PHARMCHEK®
DRUGS OF ABUSE SWEAT PATCH

Technical Guide

(The PharmChek® Sweat Patch is For Professional Use Only)

Revised January 2024

PharmChem, Inc.
2411 E. Loop 820 N.
Ft. Worth, TX 76118

855-458-4100

info@pharmchem.com

www.pharmchek.com

PharmChek® Drugs of Abuse Sweat Patch Technical Guide

Table of Contents

The PharmChek® Sweat Patch (referred to as "sweat patch" or "drug patch") is to be used only in a Professional Environment by individuals certified to apply and remove the sweat patch. It is not intended for over-the-counter retail sales.

PharmChek® Drugs of Abuse Sweat Patch - Overview

The PharmChek® Sweat Patch (or Drug Patch) by PharmChem, Inc. uses sweat as the specimen source and is worn on the skin for 7-10 days (some users can wear the patch for as long as 14 days). The patch is used to test for drugs of abuse.

The sweat patch is comprised of a white absorbent pad 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 small molecules, such as oxygen, carbon dioxide, and water vapor to pass through the film—leaving the skin underneath healthy and sterile.

Drugs excreted in sweat are trapped by this polyurethane dressing and retained in the white absorbent pad. The sweat patch captures insensible perspiration, the uncontrolled loss of sweat from the skin. Approximately 300–700 mL of insensible sweat is excreted each day, and about 2 mL is absorbed in the patch each week. When the wear period is complete the sweat patch is removed and sent to the laboratory for testing.

Once received at the laboratory it is screened by immunoassay for the presence of a drug or drug class analyte at the screening **cutoff level**. The cutoff level determines whether a negative test will be reported, or if a presumptive positive specimen will advance for confirmation testing. If the specimen tests negative at screening, the certifying scientist will release the test results. If the specimen tests positive for one or more drugs, the specimen is transferred to an additional level of confirmation testing to quantify and identify the molecules within a sample. The confirmation analysis is done by Liquid Chromatography/Mass Spectrometry (LC-MS/MS).

Technical Discussion

RELIABILITY/FALSE POSITIVES

Every presumptive positive sample is automatically sent for confirmation via LC-MS/MS. This is highly sensitive and specific with a negligible rate of error. The laboratory employs procedures substantially equivalent to those required by SAMHSA for urine testing. As an additional safeguard, the laboratory utilizes blind quality assurance samples in the testing process.

Reliability and false positives were addressed directly in clinical trials by applying patches to self-reported non-users. When tested, the target drugs were not found in patches from non-users. From this, we conclude that any "normal" constituents of sweat do not produce positive results.

Risk of "passive" or inadvertent environmental exposure

There are two possibilities for claiming exposure, either through passive inhalation of a drug or exposure of the sweat patch itself to a drug leading to the detection of that drug in the patch.

Passive inhalation is not considered ingestion. Controlled dosing studies have shown that it would be very difficult to "passively inhale" enough of a substance to test positive with the current laboratory cutoff levels required to confirm a positive result. Only trace amounts of smoke can be inhaled through passive

inhalation and any extreme repeated exposure to these conditions would not be considered “passive.”

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.

Additional studies examined the concern of exposure of the sweat patch itself by applying drugs to the exterior of the patch and subsequently collecting and analyzing the absorbent pad. Under certain conditions, albeit unrealistic, the outer polyurethane membrane can be altered and made permeable to the diffusion of applied drugs onto the absorbent pad. However, these conditions are not what one would realistically expect to encounter in real-world situations.

It may be possible to contaminate the absorbent pad only by altering the physical characteristics of the polyurethane film with organic solvents or chemicals that would compromise the properties of the polyurethane. This adulteration may make the film susceptible to external contamination if exposed to very high levels of drug vapor in a closed environment. **This does not depict real-world conditions that one could encounter in a natural environment.**

Subsequent experiments have involved variations of these initial experiments and have incorporated variants such as wetting the absorbent pad with different solutions and buffers, altering the pH of the solution containing drugs (applied to the exterior of the polyurethane film), and adjusting the temperature and time the solutions were allowed to incubate the exterior of the polyurethane film. **These studies have demonstrated that when both the inside and the outside of the patch were dry, no drug transfer could be detected.**

Finally, 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. None of the previously discussed studies met PharmChek®’s criteria for a positive result i.e., parent drug above cutoff level and the presence of metabolite.

Risk of cross-reactivity with non-target drugs

An initial screening assay will test the specimen for the presence of drugs. This initial assay provides only a preliminary analytical result. If the initial screening renders a presumptive positive test result, a more specific analytical method known as Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) is used to obtain a confirmed analytical result. This is the same procedure required by SAMHSA in the testing of urine samples. LC-MS/MS confirmation is scientifically capable of distinguishing the target drug from other drugs that might be present in sweat, preventing false positives.

A second important point is that “parent” drugs, rather than just drug metabolites, are stable and detectable in sweat after drug use. “Parent” drug is the same chemical compound that was ingested by the drug user (example, heroin). Drug metabolites are “breakdown products” of the parent drug. Many drugs such as codeine and heroin produce the same metabolites in urine, so a urine test cannot reliably distinguish between them. Because sweat contains both the parent drug and metabolites, the test can, more often than not, tell which specific drug has been ingested.

*Refer to the “**Detail by Drug**” section for additional information on specific interactions.*

Risk of adulterants, tampering, and substitution

The sweat patch is a tamper-evident device. The adhesive polyurethane film used in 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 and prevent the re-application of the patch.

Furthermore, **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 individual reports back** to have the sweat patch removed.

Solvents, such as chloroform or acetone, are sometimes applied to the covering of the PharmChek® Sweat Patch but are clearly apparent due to resulting bubbling and shriveling. To adulterate the sweat patch a substance needs to penetrate the outside covering. The only feasible method is to inject substances into the PharmChek® Sweat Patch with a hypodermic needle.

To address these potential tampers, part of the removal process for the patch includes checking for the following:

1) *Is a chemical odor observed?*

2) *Are there any holes in the film when held to the light?*

3) *Is any redness observed on the skin under the pad?*

4) *Is the pad discolored?*

Unlike urine specimens which can be diluted due to hydration/flushing, the consumption of large amounts of fluids will not decrease drug concentrations in the sweat patch. In fact, hydration may encourage sweat production, thus increasing the concentration of the drugs in sweat.

UNDERSTANDING THE WINDOW OF DETECTION

Detection periods for the PharmChek® Sweat Patch are distinct from other common testing matrices such as urine and oral fluid. The sweat patch is a collection device designed to retain evidence of drug use for an extended period of time. That means that drugs excreted through sweat during the wear-time of the patch will be collected, retained, and detected during analysis. For example, if a sweat patch was worn for 7 days, it might be positive because of drug use 24 to 48 hours prior to the application of the sweat patch, or by drug use on Day 6, or both.

Explanation: Drugs and drug metabolites are excreted through bodily fluids over the course of about a 48 to 72-hour period. Therefore, if a patch is applied to a subject today, and the subject used two days prior, the subject's body will still be excreting that drug out of his or her system when the patch is applied and will be captured in the pad when the patch is later analyzed at the laboratory.

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

A positive sweat patch result indicates that drug usage occurred but **cannot determine the exact date or time the drug/s were ingested**. If a patch is worn for 7 days, for example, a positive patch result indicates drug use occurred during the sweat patch wear period, or 24-48 hours before patch application.

*Refer to "**Understanding PharmChek® Results**" section for additional information.*

Wear time

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

Maximum wear time: The outer skin barrier (stratum corneum) has about 15 to 20 layers of dead skin cells. The top layer of cells is constantly being shed. The factor determining how long a person can wear a sweat patch is how long it takes for enough skin cells to be shed that the adhesive coating on the patch is completely covered with skin cells and can no longer stick to the testing subject's body.

The length of wear time varies between person to person and skin type to skin type. From our wear tests, we have observed that 93% of people can wear the PharmChek® Sweat Patch for 7 to 10 days when applied to the upper arm, lower back, or midriff.

There are no known consistent health concerns associated with wearing the sweat patch for periods longer than 10 days if the skin around and under the sweat patch appears healthy and blemish-free. In some instances, a donor may be able to effectively wear the patch for up to 14 days.

*Refer to "**Application Advisements**" section for additional wear considerations.*

Understanding PharmChek® Sweat Patch Test Results

METHODS AND CUTOFFS

PharmChek® Sweat Patch Testing Methods and Cutoffs (Revised - 11/23)			
Drug or Drug Class/ Analyte	**Patch Screening Cutoff**	**Drug or Drug Class/ Analyte**	**Patch Confirmation (LC-MS/MS) Cutoff**
Amphetamines	10 ng/mL	**Amphetamine** **Methamphetamine**	10 ng/mL 10 ng/mL
Benzodiazepines	2.0 ng/mL	**7-Aminoclonazepam** **Oxazepam** **Nordiazepam** **Lorazepam** **Clonazepam** **Alprazolam** **Triazolam** **Temazepam** **Diazepam**	1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL 1.0 ng/mL
Buprenorphine	1.0 ng/mL	**Buprenorphine** **Norbuprenorphine**	0.5 ng/mL 0.5 ng/mL
Cocaine	10 ng/mL	**Cocaine/BE**	10 ng/mL
Fentanyl	1 ng/mL	**Fentanyl** **Norfentanyl**	1 ng/mL 1 ng/mL
Opiates	10 ng/mL	**6 MAM** **Morphine** **Codeine**	10 ng/mL 10 ng/mL 10 ng/mL
Marijuana	.8 ng/mL	**THC**	0.5 ng/mL
Methadone	5.0 ng/mL	**Methadone**	5.0 ng/mL
Phencyclidine	7.5 ng/mL	**Phencyclidine**	7.5 ng/mL
Synthetic Opiates	10 ng/mL	**Hydrocodone** **Hydromorphone** **Oxycodone** **Oxymorphone**	10 ng/mL 10 ng/mL 10 ng/mL 10 ng/mL

BE = Benzoylecgonine **LC-MS/MS** = Liquid Chromatography/Tandem Mass Spectrometry
6-MAM = 6 Monoacetylmorphine **ng/mL** = Nanograms per milliliter of patch eluate

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 necessarily a more sensitive measurement.

To determine cutoff levels, controlled dose studies, in which known amounts of drugs were given to volunteers, were conducted for the 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, and cleared by the FDA were established using this receiver operating characteristics approach. For example, the detection of amphetamine and methamphetamine, utilizing a 10 ng/mL screening and confirmation cutoff has a true positive detection rate of 96%. This means that the testing done using these cutoff levels will correctly identify an individual that uses methamphetamine 96% of the time, but will miss 4% of the individuals that use methamphetamine.

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

Every presumptive positive is automatically sent for confirmation via LC-MS/MS, minimizing the risk of false positives.

INTERPRETING RESULTS

The PharmChek® Sweat Patch provides an innovative approach to the detection of drugs of abuse in sweat. To use the PharmChek® Sweat Patch effectively, it is important that one understand how to interpret sweat test results with confidence and how to distinguish between sweat and urinalysis test results. This understanding can help determine whether or not drug use has occurred and whether there is a legitimate reason for the presence of drug(s).

The most important concept to understand is how detection periods of drugs in sweat differ from those in urine. While the overall detection period for a single drug use is roughly the same in urine and sweat, the PharmChek® Sweat Patch is a collection device designed to retain evidence of drug use (drug molecules found in sweat) for an extended period of time. One can think of this device as a storage container that continually collects sweat while the patch is worn. Drugs excreted through sweat after drug use can be collected and stored on the cellulose pad and detected during analysis at the laboratory.

Consequently, while the results from the sweat patch **cannot** be used to reflect the **dose of drug taken** or the exact **time of use**, it does provide an extended detection window and can confirm if drug use occurred 24-48 hours before the patch wear, during the patch wear period, up to a day prior to patch removal, or a combination of all three. The level of drug on the lab report reflects any drug use that occurred during the wear period. If a positive PharmChek® Sweat Patch contains a high level of drug, it **cannot** be determined if multiple small doses or one large dose of drug is the cause of the level of drug detected.

A urine drug test measures the level of drug(s) in urine at the time the specimen is collected. Unlike sweat testing, the detection periods of drugs in urine can vary. Different drugs leave the body over varying intervals. The time also varies depending on the drug, the dose administered, and the frequency

of drug use. In general, drugs can be detected in urine approximately 48 - 72 hours after a single drug use.

Another important factor in interpreting PharmChek® Sweat Patch test results is the understanding that sweat analysis allows the laboratory to identify both the "parent" drug and metabolite. With urine tests, the laboratory usually identifies drug metabolites or breakdown products to determine if drug use occurred. This is best illustrated by the identification of cocaine in sweat. When an individual uses cocaine, the body converts the cocaine to several different forms or metabolites. While non-metabolized cocaine can be found in urine, it is excreted quickly from the body, meaning the sample must be collected within 6-12 hours after cocaine use to be detected. Therefore, the substance tested for in urine is the primary cocaine metabolite, benzoylecgonine, (BE). **The substances detected in sweat include cocaine (parent drug)** and the metabolite BE. Since the sweat patch functions as a storage device, these drugs are retained in the absorbent pad and can be subsequently detected upon analysis.

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.

Comparing results from other matrices

Many programs employ multiple testing matrices and, in some instances, the tests can return seemingly conflicting results. The unique window of detection offered by the sweat patch is a key reason a positive patch result might not match a urine or hair test. Furthermore, a negative test result does not necessarily mean that no drugs were present. It simply means the drug in question was not detected at or above the cutoff level.

Urine: As indicated above, the sweat patch is a storage device and represents a much longer detection window than does testing for drugs using urine. If "daily" is defined by your program as Monday-Friday, it leaves gaps in the drug testing window that could also lead to positive patch results and negative UA results. 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.

Urine tests must be performed frequently enough (i.e., daily), using highly sensitive cutoffs (e.g., at the laboratory's Limit of Detection) and taking into detailed account the extent of any urine dilution (i.e. through creatinine or specific gravity measurements) to be certain that any instances of drug use are effectively detected through urinalysis.

Additionally, the test could be looking for different substances, unlike urine testing that detects drug metabolites, sweat testing for methamphetamine and cocaine detects the parent drug, also known as the non-metabolized form of the drug.

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

In addition, there are several issues that 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).

DETAIL BY DRUG

The following information provides details regarding each of the drugs tested for using the PharmChek® Sweat Patch.

Amphetamine

Amphetamine and methamphetamine have relatively short detection times in urine. Depending on urine pH, the average detection period of amphetamine and methamphetamine after use is 12-72 hours. Since the detection period of those two drugs in urine is very short, it is possible to have a positive sweat test result for a patch that was worn for 7 days, but a negative urine test during the same time period.

There are some medications prescribed by physicians for attention deficit hyperactivity disorder (ADHD), obesity, or narcolepsy that contain amphetamines. Common brand names include Adderall and Vyvanse. Prescription amphetamines do not contain or convert to methamphetamine in the body. As a result, these prescriptions will not be reported as positive based on the requirement for the presence of both parent drug and metabolite. The testing laboratory also does interference testing to ensure that common over-the-counter medications such as Sudafed and Claritin do not cross-react to return amphetamine-positive test results.

Benzodiazepines

Benzodiazepines, commonly known as “benzos,” are a class of prescription medications used to treat various conditions, such as anxiety, insomnia, and seizure disorders. These medications, including popular drugs like Xanax, Valium, and Ativan, can be effective when used as prescribed by a healthcare provider. However, benzodiazepines are also associated with a risk of misuse and addiction.

PharmChek tests for the following commonly prescribed Benzodiazapines:

- Alprazolam (Xanax)
- Diazepam (Valium)
- Lorazepam (Ativan)
- Clonazepam (Klonopin)
- Temazepam (Restoril)
- Oxazepam (Serax)
- Triazolam (Halcion)
- 7-Aminoclonazepam
- Nordiazepam

Buprenorphine

Buprenorphine is a medication commonly used to manage opioid addiction. It's available in different forms, such as tablets and films, and is often prescribed to individuals in medication-assisted treatment programs. Buprenorphine helps reduce withdrawal symptoms and cravings, making it a valuable tool in opioid addiction recovery. However, buprenorphine is also sometimes misused illicitly.

Buprenorphine is prescribed in a variety of formats:

- **Suboxone:** Suboxone is a combination medication that contains both buprenorphine and naloxone. Naloxone is included to deter misuse by injection.
- **Subutex:** It contains only buprenorphine and lacks naloxone. It is typically prescribed during the initial stages of opioid addiction treatment.
- **Bunavail:** Bunavail is a buccal film (placed on the inside of the cheek) that contains buprenorphine and naloxone. It offers an alternative route of administration compared to traditional sublingual formulations.
- **Zubsolv:** Zubsolv is another combination medication like Suboxone, containing buprenorphine and naloxone.

Cocaine

Use of the sweat patch makes it more likely to identify a cocaine user due to the ongoing collection of sweat. Cocaine has a very short detection time in urine. Cocaine is metabolized by plasma and liver esterase to ecgonine methyl ester and by hydrolysis to benzoylecgonine. One reason benzoylecgonine is used in urine testing is because it can be detected for a much longer time than cocaine itself. Benzoylecgonine, which is the most common metabolite in blood and urine, is not found in high concentrations in sweat. Cocaine predominates in sweat after cocaine use.

The medical community uses TAC (tetracaine, epinephrine, cocaine) as a topical preparation prior to various surgical procedures and may use cocaine by itself as a topical anesthetic for various ear, nose, throat and bronchoscopy procedures. However, cocaine is structurally unique and does not resemble any of the other topical analgesics, such as Novocain®, Xylocaine®, Lidocaine, Benzocaine, Procaine, Prilocaine, etc. Although these compounds have similar analgesic properties, there is no structural similarity to cocaine or its metabolite (benzoylecgonine).

For cocaine, it is possible to receive a positive result with only the metabolite showing positive, as long as the level is at or above the established cutoff, since the presence of the metabolite indicates ingestion of the parent drug. This situation typically indicates ingestion of cocaine prior to patch application.

Fentanyl

Fentanyl is a potent synthetic opioid drug approved for use as an analgesic and anesthetic. It is roughly 100 times more potent than morphine and 50 times more potent than heroin. Recently there has been a re-emergence of trafficking, distribution, and abuse of illicitly produced fentanyl and fentanyl analogues with an associated increase in overdoses and deaths.

Fentanyl can be a prescribed medication and is often used for treating acute pain following surgery. Testing for Fentanyl and Norfentanyl is available on the sweat patch.

Marijuana

Tetrahydrocannabinol (THC) is the psychoactive ingredient found in marijuana. The PharmChek® Sweat Patch detects and reports the presence of parent drug 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).

Parent drug THC eliminates quickly from blood and urine. Urine testing typically detects and reports THC metabolite because it is fat soluble and remains in the body for weeks at a time. THC metabolite can be found in urine for as long as a month in heavy users. Therefore, interpreting urine test results to determine additional marijuana use can be difficult.

For THC testing, the lab is only confirming delta-9 THC. The lab is not looking for or reporting 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. Currently there is a prevalence of delta-8 THC and other cannabinoids being used across the U.S. 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”.

Marinol® (synthetic marijuana) may be used for stimulating appetite and preventing weight loss in patients with AIDS, as well as treating nausea and vomiting associated with chemotherapy. Currently there are no published studies showing Marinol® will produce a positive sweat test, although it is theoretically possible.

Methadone

Methadone is a synthetic opioid medication commonly used in the treatment of opioid addiction, primarily for people who are dependent on strong opioids like heroin or prescription painkillers. Methadone helps by relieving withdrawal symptoms and cravings, allowing individuals to work on their recovery without the intense ups and downs associated with illicit drug use. It is administered under strict supervision in specially licensed clinics and requires regular monitoring to ensure safe and effective use. While it plays a crucial role in medication-assisted treatment, it’s important to note that methadone itself has the potential for misuse and addiction.

Opiates

The PharmChek® Sweat Patch can detect several drugs that are commonly referred to as opiates. These opiates are heroin, the heroin metabolite 6- monoacetylmorphine (6-MAM), codeine, and morphine, as well as “synthetic” opiates of hydrocodone, hydromorphone, oxycodone, and oxymorphone.

The presence and reporting of 6-MAM can only come from the use of heroin. Heroin has an extremely short half-life of about two to six minutes. The half-life of 6-acetylmorphine is six to 25 minutes. Because heroin has such a short life, its metabolites, 6-MAM and morphine, are quantitated in confirmatory testing of heroin. The presence of 6-MAM is definitive proof of heroin use.

6-MAM is rapidly created from heroin in the body and is either metabolized into morphine or excreted in urine. Since the sweat patch acts like a reservoir, the use of heroin is more likely to be detected in sweat testing since the patch captures and retains the unique 6-MAM metabolite within the sample. In contrast, since 6-MAM remains in urine for no longer than 24 hours, a urine specimen must be collected soon after the last heroin use to be detected.

6-MAM is one of three active metabolites of heroin; the others being morphine and the much less active 3-MAM. In urine testing, morphine can be an indicator of heroin use, or may be present due to the use of certain medications, or the consumption of certain foods, such as poppy seeds. However, poppy seeds will not test positive for 6-MAM (heroin) in sweat testing.

Phencyclidine

Phencyclidine (PCP) is a fat-soluble drug which is detected in sweat as parent drug. There are no legal, human medical uses for PCP. Phencyclidine is used legitimately only as a veterinary tranquilizer.

No Test Criteria

For a PharmChek® Sweat Patch to be tested, the following **criteria must be met**: If any of these test criteria are absent, the laboratory personnel are instructed **not to test** the PharmChek® Sweat Patch because the results may not be defensible in court.

1. A signed **security seal** must be placed **on** the outside of the **specimen bag** (small clear bag).

2. The seal must be signed and dated by the observer and initialed by the donor.

3. A barcode sticker matching the barcode on the custody form must also be placed on the specimen bag.

4. The observer must **complete the chain of custody form (COC)** at application and removal of the patch.

5. The completed COC must be placed in the transport bag (large clear bag) with the sealed pad inside the specimen bag.

6. Attach a barcode sticker that matches the COC and the specimen to the outside of the transport bag. (Please don't staple the COC to the specimen bag – use the transport bag provided)

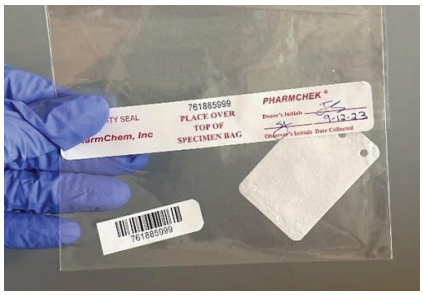
7. **Only the absorbent pad** from the PharmChek® Sweat Patch is to be placed in the small specimen bag. If the patch polyurethane film, or any other object accompanies the absorbent pad inside the specimen bag, the specimen is considered contaminated and will not be tested in the laboratory.

8. If the absorbent pad has an unusual appearance or color, the sample **may not** be tested.

9. The sample may be rejected if you fail to submit at least 50% of the white absorbent pad for testing.

10. If no security seal is properly affixed to the smaller clear specimen bag, the laboratory will not test the specimen.

Proper collection of a specimen should look like this:



Proper specimen transport to the lab should look like this:

Note: In the second photo, the pad is secured in the specimen bag. The security seal is properly affixed, and it is initialed and dated by the observer and initialed by the donor. A matching barcode sticker is on the outside of the specimen bag. The specimen bag is properly placed inside the transport bag with the COC form. A barcode label matching the specimen and the COC is placed on the transport bag.

Application Advisements

The PharmChek® Sweat Patch is not designed to be applied to skin that is compromised by lesions, abrasions, cuts, lacerations, wounds, scars, ulcerations, infections, or dermatological irritations, such as rashes and sunburns. This product is not intended as a wound dressing and is not designed or intended for use except as specifically indicated.

Even though the patch is designed to be hypoallergenic, occasionally there may be some irritations associated with the PharmChek® Sweat Patch.

Warning: The PharmChek® Sweat Patch contains no chemical compounds that are known to cause skin irritation. Should excessive skin irritation occur during wear time, the sweat patch should be removed and the skin treated appropriately.

Sensible and Insensible Sweat

The PharmChek® Sweat Patch allows water vapor (insensible sweat) to pass through the pores in the plastic covering because of their small molecular size. If the individual wearing the patch is involved in athletic activity, physical labor, or works in a hot environment, the body produces sensible sweat as a means of regulating body temperature. In some instances, the amount of sensible sweat may exceed the rate of evaporation which may cause pooling of sweat under and around the pad.

Normally, excessive sensible sweat will evaporate within a few hours. However, in some rare instances, where the amount of sensible sweat produced is significant, excess sweat could create channels under the polyurethane adhesive and begin to leak under the adhesive. This may cause the adhesive to separate and it will appear that some of the sweat patch is coming off. If this occurs, the donor must

report this to the supervising agency, however, this is a rare occurrence if the patch is worn for the recommended wear time of 7-10 days.

Excess Hair

If a Donor has excessive hair on the parts of the body recommended for PharmChek® Sweat Patch application, **do not shave the area; rather, select another application site**. If the sweat patch adhesive does not provide a complete seal around the absorbent pad because of the hair, consider using an alternative application site. If alternative application sites are not viable, the donor may not be a good candidate to wear the sweat patch and another method of drug testing should be considered.

Tattoos

The PharmChek® Sweat Patch can be placed over tattoos if the tattoo is light in color and does not contain obvious scar tissue.

Intermittent Itching

The most common adverse reaction to the PharmChek® Sweat Patch is intermittent itching. **This is not an allergic reaction.** It is a sensitivity to a foreign object on the skin, similar to wearing a Band-Aid, which may occur for a short period of time. This can also be caused by soaps, perfumes, or other skin preparations trapped under the patch adhesive. If intermittent itching occurs it is up to the judgment of the Trained Observer to determine whether the Donor is uncomfortable enough that the patch should be removed and the individual tested by another method, or at another time.

Mechanical Skin Injury

If the PharmChek® Sweat Patch is put onto the Donor's skin and the skin is not flexed, the non-elastic patch covering can pull on the skin surface as the Donor moves. This can cause a line of small skin eruptions at the edge of the patch where it is pulling on the skin. Always have the Donor flex the muscle prior to patch application.

If this happens, remove the PharmChek® Sweat Patch. Apply another PharmChek® Sweat Patch on a different area of the body that is properly cleansed with 70% isopropyl alcohol and flexed.

Chemical Reaction

The adhesive of the PharmChek® Sweat Patch or the substances that the skin is releasing can occasionally cause a chemical reaction with the skin. The usual reaction is a series of small skin eruptions underneath the patch or a reddening (but not an allergic reaction) under the patch.

If this happens, remove the sweat patch. Wash the area with soap and water. Apply another sweat patch to a different body area. If the reaction repeats itself, the second sweat patch should be removed and the area washed with soap and water. The Donor should then be given a urine drug test. The urine drug test should be repeated every 24-48 hours.

Allergic Reaction

If the itching is continuous rather than intermittent and accompanied by redness, swelling, and heat, it may be an allergic reaction to the adhesive used in the PharmChek® Sweat Patch. If this is the case, remove the sweat patch immediately and have the wearer wash the area to remove any residual adhesive that might be present.

The most likely cause of an allergic reaction would be the surgical adhesive used. 3M (the manufacturer of the adhesive) has sold over a billion wound dressings made of this polyurethane film and adhesive over the last 30 years; they have never had a serious documented allergic reaction to the surgical adhesive in the wound dressing.

Alcohol Burns

The PharmChek® Sweat Patch application area must be cleaned before application with 70% isopropyl alcohol wipes (included in each kit). The area should be thoroughly dry, so the Observer must wait 60 to 90 seconds before applying the sweat patch to the skin. If all the alcohol has not evaporated from the skin when the sweat patch is applied, an “alcohol burn” or red spot may develop underneath the patch. This spot is not permanent but may stay on the skin for several weeks until the layers of skin are naturally replaced.

Hyperpigmentation

Occasionally, the PharmChek® Sweat Patch may cause a temporary darkening of the skin underneath the patch in Donors with mid to dark-toned skin. This is only a temporary phenomenon and will disappear after the sweat patch is removed and the skin cells are naturally replaced.

Reporting Complications

Small skin eruptions and intermittent itching do not need to be reported to PharmChem, Inc. However, since PharmChem is the distributor of the PharmChek® Sweat Patch, we are obligated to keep records of adverse reactions. Once an adverse reaction is reported, you will receive a Medical Device Reporting questionnaire, which will help you provide PharmChem with specific information related to a reaction. We will need to know the name of the Donor, the date of the reaction, a description of the reaction, and a telephone number or email address to follow up. Should there be any questions about the patch or reactions to the patch, please call PharmChem, Inc. at **855-458-4100** within 24 hours. Food and Drug Administration Regulations require PharmChem to report any complications that require medical intervention.

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