

PharmChek[®]

Drugs of Abuse Sweat Patch | *by PharmChem, Inc.*

PharmChek[®] Drugs of Abuse Sweat Patch

Technical Questions & Answers

(The Sweat Patch is For Professional Use Only)

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PharmChek® Drugs of Abuse Sweat Patch

Technical Questions & Answers

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The PharmChek® Sweat 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

Technical Discussion

Reliability/False Positives

Will "passive" or inadvertent-environmental exposure to a drug cause a positive test result?

We studied this question directly, even though there is a strong theoretical reason not to believe in such possibility. The absorption pad of 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. Initial studies involving this concern were conducted by applying drugs to the exterior of the patch and subsequently collecting and analyzing the absorption pad.

No drugs were found in the patches in these experiments.

Altering the physical characteristics of the polyurethane with organic solvents or other chemicals can compromise the properties of the polyurethane and make it susceptible to external contamination. When exposed to very high levels of drug vapor in a closed environment (not real world conditions) it may be possible to contaminate the absorption pad.

Discussion of this experiment can be found in the FDA submission documents, (Hypothesis 7 of SECTION 4 DISCUSSION).

Subsequent experiments have involved variations of these initial experiments and have incorporated such variations as wetting the absorbent pad with various solutions and buffers, varying the pH of the of the solution containing drugs that was applied to the exterior of the polyurethane membrane, and varying the temperature and time that the varying solutions are allowed to sit or incubate on the exterior of the polyurethane membrane.

These studies have demonstrated that when both the inside and the outside of the patch were dry, no drug transfer could be noted. Under certain conditions, the outer polyurethane membrane can be altered and made permeable to the diffusion of applied drugs onto the absorption pad.

However these conditions are not what one would realistically expect to encounter in real world situations.

Will the PharmChek® patch be positive if the target drug is not taken?

This question was 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.

Results of these studies are represented in Hypothesis 3 of SECTION 4 DISCUSSION in each summary book given to the FDA as part of the submission for the drug.

In addition, while drugs may be present in the environment in certain situations and even possibly present on skin surfaces, none of these studies has demonstrated in realistic scenarios that the transfer of such environmental drugs into patches worn by those individuals present in these environments.

Will drugs other than the target drugs produce false positives?

This is not directly addressed in our studies because the FDA deemed it unnecessary. The testing procedure cleared by the FDA requires GCMS confirmation testing of initial immunoassay test positives. This is the same procedure required by SAMHSA (formerly NIDA) in the testing of urine samples. GCMS (and its successor LS/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 found in sweat after drug use. "Parent" drug is the same chemical compound that was taken 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 the metabolites, the test can, more often than not, tell which drug has been taken.

Is the laboratory process subject to false-positive error?

The laboratory (CRL) employs procedures substantially equivalent to those required by SAMHSA for urine testing. Years of experience with these procedures have demonstrated that there is a negligible problem with false positives. As an additional safeguard, the laboratory utilizes blind quality assurance samples in the testing process.

Detection Periods

Detection periods for the PharmChek® sweat patch are different from urine testing. The PharmChek® 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 because of drug use at any time during the wearing of the patch will be collected, retained, and detected during analysis. If a PharmChek® patch were worn for 7 days, for example, 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 - 72 hour period. Therefore, if a patch is applied to a subject today, and the subject used yesterday, the subject's body would still be excreting that drug out of his or her system when the patch is applied, and would therefore result in a positive laboratory confirmation when the patch is removed from the subject's body. See also page 7 for additional information.

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 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® patch is constantly sampling the sweat and retaining all evidence of drug use.

A positive PharmChek® patch cannot show when drug use occurred. If a patch is worn for 7 days, for example, a positive patch result indicates drug

use occurred during the patch wear period, or 24-48 hours before PharmChek® patch application, or up to 24 hours prior to the patch removal.

How long after use must the PharmChek® patch be worn in order 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.

Analytical Methods and Cutoffs

Adulterants

Solvents, such as chloroform or acetone, have been applied to the covering of the PharmChek® patch. They bubble and shrivel the PharmChek® patch covering. It is clearly apparent if the patch is tampered with using these chemicals.

In order to adulterate the PharmChek® patch a substance would have to penetrate the outside covering of the patch. The only feasible method that has been tried is to inject substances into the PharmChek® patch with a hypodermic needle. Part of the removal process for the patch includes holding the outside cover of the used PharmChek® patch to the light to see if there are signs of needle holes.

PharmChek® Wear Period

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

The skin has about 15 to 20 layers of skin cells. The top layer of cells is constantly shed. The factor that determines how long a person can wear a PharmChek® 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 testing subject's body.

This length of time varies between person-to-person and skin type to skin type. From our wear tests we have observed that most people can wear the patch for 7 to 10 days. The Michigan Pilot Study showed 87% of the people who wore the patch could wear it for 14 days. There is no known consistent

health concerns associated with wearing the PharmChek® patch for periods longer than 14 days if the skin around and under the PharmChek® patch appears healthy and blemish-free.

Understanding PharmChek® Drugs of Abuse Patch Test Results

PharmChek Drugs of Abuse Patch			
Testing Methods and Cutoffs (Revised - 3/14)			
Drug or Drug Class/ Analyte	Patch Screening EIA Cutoff/ng/mL	Drug or Drug Class/ Analyte	Patch Confirmation/LC/MS/MS Cutoff/ng/mL
Cocaine	10 ng/mL	Cocaine/BZ	10 ng/mL
Opiates/Heroin	10 ng/mL	6 MAM Morphine Codeine	10 ng/mL 10 ng/mL 10 ng/mL
Synthetic Opiates	10 ng/mL	Hydrocodone Hydromorphone Oxycodone Oxymorphone	10 ng/mL 10 ng/mL 10 ng/mL 10 ng/mL
Amphetamine	10 ng/mL	Amphetamine Methamphetamine	10 ng/mL 10 ng/mL
Marijuana	1.5 ng/mL	THC	0.5 ng/mL
Phencyclidine	7.5 ng/mL	Phencyclidine	7.5 ng/mL

BZ

6-MAM

EIA

LC/MS/MS

ng/mL

Benzoyllecgonine

6 Monoacetylmorphine

Enzyme Immunoassay

**Liquid Chromatography/Tandem Mass Spectrometry
nanograms per milliliter of patch eluate**

The PharmChek® Drug of Abuse Patch provides an innovative approach to the detection drugs of abuse in sweat. To let you (the probation/parole officer, the pretrial services officer, the Drug Court officer, the hearing officer or the substance abuse professional) use the PharmChek® patch effectively, it is important that you understand how to interpret sweat test results with confidence and how to distinguish between sweat and urinalysis test results. It is hoped this understanding can help you 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 absorption 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 time of use, it does provide an extended detection window.

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.

REMINDER: With a positive Patch result, it is not possible to determine precisely when the drug use took place -- only that the drug use took place 24 - 48 before the application of the patch or during the wear period, up to 24 hours prior to removal, or both.

Based on several studies in which individuals were given drugs, that the patch must be worn for a minimum of 24 hours. This allows sufficient collection of the sweat to permit a valid analysis.

A urine drug test measures the level of drug(s) in urine at the time the specimen is collected. Unlike sweat testing, which provides a detection period equal to the length of time the PharmChek® patch is worn, the

detection periods of drugs in urine can vary. Different drugs leave the body over various time intervals. The time varies depending on the drug, the dose administered and the frequency of drug use. In general, drugs can be detected in urine up to 72 hours after a single drug use.

Another important factor in interpreting PharmChek® 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 and these other metabolites can be found in urine, the sample must be collected within 6-12 hours after cocaine use. Consequently the substance that is tested for in urine is the primary cocaine metabolite benzoylecgonine. The substances that can appear in sweat include cocaine (parent drug), benzoylecgonine and ecgonine methyl ester (both of these are breakdown products). Because the sweat patch functions as a storage device, these drugs are retained on the absorption pad and can be subsequently detected. This concept holds true for opiates (codeine, morphine and heroin) as well as tetrahydrocannabinol (marijuana).

It is also important to note that the laboratory will not provide a confirmed positive result for Cocaine or Methamphetamine **unless both the actual metabolite and the parent of each drug are also detected at or above the limit of detection (LOD).** This reporting requirement eliminates the possibility of environmental contamination. The only way the drug metabolite is produced in the system is by actual ingestion (use) of the drug.

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

Cocaine

Cocaine has a very short detection time in urine. Cocaine is metabolized by plasma and liver esterases to ecgonine methyl ester and by hydrolysis to benzoylecgonine. One reason benzoylecgonine is detected in urine is it can be detected for a much longer time than cocaine itself. Use of the sweat patch makes it more likely to identify a cocaine user due to the ongoing collection of sweat. 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 analgesic properties, there is no structural similarity to cocaine or its metabolite (benzoylecgonine).

Opiates

The PharmChek® sweat patch can detect a number of 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 hydrocodone, hydromorphone, oxycodone and oxymorphone.

The presence and reporting of 6-MAM can only come from the use of heroin.

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 sweat sample.

Since 6-MAM remains in the urine for no longer than 24 hours, a urine specimen must be collected soon after the last heroin use.

6-MAM is one of three active metabolites of heroin with the others being morphine and the much less active 3-MAM. Morphine can be an indicator of heroin use or may be present due to the use of certain medications or in the consumption of certain food products such as poppy seeds.

Poppy seeds, however, will not test positive for 6-MAM (heroin) in sweat testing.

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. Amphetamine and methamphetamine can appear unchanged in sweat 2-4 hours after use. However, the patch should be worn for at least 24 hours after use to collect enough drug to be identified. Since the detection period of these 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 negative urine tests during those same 7 days. There are some medications prescribed by physicians that contain amphetamines. These medications can be prescribed for attention deficit disorder (ADD), obesity or narcolepsy.

Phencyclidine

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

Marijuana

Tetrahydrocannabinol (THC) is the psychoactive ingredient found in marijuana. It is rapidly absorbed through the lungs during smoking. Like cocaine, marijuana use is determined by detecting the metabolite of THC in urine. Since THC is fat-soluble and is eliminated by the body slowly, interpreting sweat test results to determine if additional marijuana use occurred can be complex. Parent THC is found in sweat after smoking marijuana. Marinol® (synthetic marijuana) may be used for stimulating appetite and preventing weight loss in patients with AIDS and treating nausea and vomiting associated with cancer chemotherapy. Currently there are no published studies that have determined if Marinol® will produce a positive sweat test, although it is theoretically feasible.

No Test Criteria

In order for a PharmChek® patch to be tested these **criteria must be met**: If any of these test criteria are missing the laboratory personnel are under instructions **not to test** the PharmChek® patch because the results may not be defensible in court.

1. The absorption pad must be accompanied by the 2nd (middle) ply of the PharmChek® chain-of-custody form.
2. Only the absorption pad from the PharmChek® patch must be placed in the small specimen bag; the bag must be sealed with the security seal.
3. A barcode label from the chain-of-custody form must be fixed to the specimen bag and the label must match the barcode on the chain-of-custody form.
4. The Trained Observer must have signed both the “*Observer’s Certification* at PharmChek® Application” and the “*Observer’s Certification* at PharmChek® Removal”.
5. The Donor must have signed or initialed on the line in the box labeled “Donor Completes”.
6. If the patch polyurethane film, or any other object accompanies the absorption pad in the specimen bag, the specimen is considered contaminated and WILL NOT be tested in the laboratory.
7. If an incomplete PharmChek® patch is submitted for laboratory analysis (example: only half of the absorption pad is submitted) the specimen will not be tested.
8. If the absorption pad has an unusual appearance or color, the sample WILL NOT be tested.

Application Advisements

The PharmChek® Drugs of Abuse Patch is not designed to be applied to skin, which 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. This product is not designed or intended for use except as indicated.

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

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

Sensible and Insensible Sweat

From your training, you have learned that the 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, this excessive sensible sweat will evaporate within a few hours. However, in some extreme 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 office/individuals that applied the sweat patch. This is a rare occurrence.

Excess Hair

If a prospective Donor has excessive hair on the parts of the body recommended for PharmChek® patch application, do not shave the area;

rather, select another application site. If the PharmChek® patch adhesive does not provide a complete seal around the absorbent pad because of the hair, consider using an alternative application site. This donor may not be a good candidate to wear the sweat patch and another method of testing for drugs should be considered.

Intermittent Itching

The most common adverse reaction to the PharmChek® patch is intermittent itching. For the most part this is not an allergic reaction but a sensitivity to the patch, 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 should be tested by another method or at another time.

Mechanical Skin Injury

If the patch is put onto the Donor's skin and the skin is not flexed, the non-elastic patch covering can pull on the more elastic 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.

If this happens, remove the PharmChek® patch. Apply another PharmChek® patch on a different area of the body that is properly flexed.

Chemical Reaction

The adhesive of the PharmChek® 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 PharmChek® patch. Wash the area with soap and water. Another PharmChek® patch should be applied to a different area. If the reaction repeats itself, the second PharmChek® 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 72 hours later.

Allergic Reaction

If the itching is continuous rather than intermittent and is accompanied by redness, swelling and heat, it may be an allergic reaction to the adhesive used in the PharmChek® patch. If this is the case, remove the PharmChek® 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 adhesive on the PharmChek® patch. 3M (the manufacturer of the adhesive) has sold over a billion wound dressings made of the polyurethane film and the adhesive over the last 15 years. They have not had a serious documented allergic reaction to the wound dressing.

Alcohol Burns

The PharmChek® patch application area is cleaned before application with standard 70% isopropyl alcohol wipes. This area should be thoroughly dry (wait approximately 60 to 90 seconds) before the PharmChek® patch is applied to the skin. If all of the alcohol has not evaporated from the skin when the PharmChek® 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 that are reddened are naturally replaced.

Hyperpigmentation

Occasionally, the PharmChek® patch may cause a temporary darkening of the area underneath the patch in people with "mid-tone" skin coloring. This is only a temporary phenomenon and will disappear after the PharmChek® patch is removed as the layers of skin cells are naturally replaced.

Reporting Complications

Small skin eruptions and intermittent itching need not be reported to PharmChem. Other, stronger reactions should be reported.

If a Donor does have a strong allergic reaction, report the reaction to PharmChem immediately. Since PharmChem is the distributor for the PharmChek® patch we are obligated to keep records of adverse reactions to the PharmChek® patch. There is also a Medical Device Reporting questionnaire. This questionnaire is included to help you provide PharmChem with information should you need to report 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 other means to follow-up on the after affects of the reaction.

Should there be any questions about the patch or reactions to the patch call **855-458-4100**. Food and Drug Administration Regulations necessitate PharmChem to report any complications that require medical intervention.

PharmChek® Sweat Patch Frequently Asked Questions

1. Is the sweat patch new technology?

No. Drugs have been known and detected in sweat since the early 1970's. The principle challenge with respect to sweat testing has been the collection of sweat. The PharmChek® Sweat Patch is a non-occlusive device that facilitates the collection of sweat.

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 urine specimen. Specimens are screened using an enzyme 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, through its procedures have 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. Why is this different from hair testing?

Hair testing is capable of detection chronic drug use but has difficulty detecting occasional or recreational drug use.

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

Unlike urine testing that detects drug metabolites, sweat testing detects the parent or non-metabolized form of the drug. This is particularly important when testing for abused drugs such as heroin that can only be detected in urine for a short time period following use. Heroin is rapidly metabolized to 6-acetyl morphine then to morphine. Consumption of poppy seeds can also produce a positive morphine result, as can the use of a codeine based medication. Because the sweat patch can detect heroin, it can determine if a heroin user is attempting to mask the heroin use with either codeine or poppy seed use.

6. How does the sweat patch work?

The sweat patch is comprised of a white absorption pad, covered with a unique polyurethane dressing. The absorption pad of 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. Drugs excreted in sweat are trapped by this polyurethane dressing and retained on the white absorption pad.

7. How does testing for drugs using the sweat patch differ from testing for drugs using urinalysis?

Urinalysis for drugs represents a snapshot in time. Using urine testing, drugs such as amphetamines and cocaine are cleared from the body within 72 hours from a single drug use. Opiates will typically be cleared from the body within 72-96 hours following the last use. From a single use, marijuana will clear from the body within 96 hours. Long term heavy use may be detected for up to two weeks. Phencyclidine use may be detected for up to two weeks depending on history of use.

The sweat patch, unlike urine testing, functions as a storage device. Therefore, drugs used 1-2 days before the patch is applied, while the patch is worn, and up to 24 hours prior to the removal of the patch will be detected and stored in the patch. Consequently, the sweat patch is a constant monitoring device, which provides the sweat patch with a longer detection window than urine testing.

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

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.

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

Yes. It has been demonstrated that while hair testing may be able to detect chronic drug use, it cannot detect occasional drug use.

In addition, there are a number of 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). At present there is no consensus regarding what the appropriate testing levels should be in hair. There is considerable variation in these testing levels depending on which laboratory performs the testing.

10. Is the sweat patch subject to adulteration?

No, not in the same sense that urine specimens can be adulterated. The sweat patch is a tamper evident device. The adhesive material used on the sweat patch penetrates the upper layer epithelial layer of the skin. When the sweat patch is removed, these epithelial skin cells adhere to the adhesive and will prevent the re-application of the sweat patch. While there have been attempts to adulterate the absorption pad by introducing common chemicals used to adulterate urine test (bleach) these attempts are very obvious. Based on the physical properties of the polyurethane covering as noted above, these chemicals will be trapped under this polyurethane covering, and in one case the bleach resulted in a second-degree chemical burn.

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

11. Is the sweat patch subject to substitution?

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

12. What are the most common means used to try and beat the sweat patch?

- A. Removal of the sweat patch sometime after application and re-attaching the patch using band-aids or other adhesives.
- B. Peeling back the upper portion of the sweat patch, removing the absorption pad, and replacing the absorption pad prior to reporting back for sweat patch removal. This usually results in an absorption pad that is 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 band-aids or other adhesives. In some instances, individuals have reported back to have the sweat patch removed and the absorption pad is absent, although the release liner is still present, indicating that the pad has been physically removed from the sweat patch.

Therefore it is imperative that the protocols established for examining the sweat patch for signs of tampering be followed. While some roll-up of the outer edges of the sweat patch may occur in some instances, the areas immediately surrounding the absorption pad should be adhering 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 Sweat Patch and transparent covering must be closely examined for signs that the Sweat Patch may have been compromised.

13. Can the sweat patch detect 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 accumulative, the patch cannot distinguish multiple instances of drug use.

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

None. Unlike urine specimens which can be diluted as a result of hydration/ flushing which may correspondingly dilute the concentration of drugs in the urine, the consumption of large amounts of fluids will not decrease the drug concentrations in the sweat patch. In fact, hydration may encourage sweat production, thus increasing the concentration of the drugs in sweat.

15. How were the testing levels for the sweat patch determined?

Scientifically using controlled dose studies in which known amounts of drugs were given to volunteers for all drugs with the exception of phencyclidine. Multiple sweat patches were applied, removed and

tested from these volunteers and the data analyzed from these studies using a well-established scientific approach known as receiver operating characteristics. This approach examines the analytical data and is able to establish cutoff testing levels based on true positive; true negative; false positive; and false negative results. The testing levels submitted to, reviewed and subsequently and cleared by the FDA were established using this receiver operating characteristics approach. For example, the detection of amphetamine and methamphetamine, utilizing a 10ng/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.

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

Yes. There have been many court cases, both at the Federal and local 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 and 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).

17. Is the sweat patch subject to contamination?

The sweat patch can be contaminated either during the procedure of applying the sweat patch or during the removal of the sweat patch. If the area that the sweat patch is being applied to is not properly cleaned, and drugs present on the skin's surface were not removed during the cleaning process, the drugs left on the skin's surface can be deposited on the absorption pad. If there are sufficient quantities of the drug present on the skin, a positive test could result. In addition, if the individual applying the patch has drugs on their hands or gloves, and touches the absorption pad, those drugs may cause a positive test result. Similarly, if during the removal process of the sweat patch, if the individual that removes the absorption pad from the sweat patch has drugs on their hands, or on the disposable tweezers, and these

drugs are deposited in sufficient quantity onto the absorption pad, a positive test may result.

Subsequent experiments have involved variations of the initial experiments submitted to the FDA and have incorporated such variations as wetting the absorbent pad with various solutions and buffers, varying the pH of the of the solution containing drugs that was applied to the exterior of the polyurethane membrane, and varying the temperature and time that the varying solutions are allowed to sit or incubate on the exterior of the polyurethane membrane.

These studies have demonstrated that when both the inside and the outside of the patch were dry, no drug transfer could be noted. Under certain conditions, the outer polyurethane membrane can be altered and made permeable to the diffusion of applied drugs onto the absorption pad. However these conditions are not what one would realistically expect to encounter in real world situations.

18. Has the PharmChek® Sweat Patch been accepted by the scientific community as a means to detect drug use?

Yes. There were two court cases in Nevada where the PharmChek® Sweat Patch underwent challenges to the Daubert statute, 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 statute states that if evidence is to be presented as scientific knowledge, the following are to be present:

- 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.

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