



PharmChek® Drugs of Abuse Sweat Patch

Training Manual

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

For Professional Use Only

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**** For use ONLY in Professional Environments by individuals trained and certified to apply and remove The PharmChek® Sweat Patch.

****Not intended for over-the-counter retail sales.

Components of PharmChek® Drugs of Abuse Collection Kit

- A. **PharmChek® Drugs of Abuse Patch:** The Patch is sealed in a sterile envelope, which has a two-year shelf life (if stored at room temperature). The PharmChek® patch ID number is visible through the envelope.
- B. **Patch Storage Conditions:** Unused patches must be stored away from excess heat (over 120 F) and away from direct sunlight.
- C. **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.
- D. **Instruction Card:** An instruction card for the proper application and removal of PharmChek® Patch is included with your patch product purchase.
- E. **Alcohol Wipes:** Standard 70% isopropyl Alcohol Wipes are included with your patch purchase, and are to be used for thoroughly cleaning application area of oil and dead skin cells prior to application of the PharmChek® patch.
- F. **Specimen Bag:** The small clear bag is used to seal the white absorption pad from the PharmChek® Patch. The specimen bag, containing the absorption pad is placed inside the large transport bag (see below) for transport to the laboratory for testing. Place only one absorption pad per specimen bag.
- G. **Disposable Plastic Tweezers:** Single-use plastic tweezers, included with your Patch purchase, are used to remove the absorption pad from the PharmChek® Sweat Patch after removal; and must be discarded after a single use.
- H. **Transport Bag:** The large clear bag is used to transport the absorption pad from the used sweat patch (contained in the sealed specimen bag) along with the chain-of-custody form to the laboratory for testing.
- I. **Mailing envelopes:** Mailing envelopes for U.S. Mail (*postage not paid*) is included with your patch purchase. These mailers can hold many PharmChek® specimens, (each containing one PharmChek® patch and one chain-of-custody form).

PharmChek® Patch Application Procedures

A. Body Area Selection

1. Select the area of the body for patch application and wear. The patch should be placed on an area of skin that is free of hair and 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. The upper, outer arm should be used as the primary application site. If the arm is not acceptable due to excessive hair, scars, or open wounds, the midriff, or back, above the waist and below the rib cage, are recommended application areas.

B. Chain-of-Custody Form—Application

1. Fill out the left side of the patch chain-of-custody form at the time of the PharmChek® patch application.

NOTE: If requesting the synthetic opiate panel, apply the red sticker to the left side, second box) on ply 2.

2. Ensure that the information entered in the ***“Results Name and Address”*** box is correct, as well as the information in the ***“Account No.”*** box.
3. **Donor ID Number:** Fill in the donor's ID number in the box marked ***“Donor ID”*** under ***“Specimen ID Information”***. The client's social security number, docket number or any unique identifying number may be used. This is particularly important if anonymity is desired.
4. **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 ***“Donor Name”*** blank, but be sure to fill in the ***“Donor ID Number”*** box. **Please print legibly**
5. **PharmChek® Patch ID Number:** Write the PharmChek® Patch ID number in the box in the middle left section of the form marked ***“PharmChek® No.”*** This number is imprinted on the PharmChek® patch.

6. **Date:** Write the application date in the box marked “*Date Patch Applied*”. This date is considered the *Drug Test Date*.
7. **Observer's Initials:** The trained observer must initial the box marked, “*Observer's Initials*”.
8. **Donor's Initials:** The donor must initial the box marked “*Donor's Initials*”.
9. **Treatment Status/Reason for Specimen:** Check the reason for drug testing the donor in the appropriate box for “*Treatment Status/Reason for Specimen*”.
 - A. **Random.** Use for a donor selected because his/her name appeared on the “Random List”.
 - B. **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.
 - C. **Retest.** Use for a donor selected because his/her name appeared on the Retest/Relist Report.
 - D. **In Treatment.** Use for an offender selected to be tested because they are receiving treatment for substance abuse.
 - E. **Medical.** Use for a donor selected to use the PharmChek® patch for medical reasons.
 - F. **Other.** Use only as prescribed by your agency.

C. Prepare Skin for Patch Application

1. **Disposable Gloves (Not Included):** It is required that the trained observer wear disposable gloves before preparing and applying the patch to the application site. It is further encouraged that trained observers wash his/her hands before applying disposable gloves.

NOTE: A thorough cleaning/exfoliation of the skin (by the donor) with a washcloth (not included) prior to the trained observer using the alcohol wipes may assist in better patch adhesion.

2. **Clean the Application Area:** Aggressively clean an 8x8 inch area, using at least two (2) or three (3) 70% isopropyl alcohol wipes (included) to rid the area of excess oils, dead skin cells, and any contaminants. The surface of the alcohol pad must be free of oils, skin cells, and debris. If not, continue to aggressively clean the area with a new alcohol pad until the pad is no longer discolored.

****IF DONE PROPERLY, THE DONOR'S SKIN WILL BE SLIGHTLY REDDENED****

3. **Let the Area Dry:** Let the prepared area dry completely (60 to 90 seconds) before applying the PharmChek® patch. If the area is not completely dry, the patch may not stick properly, or the wearer may develop an *alcohol burn* from alcohol that may be trapped under the PharmChek® patch.

D. Applying the PharmChek® Sweat 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 bend forward (for the back) or backwards (for the midriff). The purpose of flexing or bending is to stretch the skin during application.
4. Next, place the PharmChek® patch over the cleaned and slightly 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. (Make sure to press firmly on the outside corners of the patch, to ensure adhesion).
5. **Remove the Outer Border:** Find the slit on the paper border around the PharmChek® patch. Slowly remove the border, as you press the film to the skin. Gently rub the area of the film around the pad and the outside edge of the PharmChek® patch.
6. **Observer's Certification:** The trained observer signs the box marked "*Observer's Certification at Patch Application*".

7. **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/her responsibility to report this to the monitoring agency prior to the PharmChek® patch removal date. If the PharmChek® patch is removed early, another patch may be applied to the donor.
8. **ACTIVITIES:** Inform the donor that s/he may perform normal activities such as work, bathing, showering and exercising, such as swimming, etc. However, the donor should be cautioned to pat, not rub, over the patch when washing and drying with a towel.
9. **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

Always use a new pair of disposable gloves when applying or removing the PharmChek® Patch (not included)

A. Chain-of-Custody (COC)

1. **Complete the RIGHT side of the Chain of Custody at Patch Removal.**
2. **Date:** Write the date of removal in the box marked “*Date Patch Removed*”. Initial the box labeled “*Observer’s Initials*”. Have the donor initial the box labeled “*Donor’s Initials*”.
3. **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*”.

B. PharmChek® Patch Examination

1. **Examine Patch for Tampering:** Examine the patch for signs of tampering. This may include signs of an attempt to remove and re-apply the patch or to inject substances into the absorbent pad. 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.

2. **PharmChek® Patch Use Information:** If the donor did not complete the wear period, complete this box.

A. 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*. (The Donor is in considered in “non-compliance” if s/he claims the patch fell off, or if it was taken off by anyone other than a trained observer employed by the monitoring agency).

3. If the wear period was not completed, indicate why the patch was removed. Check the box marked “*skin Irritation*”, “*patch started to come off*”, or “*other*”. If “*other*” is checked, indicate the reason.

NOTE: True allergic reactions to the patch are extremely rare. If a skin irritation or allergic reaction is observed, it should be noted on the line by the box marked “*other*”.

4. **Tampering/Compromised Patches:** Must be indicated for all patches.

- A. Inspect the patch, while it is still on the donor, to 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?*” Indicate why you believe the patch to be compromised.
- B. 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 non-compliance. 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.

C. PharmChek® Patch Removal

1. **Starting the PharmChek® Patch Removal:** Have the donor peel down the film from one of the upper corners, just enough to loosen the outer corner. With a 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. Using a pair of single-use disposable tweezers, 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.

NOTE: Do not place anything, other than the absorption pad, into the specimen bag. The absorbent pad **MUST** be separated from the film before being placed in the specimen bag. Failure to follow this procedure will result in a “no-test.” due to the lab’s inability to analyze the patch.

3. 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. The absorbent pad from a worn patch will be soft and slightly discolored due to the absorption of the sweat, body oils and skin debris. If the absorbent pad does not reflect these characteristics, or is dry and does not easily separate from the release liner, the donor may have attempted to remove and reapply the sweat patch. The sweat patch and transparent covering must be closely examined for signs that the sweat patch may have been compromised.
4. **PharmChek® Film Removal:** The transparent covering of the used patch can be removed. Hold the transparent film up to the light to examine for needle holes. In no puncture holes are observed, throw the covering away. If puncture holes are observed, 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**).

3. **Observer's Certification:** The trained observer signs the “*Observer's Certification at PharmChek® Removal*”.

E. Transporting Specimen to CRL for Analysis

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:** Place the middle sheet (ply 2) of the PharmChek® chain- of-custody form 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. **Specimen Transport:** Remove the transparent tape from the transport bag. Fold the top of the bag over and seal the transport bag.

Shipping & Handling Instructions

1. **Specimen Handling:** Sealed PharmChek® patches, contained in within their transport bags, can be safely stored at room temperature up to several weeks before shipping to the laboratory.
2. **Mailing Envelopes:** Several specimens can be placed into one manila mailer for transport to the lab. You may also choose to use USPS Priority Mail, which can be tracked, and may shorten in-transit time.

<u>U.S. Mail</u> CRL, Toxicology Set-up PO Box 218991 Kansas City, MO 64121-7263	<u>FedEx</u> CRL 11711 W. 83 rd Terrace Lenexa, KS 66150
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Application

Always wear gloves when applying or removing the patch.



1 Fill out the application section of the chain-of-custody form (in the donor's presence.) It is mandatory for the observer to sign the chain-of-custody form.



2 Thoroughly cleanse the skin where the patch will be placed with an alcohol pad. The arm should redden as you aggressively cleanse the skin. Continue cleansing with additional pads until the pad is no longer discolored. *(If using an overlay, an area at least 5x6 inches must be cleansed with another alcohol wipe to ensure the overlay will adhere properly.)* Wait 60-90 seconds for the alcohol to dissipate.



3 Remove the patch from the sealed wrapper. Ensure the arm is flexed while you apply the patch to the donor. Rub your finger around the clear film several times, paying close attention to the corners and edges of the patch.



4 Find the slit in the paper border on the outside of the patch. As you peel off the border, press the film to the skin to ensure adhesion.



5 Continue to press the patch to the skin, making sure that the edges and corners are well-adhered to the skin.



6 If using an overlay, remove the full back from the film and place over the top of the patch. Be careful that the only portion showing in the window is the pad. Before removing the quadrant cast liners, rub your index finger around the film for several seconds, paying close attention to ensure the edges and corners are well-adhered.

OPTIONAL OVERLAY

INSTRUCTIONS FOR:

Removal

Always wear gloves when applying or removing the patch.



1
Verify the ID # on the outside of the patch matches that of the number written on the donor's original chain-of-custody form.



2
Place your index finger over the corner of the pad, while you instruct the donor to pull down ONLY the top edge of the film to release it from the skin.



3
With the tweezers in hand, continue to pull down the film to expose the top of the pad. Clamp the tweezers over the pad. In one fluid motion, pull up on the pad as you pull down the film.



4
Promptly place ONLY the pad into the specimen bag (the small, clear bag) and seal completely. Discard the film! DO NOT place anything other than the pad into the specimen bag.

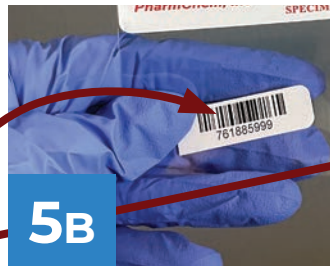


Digital CoC Form:

If using a traditional CoC form with a second ply, proceed to step 5B.

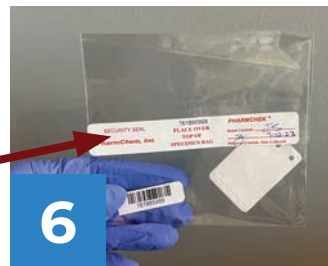
Remove a single sticker group from the provided digital chain-of-custody barcode stickers sheet (provided) and apply the sticker group to the space provided on the digital form. Remove one barcode sticker from the chain of custody form and affix it to the space provided at the form's top-right corner.

From this point, follow the remaining instructions beginning in step 5B.

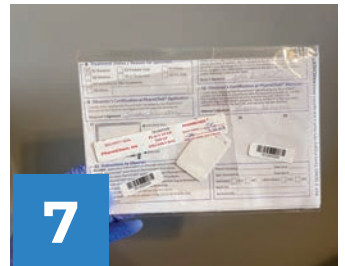


Traditional CoC Form:

Whether you use a digital or traditional CoC form, remove one barcode sticker from the chain of custody form and affix it to the outside of the specimen bag. Complete the chain of custody form in the donor's presence. Both the observer and the donor **MUST** sign in the required spaces provided.



6
Use the security seal from the chain of custody form to seal the specimen bag. Both the observer and the donor must initial the seal.



7
Place the specimen bag (containing only the pad) and the second ply of the chain of custody form (if using the traditional CoC form) into the transport bag (the larger of the two bags) and seal completely. DO NOT staple the CoC form to the specimen bag. Affix the final barcode label to the outside and insert it into the brown laboratory mailer (provided).

8

Mail the specimen to one of the three available locations. For timely delivery, the return address must be placed on the top left-hand corner of the shipping envelope.

FedEx GROUND

Clinical Reference Lab, Inc.
11711 W. 83rd Terrace
Lenexa, KS 66214

FedEx EXPRESS

Clinical Reference Lab, Inc.
11711 W. 83rd Terrace
Lenexa, KS 66150

US MAIL

Clinical Reference Lab, Inc.
PO Box 218991
Kansas City, MO 64121