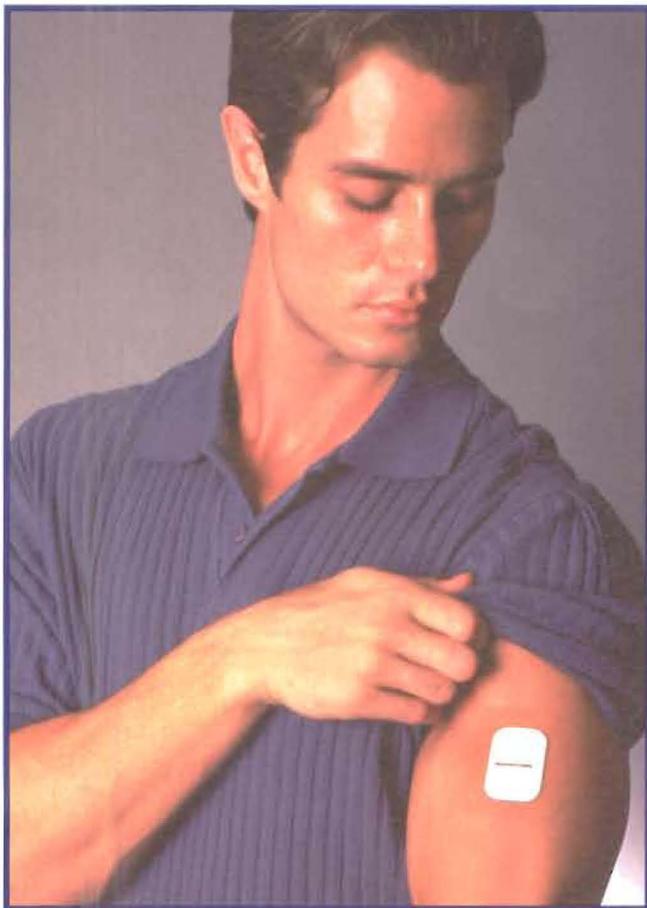


PHARMACEUTICAL CHEMICAL

Drugs of Abuse Patch



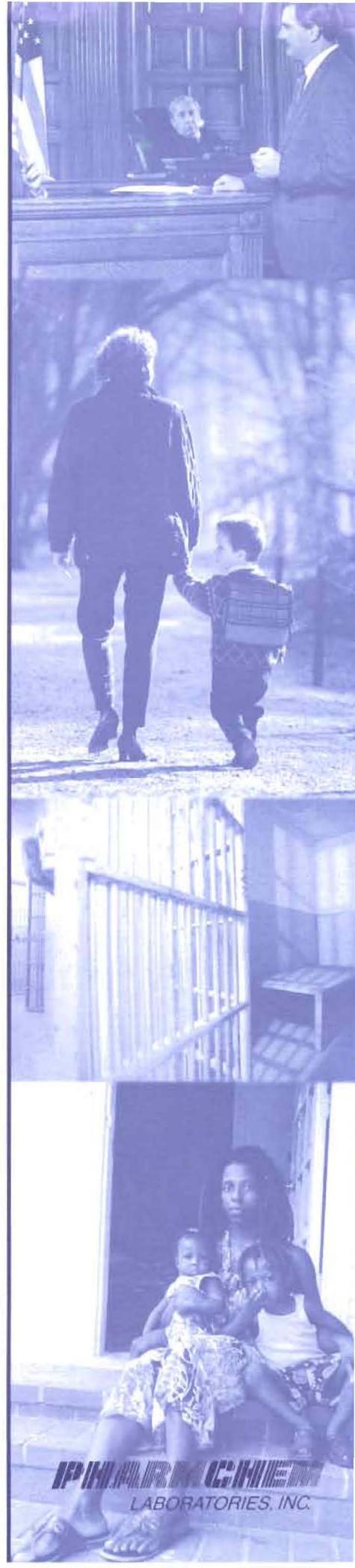
Tests sweat for cocaine, opiates, amphetamines, PCP, and marijuana

Tests for both the drug metabolite and the parent drug

Continuous monitoring; 24 hours per day, 7 days per week

Retains drugs used any time during wear period

Cannot be diluted and is tamper-evident



Drugs of Abuse Patch

F O R C O N T I N U O U S M O N I T O R I N G W I T H S W E A T

The Patch

The PharmChek® Drugs of Abuse Patch acts as a collector for nonvolatile components of sweat, including drugs of abuse. It consists of an adhesive plastic film that holds an absorption pad in place against the skin.

The adhesive film of the patch is a semipermeable barrier that allows oxygen, carbon dioxide, and water vapor to pass through so that the skin can breathe normally. Larger molecules (such as drugs) are trapped in the absorption pad portion of the patch. Contaminants from the environment cannot penetrate the adhesive barrier from the outside, so the patch can be worn during normal activities, including bathing and swimming.



Usage



The PharmChek® Drugs of Abuse Patch can be worn on the upper arm, the lower midriff, or the lower back. The skin where the patch will be worn is thoroughly cleaned with alcohol wipes prior to application. The PharmChek® Drugs of Abuse Patch should be worn for a minimum of 24 hours to ensure that an adequate amount of sweat is collected.

After the patch is worn, the absorption pad is removed and sent with a completed chain-of-custody form to PharmChem Laboratories to be tested for drugs of abuse. Clinical studies have shown that drugs and drug metabolites on the pad are stable for days at room temperature and months in a freezer. The PharmChek® Drugs of Abuse Patch is tamper-evident when applied correctly. A unique number is imprinted on each patch to aid with chain-of-custody identification. The PharmChek® Patch is also gender-neutral and eliminates the need for same sex observations.

Analysis

Once the pad is received at PharmChem Laboratories, any drugs present are washed from it into an extraction solvent and tested by assays similar to those used for testing urine samples.

Immunoassay (ELISA or RIA) technology is currently used for the screening test. A positive screening test is confirmed by GC/MS (Gas Chromatography/Mass Spectrometry).



Advantages

The PharmChek® Drugs of Abuse Patch provides distinct advantages over urine testing:

- ✓ **Drug metabolite and parent drug detection**
The patch traps the drug metabolite and in addition traps the parent drug which can be detected in sweat more accurately than in urine.
- ✓ **Continuous monitoring; 24 hours per day, 7 days per week**
The patch retains drugs used at any time during its wear period until the patch is removed, up to 7 days later.
- ✓ **Tamper-Evident**
The adhesive plastic film cannot be reapplied once removed, and a unique serial number prevents fraud and tampering.
- ✓ **Cannot be diluted**
The sweat patch specimen cannot be diluted as can a standard urine specimen.
- ✓ **Deterrent to additional drug use**
Because the patch is a visible sign of continuous drug monitoring, it can act as a powerful deterrent to additional drug use and may help reduce the effects of peer pressure.

PHARMCHEM
LABORATORIES, INC.

CORPORATE HEADQUARTERS
1505A O'Brien Drive
Menlo Park, California 94025
(800) 446.5177
T (650) 328.6200
F (650) 463.7500
www.pharmchem.com

Drugs of Abuse Patch

APPLICATION INSTRUCTIONS

Always wear gloves when applying or removing the patch.



1 Apply the patch to the upper arm, the lower midriff, or the lower back. Application procedures are the same for each location.



2 Using a gloved hand, thoroughly cleanse the location with at least two alcohol pads. Be sure the area is completely clean. Let the area dry for 60-90 seconds.



3 Remove the patch from the sealed wrapper. Be sure the number on the patch shows right side up, so it can be easily read. Remove the backing and apply to the skin. Press the entire surface of the patch to ensure proper adhesion.



4 Remove the paper edge around the patch with your gloved hand.



5 Using a gloved hand, seal the edges of the patch with your fingers.



6 Fill out the application section of the chain-of-custody form in the donor's presence.

Drugs of Abuse Patch

REMOVAL INSTRUCTIONS

Always wear gloves when applying or removing the patch.



1 Verify the unique number imprinted on the patch with the number written on the donor's original chain-of-custody form.



2 Request that the donor pull down the top edge of the patch.



3 Using a gloved hand, pull the top edge of the patch halfway down.



4 Remove the single-use tweezers from their sealed packaging. Proceed to remove the cellulose pad using the tweezers.



5 Place the cellulose pad in the plastic specimen bag and seal immediately. Affix a barcode sticker from the chain-of-custody form to the outside of the specimen bag.



6 Complete the chain-of-custody form in the donor's presence.



7 Place the plastic specimen bag into the transport bag with the chain-of-custody form. Then place the transport bag into the appropriate shipping envelope and send to PharmChem Laboratories for testing.

**If shipping by U.S. Mail,
send patches to:**

PharmChem Laboratories
P.O. Box 7662
San Francisco, CA 94120

**If shipping by overnight delivery,
send patches to:**

PharmChem Laboratories
I/B Sweat Patch
1505A O'Brien Drive
Menlo Park, CA 94025

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Components of PharmChek® Drugs of Abuse Collection Kit

- A. PharmChek® Drugs of Abuse Patch.** The patch is sealed in a sterile envelope. The sterilization date is imprinted on the outside of the envelope. The PharmChek® Patch ID Number is visible through the envelope.
- B. Chain-of-Custody Form.** The PharmChek® sweat patch has its own chain-of-custody form preprinted with your PharmChem client account number. Do not substitute any other chain-of-custody form for your patch chain-of-custody form.
- C. Package Insert.** A package insert for the PharmChek® patch is included with each kit.
- D. Instruction Card.** An instruction sheet for PharmChek® patch application and removal.
- E. Alcohol Wipe.** These are standard 70% isopropyl Alcohol Wipes to be used for thoroughly cleaning body oil and dead skin cells from the area of skin prior to application of the PharmChek® patch.
- F. Specimen Bag.** The white absorption pad from the used PharmChek® patch is sealed in the specimen bag for return to the laboratory for testing. Place only one absorption pad per bag.
- G. Disposable Plastic Tweezers.** These single-use plastic tweezers are used to remove the absorption pad from the PharmChek® sweat patch after wear. They are to be discarded after a single use.
- H. Disposable Plastic Gloves.** These plastic gloves are to be used during application of the PharmChek® patch. They must also be used when removing the PharmChek® patch for shipment to PharmChem Laboratories. They are to be discarded after each use.
- I. Double Sided Transport Bag.** This is the bag that is used to send the absorption pad from the used sweat patch and the chain-of-custody form to the laboratory.
- J. Mailer.** Depending on your transport arrangements, you will receive either overnight delivery supplies or mailing envelopes for U.S. Mail. These mailers can hold many PharmChek® transport bags, each containing one PharmChek® patch and one chain-of-custody form.

PharmChek[®] Patch Application Procedures

A. Body Area Selection

1. Area Selection: Select the area of the body for patch application and wear. The upper, outer arm or the front or back of the midriff above the waist but below the rib cage are recommended application areas. The patch should be placed on an area of skin that is as free of hair as possible and that is not exposed to excessive flexing and wrinkling of the skin or rubbing against clothing. Make sure that the skin is smooth and taut when applying the patch. If the patch is applied to the arm, make sure that the muscles are flexed.

B. Prepare for Patch Application

1. Wash Hands: The Trained Observer applying the patch should thoroughly wash his hands (latex gloves or disposable plastic gloves must be worn) before starting to clean the application site.

C. Start the Chain-of-Custody Form.

1. Observe that the information in the Results Name And Address box is correct, as well as the information in the Account No. box.

2. Donor ID Number. Fill in the Donor's ID number in the box marked **Donor ID** under **Specimen ID Information**. The Social Security Number, docket number or any unique number may be used. This is particularly important if anonymity is desired.

3. Donor Name. Enter the Donor's name in the box marked **Donor Name** under **Specimen ID Information**. Enter the offender's last name, first name and middle initial exactly as it appears on the photo ID or department records. If anonymity is desired, leave blank, but be sure to fill in the **Donor ID Number** box.

4. Treatment Status/Reason for Specimen. Check the reason for testing the donor in the appropriate box for **Treatment Status/Reason for Specimen**.

Random. Use for a donor selected because his/her name appeared on the Random List.

Probable Cause. Use for a donor selected because of probable cause for drug use, special conditions of Parole or Probation, or showing behavior which may be a sign of drug use.

Retest. Use for an donor selected because his/her name appeared on the Retest/Relist Report.

In Treatment. Use for an offender selected to be tested because they are receiving treatment for substance abuse.

Medical. Use for an offender selected to use the PharmChek[®] patch for medical reasons.

Other. Use only as prescribed by your agency.

5. PharmChek[®] Patch Number. Write the PharmChek[®] Number in the box in the upper, right area of the form marked **PharmChek[®] No.** This number is found imprinted on the PharmChek[®] patch.

6. Date. Write the day's date in the box marked **Date Patch Applied.** This date is considered the **Drug Test Date.**

7. Observer's Initials. The Trained Observer initials the box marked **Observer's Initials.**

8. Donor's Initials. The Donor initials the box marked **Donor's initials.**

D. Cleaning the Application Area.

1. Clean the Application Area: Clean an area approximately eight inches by eight inches using at least two of the alcohol wipes provided. Aggressively clean the area completely to remove excess oils, dead skin and any possible contaminants.

2. Let the Area Dry: Let the cleaned area dry completely (between 60 and 90 seconds) before applying the PharmChek[®] patch. If the area is not completely dry there is a risk that the patch will not stick properly or that the wearer will develop an *alcohol burn* or *reddening* from the alcohol trapped under the PharmChek[®] patch.

E. Applying the PharmChek[®] Patch

1. Remove Patch From the Envelope: Remove the patch from the transparent outside envelope.

2. Remove Backing: Remove the white backing with the PharmChek logo on it from the patch. Hold the PharmChek® patch by the unglued ends to avoid touching the adhesive surface of the PharmChek® patch.

3. PharmChek® Patch Application: Have the Donor flex his arm muscles for the upper arm application. For the back or midriff application area, have the donor either bend forward (for the back) or bend back (for the midriff). ~~The purpose of flexing or bending is to stretch the skin during application.~~ Next, place the PharmChek® patch over the cleaned and stretched area of the skin. Press the PharmChek® patch onto the skin and gently rub the area of film around the absorption pad with the index finger for approximately 10 seconds.

4. Remove the Outer Border. Find the slit in the side of the paper border around the PharmChek® patch. Remove the border and discard it. Gently rub the area of the film on the outside edge of the PharmChek® patch.

5. Observer's Certification: The Trained Observer signs the box marked **Observer's Certification at Patch Application.**

6. Instructions to Donor. After the PharmChek® patch has been applied, let the donor know when to return to have the patch removed. Instruct the donor that if the PharmChek® patch appears to be coming loose, it is his responsibility to tell a staff person prior to the PharmChek® patch removal date. If the PharmChek® patch is removed early, another patch may be applied to the donor. Inform the donor he may perform normal activities such as work, bathing, showering and exercising, etc. However, the donor should be cautioned to pat, not rub, over the patch when washing and drying.

7. Tracking Patches. Place the chain-of-custody forms in a file so that the donor can be called for patch removal at the appropriate time.

PharmChek® Patch Removal Procedures

A. Chain-of-Custody Form

The area of the patch chain-of-custody form that is filled out at the time of PharmChek® patch removal is the area on the right hand side of the form.

B. PharmChek® Patch Examination and Chain-of-Custody Completion

- 1. Date.** Write the day's date in the box marked **Date Patch Removed**. Initial the box labeled **Observer's Initials**. Have the donor initial the box labeled **Donor's Initials**.
- 2. Confirm PharmChek® Patch Number:** The Trained Observer will compare the number on the PharmChek® patch with the number on the chain-of-custody form. The Trained Observer must initial the boxes marked **Observer's Initials**.
- 3. Examine Patch for Tampering:** Examine the patch for signs of tampering. This may include signs of attempts to remove and re-apply the patch or to inject substances into the PharmChek® patch. The edges of the patch may have lifted slightly from wear - this is normal. An uncompromised PharmChek® patch should have adhesive still adhering to the skin completely surrounding the absorption pad. If this is not the case, the PharmChek® patch is considered compromised.
- 4. PharmChek® Patch Use Information.** If the donor did not complete the wear period, complete this box.

Indicate whether the patch **Fell Off** or was **Taken Off**. If the patch was **Taken Off** indicate whether it was taken off **By Staff** or **By Donor**. (A sanction is expected to be applied if the patch **Fell Off** or if the patch was **Taken Off** by the donor rather than by the staff.)

Indicate why the patch was removed if the wear period was not completed. Check the box indicating that there was **Skin Irritation**, that the **Patch started to come off** or **Other**. If the box marked **Other** is checked, write the reason on the line by the box. A severe skin irritation or an allergic reaction should be noted on the line by the box marked **Other**.

****Note: True allergic reactions to the patch are VERY rare.****

Tampering/Compromised Patches. This box must be checked for all PharmChek[®] patches.

After inspecting the patch while it is still on the donor, determine if the adhesive still surrounds the white, absorption pad in the center of the patch. If it does not and the white, absorption pad is exposed, check **Yes** under **Did the patch appear to be tampered with or compromised?** Write why you believe the patch to be compromised.

Once the absorption pad has been removed and placed in the specimen bag, remove the outside covering of the patch from the Donor's body. Determine if there are puncture holes in the covering or other evidence of tampering. If so, check **Yes**, and describe the problem. If the PharmChek[®] patch shows no evidence of tampering or compromise, check **No**.

****Note: Evidence of tampering may result in a sanction for not complying with drug testing. If necessary indicate on the chain-of-custody form any additional comments about the PharmChek[®] patch to document the tampering.****

5. Last Use Questionnaire. Fill out the box marked **Last Use Questionnaire**. List medicines that were taken during the time that the patch was worn. (Optional)

C. PharmChek[®] Patch Removal

1. Starting the PharmChek[®] Patch Removal: Have the Donor peel the patch from one of the upper corners. Have him peel the patch covering halfway down until the top edge of the absorption pad is exposed.

2. Remove Absorbent Pad: The Trained Observer will complete the removal of the absorption pad. Use a pair of single-use disposable tweezers to pull the absorption pad out of the PharmChek[®] patch and place the absorption pad in the specimen bag. Seal the bag by removing the blue tape across the top of the bag. Dispose of the tweezers immediately.

3. Complete PharmChek[®] Patch Removal: The transparent covering of the used patch can be removed. Hold the transparent covering up to the light to examine for needle holes. Throw the covering away.

D. Labeling the PharmChek[®] Patch.

1. Apply Chain-of-Custody Barcode: Peel a barcode label from the chain-of-custody form and place it on the bottom, right-hand corner of the specimen bag.

2. Apply the Security Seal: Fold the specimen bag one third of the way down. Remove the security seal from the chain-of-custody form and place it over the edge of the bag (See illustration on chain-of-custody form). The security seal is initialed and dated by the Trained Observer. Donor may initial the security seal (optional).

E. Complete the Chain-of-Custody Form

1. Observer's Certification. The Trained Observer signs the Observer's Certification at PharmChek® Removal.

G. Transport to the Laboratory

1. Transport Bag. The transport bag has two pockets. The specimen bag is placed in the inner pocket of the transport bag.

2. Chain-of-Custody Form: The middle sheet (ply 2) of the PharmChek[®] chain-of-custody form is placed in the pocket with the clear outside panel. The Trained Observer keeps the top sheet for his records.

3. Sending the Specimen to PharmChem Laboratories: Remove the tape from the transport bag. Fold the top of the bag to the FOLD FLAP TO HERE mark and seal it.

4. Specimen Storage: PharmChek[®] patches, once they are sealed in their specimen bags and their transport bags, can be stored for weeks at room temperature or in a refrigerator.

5. Overnight or U.S. Mail Envelopes. Many transport bags can be put in an Overnight Envelope or a manila mailing envelope. A PharmChek[®] Sweat Patch sticker should be on the envelope.



To certify that you have been trained to apply and remove the PharmChek[®] Drugs of Abuse Patch, please fill out the following information and send your examination to:

**Sales Department
PharmChem, Inc.
4600 North Beach Street
Haltom City, TX 76137**

(PLEASE PRINT LEGIBLY & FILL OUT COMPLETELY)

Date _____

Name _____

Agency / Institution _____

Position / Title _____

Address _____

City, State, Zip Code _____

Work Phone Number _____

Date Trained _____

Trained by: PharmChem
staff; own staff trainer _____

Examination

PharmChek® Drugs of Abuse Patch

1. After the application area is cleaned with alcohol, how long should the area dry?

- A. One half hour
- B. 60 to 90 seconds
- C. 10 seconds

2. Which portion of the PharmChek® patch does one return to PharmChem for analysis?

- A. The entire patch
- B. The outside polyurethane film that has the number on it
- C. The white absorption pad only

3. A PharmChek® patch is compromised if:

- A. The edges are curled
- B. The outside polyurethane film on the patch is dirty
- C. The adhesive seal around the absorption pad is no longer intact

4. The PharmChek® patch can be used to test for:

- A. Cocaine, Opiates, Amphetamines, PCP, Marijuana
- B. Alcohol
- C. Cocaine, Barbiturates and Inhalants

5. If you place the PharmChek® patch on the upper, outer arm, why should the muscles be flexed?

- A. It makes the Donor look stronger
- B. The patch will rip in two if the person flexes his muscles later
- C. The Donor can develop a “mechanical injury” or skin eruptions while wearing the patch on un-stretched skin

6. When should a Donor not wear a PharmChek® patch?

- A. When he doesn't want to
- B. When his skin is scratched, “broken out” or has acne present
- C. When he would rather have a urine test because he took drugs

7. When sending in the PharmChek[®] patch chain-of-custody form, which copy is returned to PharmChem?

- A. The top copy
- B. The bottom copy
- C. The middle or the second copy

8. Why does the Trained Observer use single-use disposable tweezers and plastic disposable gloves when removing the absorption pad from the PharmChek[®] patch?

- A. So the Donor won't catch any germs from the Observer
- B. So the Observer won't catch any germs from the Donor
- C. So the Donor can't say that drug found on the patch got there because the Observer touched the pad with his hands

9. If a Donor is excessively "hairy" and the PharmChek[®] patch can't be applied in any of the approved application areas, you should:

- A. Shave the hair from the area
- B. Place the PharmChek[®] patch on the soles of the feet
- C. Have the Donor provide a sample for a urine drug test instead

10. Why doesn't the Donor completely remove the PharmChek[®] patch himself during the PharmChek[®] patch removal process?

- A. Because the Observer would have nothing to do
- B. Because the Donor could drop the PharmChek[®] patch on the floor or desk and compromise the patch
- C. Because the Observer might have drugs on his/her hands

11. If a Donor has an allergic reaction to the PharmChek[®] patch it usually will:

- A. Appear several days after the patch has been applied
- B. Appear as a red, itching area around and under the patch **very soon** after application
- C. It is impossible to have an allergic reaction to the patch

12. What is the most common problem that can occur using the PharmChek[®] patch?

- A. Most people are too "hairy" to wear the patch
- B. The patch does not stick properly because the Donor's skin has not been cleaned properly of dirt, oil, and dead skin cells
- C. Allergic reaction

13. If a Donor does have a severe adverse reaction to the PharmChek[®] patch, call PharmChem Laboratories within:

- A. 24 hours
- B. 7 days
- C. A calendar year

14. If the absorption pad from a patch is received at the laboratory and the specimen bag does not have a barcode on it, the laboratory personnel will:

- A. Write the number that is on the chain-of-custody form onto the bag
- B. Call you to find out what the barcode number is supposed to be
- C. **Will not** be able to test the sample

15. A specimen will be “No Tested” if:

- A. The absorption pad inside the specimen bag looks dirty
- B. If the Trained Observer does not sign the “Certification at Patch Removal” on the chain-of-custody form
- C. If you send in the second copy of the chain-of –custody instead of the first copy

16. The PharmChek[®] patch is usually able to detect more people who take cocaine and amphetamines than urine testing because:

- A. It is only used on cocaine or amphetamine addicts
- B. The PharmChek[®] patch has a longer “Window of Detection”
- C. Cocaine and amphetamine only show up in sweat, not urine

17. Will “flushing” or drinking a lot of water after taking drugs keep you from having a positive drug result with a PharmChek[®] patch?

- A. No.
- B. Yes.

18. If a person has a tattoo on the area where you want to put the PharmChek[®] patch:

- A. Do not put the patch on at all
- B. If the tattoo is in the shape of a dragon, put the tattoo on the upper, outer arm of the dragon
- C. Put the patch over the lightest portion of the tattoo

19. When preparing the area of the body for patch application:

- A. Slap the patch on and hope it sticks
- B. Thoroughly clean the area with a minimum of two alcohol pads, aggressively rubbing to remove the dirt, oil & dead skin cells
- C. Let the donor clean his own arm

20. If more than one drug 'screens' positive, how many drugs will be confirmed?

- A. Only one.
- B. All drugs that have screened positive.
- C. All 5 drugs that the patch detects.

21. What are the reasons the patch would "just fall off".

- A. The donor took a shower.
- B. The donor went swimming.
- C. The donor got tired of wearing the patch and took it off.

22. How do we know that a positive Cocaine or Methamphetamine result is not caused by passive contamination from the environment?

- A. PharmChem will not issue a positive cocaine or methamphetamine result without detecting the drug metabolite at or above 'limit of detection'.
- B. The molecular structure of the polyurethane film will only permit molecules the size of water vapor to pass in and out. Drug molecules are much larger.
- C. The donor was never in the company of a drug user.

23. Is the laboratory analysis for sweat the same as for urine?

- A. Yes
- B. No

24. Is it possible to have a positive sweat patch result and a negative urine result?

- A. Yes
- B. No

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

- A. Yes, there have been many court cases, both at the Federal and local level in which the results of the sweat Patch have been challenged and successfully defended.
- B. No, the Patch has never been challenged in a court of law.