs in urine. The difference is that the PharmChek® patch is retaining all evidence of drug use in the pad.

### 9. How long after use must the PharmChek® patch be worn to produce a positive result?

Data from clinical trials show that patches worn at least **24 hours** after drug use can reliably test for that drug.

### 10. How long can a person wear the PharmChek® Drugs of Abuse Patch?

**The length of time varies from person-to-person** based on factors including skin type and level of activity. The recommended wear-time is 7-10 days.

From our wear tests we have determined that most clients can successfully wear the patch for

10 days. Use of the overlay, applied at the same time as the patch, may extend wear-time up to a maximum of 14 days for some clients.

### 11. Can a Sweat Patch be applied on a hairy client?

The area for application should not have excessive hair, wrinkles, or be rubbed by tight clothing. If the client has excessive body hair, **DO NOT** shave the area.

Instead, choose an alternate body site location. The arm, lower back, and midriff are appropriate site locations for patch application.

### 12. Is it possible to be allergic to the PharmChek Sweat Patch?

Allergic reactions do happen, but they are extremely rare. 3M, the maker of Tegaderm used in the manufacturing of the Sweat Patch states that less than 1% of the population is allergic to Tegaderm. Furthermore, any individual truly allergic to Tegaderm is allergic to the surgical adhesive, not the film, and would be allergic to ALL surgical adhesives. This includes Band-Aids. Tegaderm is a hypoallergenic material used as a wound dressing to cover catheter and IV sites of individuals in hospitals, and widely used within the medical field.

### 13. What is the shelf-life of the Sweat Patch? How about the specimen, once collected?

The shelf life of the Sweat Patch is 2 years from the date of purchase. Collected specimens, awaiting shipment to the laboratory, can be stored for 30 days at room temperature.

### 14. How long do the results take?

Once the lab receives the specimen, negatives are typically reported within 24 hours, and LC-MS/MS confirmed positives are reported within 72 hours.

## Adulteration & Tampering

### 15. Is the sweat patch subject to adulteration?

The sweat patch is a tamper-evident device. The adhesive material used on the sweat patch penetrates the upper epithelial layer of the skin. When the sweat patch is removed, these epithelial skin cells adhere to the adhesive, which makes the re-application of the patch difficult.

While there have been attempts to adulterate the absorbent pad by introducing common chemicals used to also adulterate a urine test (e.g., bleach) these attempts are obvious to a trained observer. Based on the physical properties of the patch these chemicals will be trapped under the film.

In addition, attempts to adulterate the sweat patch will typically result in a visible discoloration of the white absorbent pad and/or discoloration or deformation of the polyurethane covering, and should be noted on the chain of custody document.

Part of the removal process for the patch includes checking for the following:

- **Is a chemical odor observed?**
- **Are any holes observed in the film, when held to the light?**
- **Is any redness observed under the pad?**
- **Is the pad discolored?**

Administrators are also encouraged to take a photo of the patch at application and removal.

## 16. Is the sweat patch subject to substitution?

No. Each sweat patch has a unique identifier number imprinted outside the absorbent pad on the release liner. This number is recorded on the chain of custody form and must be verified when the client reports back to have the sweat patch removed.

## 17. How can I tell if someone has tried to remove or replace the absorbent pad?

A client may try peeling back the upper portion of the sweat patch, removing the absorbent pad, and replacing the absorbent pad prior to reporting back for sweat patch removal. This results in an absorbent pad that is dry, wrinkled, folded, creased, or otherwise deformed. When this procedure is used, one side, typically the top of the sweat patch, is held in place using tape or other adhesives. While some roll-up of the outer edges of the sweat patch may occur during natural wear, the film immediately surrounding the absorbent pad should be well-adhered to the skin and otherwise intact.

It is normal for the absorbent pad to be slightly moist due to the collection of sweat. This moisture will facilitate the separation of the absorbent pad from the release liner. If the absorbent pad is very dry and does not easily separate from the release liner, the donor may have removed and re-applied the sweat patch. The absorbent pad from a worn patch will be soft and slightly discolored due to the absorption of sweat, body oils, and skin debris. If the absorbent pad does not reflect these characteristics, the patch and polyurethane covering must be closely examined to confirm that the patch has not been compromised.

## 18. What effect does hydration or flushing have on the sweat patch results?

None. The consumption of large amounts of fluids will not decrease drug concentrations in sweat.

## 19. Is the sweat patch subject to contamination?

No, not when following proper operating procedures in a real-world environment.

The absorbent pad within the patch is protected from the environment by a layer of film composed of polyurethane coated with adhesive. The polyurethane film is a “semi-permeable membrane,” which allows the transfer of water vapor and gases while preventing outside contaminants from entering. In real-world conditions, there is no evidence that the membrane can be compromised.

Furthermore, to report a positive for cocaine or methamphetamine, the parent drug must be

at or above the cutoff level AND the respective metabolite MUST be present at or above the LOQ (limit of quantitation). This reporting requirement minimizes the possibility of environmental contamination. The only way the drug metabolite is produced in the system is by actual ingestion (use) of the parent drug.

# Interpreting Results

### 20. How were the testing levels for the sweat patch determined?

Cutoff levels between different testing matrices are not directly comparable. The lower cutoff levels for sweat than urine is the result of the varying concentration of analytes in the respective matrices, not due to a more sensitive measurement.

To determine cutoff levels, controlled dosing studies, in which known amounts of drugs were administered to volunteers, were conducted for each of the Standard Panel drugs, except PCP. Multiple sweat patches were applied, removed, and tested from these volunteers. The data was analyzed from these studies, using a well-established scientific approach known as receiver operating characteristics. This approach examines the analytical data to establish cutoff testing levels based on true positive; true negative; false positive; and false negative results. The testing levels submitted to, reviewed by, and cleared by the FDA were established using this receiver operating characteristics approach.

For PCP and the Expanded Panel drugs, lab-spiked sweat patch samples were used to similarly calibrate appropriate cutoff levels.

### 21. If a patch is a “no-test” because it came into the lab with no chain of custody form, can it be revived?

No. This is considered a “Fatal Flaw” and it is a non-recoverable error because the Chain of Custody has been broken.

### 22. The lab report is showing NSA for THC, what does that mean?

For THC testing, the lab is only confirming delta-9 THC. The lab is not testing delta-8 THC or delta-10 THC. During the initial screening process, any presumptive positive for delta-9 THC is automatically sent to LC-MS/MS (mass spec) confirmation testing. On rare occasions, if there is an abundance of delta-8 THC along with the delta-9 THC that screened presumptive positive, that influx of delta-8 THC can interfere with the delta-9 confirmation on the mass spec instruments. The lab will attempt to rectify this situation with repeat testing and possible dilution of the sample. If the lab is unable to rectify this occurrence, the sample is reported out as “NSA” on the THC portion of the lab report. NSA stands for not suitable for analysis. This will only occur during the mass spec confirmation analysis for delta-9 THC. In addition, a comment is added to the lab report stating “LC-MS/MS interference”.

### 23. Can the sweat patch distinguish between multiple drug uses?

No. The sweat patch is a storage device. Consequently, multiple drug uses while wearing the patch will result in increased drug levels in the patch. However, as these are cumulative, the patch cannot distinguish multiple instances of drug use.

### 24. Can a positive result be from residual usage prior to the wear period?

With a positive patch result, it is not possible to determine exactly when the drug use took place, only that the drug use took place approximately 24-48 hours before the application of the patch, during the wearing of the patch, or both. It is possible to detect residual usage between multiple patch wear periods if drugs were consumed late in the first wear period and thus picked up early in the second patch wear period.

### 25. Does a THC positive on the patch indicate new ingestion of THC?

A THC positive on the patch indicates recent ingestion. For daily marijuana users, some short-term residual carryover is possible, but is unlikely to confirm above the cutoff level beyond the first patch wear (7-10 days).

### 26. Will "passive" or inadvertent environmental exposure to a drug cause a positive test result?

The absorbent pad within the patch is protected from the environment by a layer of film composed of polyurethane coated with adhesive. The polyurethane film is a "semi-permeable membrane," which allows the transfer of water vapor and gases while preventing outside contaminants from entering. In real-world conditions, there is no evidence that the membrane can be compromised.

Furthermore, to report a positive for cocaine or methamphetamine, the parent drug must be at or above the cutoff level AND the respective metabolite MUST be present at or above the LOQ (limit of quantitation). This reporting requirement minimizes the possibility of environmental contamination. The only way the drug metabolite is produced in the system is by actual ingestion (use) of the parent drug.

### 27. The client is taking amphetamines by prescription but has also tested positive for methamphetamines. Is that expected?

No. Prescription amphetamines (Vyvanse, Adderall, Dextroamphetamine, etc.) will result in a positive for amphetamine only, no methamphetamine should be in the sample if only prescription amphetamine was ingested.

## Comparing to Other Drug Testing Matrices

### 28. What does the sweat patch detect, and how does this differ from urine testing?

Unlike urine testing that detects only the drug metabolites, sweat testing can detect the parent or non-metabolized form of the drug.

This is particularly important when testing for abused drugs such as heroin, which can only be detected in urine for a short time following use. Heroin is rapidly metabolized to 6-acetylmorphine then to morphine, which can make results interpretation difficult.

### 29. How does the difference in the window of detection for the sweat patch versus urinalysis impact the interpretation of results?

The PharmChek® Sweat Patch functions as a storage device. Therefore, drugs used 1-2 days before the patch is applied, while the patch is worn, or both, will be detected and stored in the pad. Consequently, the sweat patch is a constant monitoring device, which provides a longer detection window than urine testing.

Urinalysis testing for drugs represents a snapshot in time. In urine, drugs such as amphetamines and cocaine are cleared from the body within 72 hours from a single drug use, opiates within 72-96 hours from last use, and marijuana within 96 hours from a single use.

## 30. Is it possible to have a positive sweat patch result and a negative urine test?

Yes. As indicated above, the sweat patch is a storage device and represents a much longer detection window than does testing for drugs using urine. In addition, urine tests are subject to various forms of adulteration including, but not limited to, hydration, substitution, and physical adulteration using products designed to affect the testing procedures. Furthermore, a negative test result does not necessarily mean that no drugs were present. It simply means the drug in question was not detected above the cutoff level.

## 31. Is it possible to have a positive sweat patch result and a negative hair test?

Yes. It has been demonstrated that while hair testing may be able to detect chronic drug use, it is less effective in detecting occasional drug use.

In addition, several issues have been raised by the scientific community relative to the detection of drugs in hair. These include, but are not limited to, the procedures used to wash the hair for the removal of externally deposited drugs (potential for false positive results), the procedures used for the digestion and subsequent extraction of the drugs from the hair (potential for false negative results), differences based on the color of the hair (dark hair appears to incorporate drugs at a higher rate than light colored hair), and the removal of drugs from the hair by shampoos or other hair treatment products (relaxers, dyes or other chemical treatment).

Furthermore, a negative test result does not necessarily mean that no drugs were present. It simply means the drug in question was not detected above the cutoff level.

For further information, please visit our website at www.pharmchek.com.