

PharmChek® Drugs of Abuse Patch

Training Manual

**For the Application, Removal and Transport of the
PharmChek® Drugs of Abuse Patch**

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1) Components of PharmChek® Drugs of Abuse Collection Kit

A. PharmChek® Drugs of Abuse Patch: The patch is sealed in a sterile envelope. The patch has a two-year shelf life if stored in ambient room temperature. 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. Instruction Card: An instruction sheet for PharmChek® patch application and removal.

D. 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.

E. 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.

F. 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.

G. 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 CRL (see below). They are to be discarded after each use.

H. 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.

I. Mailer: You will receive mailing envelopes for U.S. Mail (postage paid by customer). These mailers can hold many PharmChek® transport bags, each containing one PharmChek® patch and one chain-of-custody form.

US Mail: The address label should read:

CRL, ATTN. Toxicology Set Up
8433 Quivira Road

Lenexa, KS 66215

Patch Storage Conditions: Unused patches do not need to be stored under special conditions. They do need to be stored away from excess heat (over 120 F) and/or stored away from direct sunlight.

2) 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 should be used as the primary application site. If the arm is not acceptable for patch application because of excessive hair, scarring, or open sores, the front or back of the midriff above the waist but below the rib cage is 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

The area of the patch chain-of-custody that is filled out at the time of PharmChek[®] patch application is the area on the left hand side of the 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 donor'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. PharmChek® Patch Number:** Write the PharmChek® Number in the box in the middle left section of the form marked **PharmChek® No.** This number is found imprinted on the PharmChek® patch.
- 5. Date:** Write the day's date in the box marked **Date Patch Applied.** This date is considered the **Drug Test Date.**
- 6. Observer's Initials:** The Trained Observer initials the box marked **Observer's Initials.**
- 7. Donor's Initials:** The Donor initials the box marked **Donor's initials.**
- 8. 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 a donor selected to use the PharmChek® patch for medical reasons.

Other. Use only as prescribed by your agency.

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. The surface of the second alcohol pad must be clean and white, if not continue aggressively cleaning the application area until the alcohol pad surface is clean and white.
- 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.

3) 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 with the plastic well adhered and clear. 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 just enough to loosen the outer corner. With you gloved hand, peel the plastic 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 transparent 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. In no puncture holes are observed, throw the covering away. If puncture holes are observed, it would be advisable to keep the transparent covering as evidence of tampering and/or adulteration.

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**.

F. Transport to CRL for Screening

- 1. Transport Bag:** The transport bag is the larger of the two bags provided in your kit. Place the sealed specimen bag in the transport bag.
- 2. Chain-of-Custody Form:** The middle sheet (ply 2) of the PharmChek® chain-of-custody form is placed in the transport bag. The Trained Observer keeps the top sheet for his records. Ply 3 is available to the Trained Observer as additional documentation.
- 3. Sending the Specimen to CRL for screening:** Remove the transparent tape from the transport bag. Fold the top of the bag over and seal the transport bag.
- 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. U.S. Mail Envelopes.** Many transport bags can be put in a manila-mailing envelope.

4) Shipping and Handling Instructions

Note: Many PharmChek[®] patches can be put into a shipping envelope. Used PharmChek[®] patches do not have to be shipped immediately

Mailing Address:

**CRL, Attn: Toxicology Set-Up
8433 Quivira Rd.
Lenexa, KS 66215**