

# ***PharmChem, Inc.***

## **PharmChek® Drugs of Abuse Sweat Patch**

PharmChem, Inc.

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PharmChek®  
Drugs of Abuse  
Sweat Patch



# PharmChek® Drugs of Abuse Sweat Patch

- The sweat patch is a non-occlusive, hypoallergenic collection device.
- The sweat patch was cleared as a collection device by FDA on October 4, 1990.
- The FDA cleared the sweat patch for the detection of cocaine, opiates and methamphetamine in 1995; for marijuana and phencyclidine in 1996.

# PharmChek® Drugs of Abuse Sweat Patch

## How the sweat patch works

- There are two means by which the body produces sweat.
  - Insensible perspiration
    - The passive uncontrolled loss of sweat from the skin
  - Sensible sweat
    - The active controlled loss from specific glands in the skin

# PharmChek® Drugs of Abuse Sweat Patch

## How the sweat patch works

- The insensible perspiration is captured by the absorbent pad in the patch and analyzed for drugs.
  - approximately 300-700 ml of insensible sweat is excreted each day.
  - approximately 2ml is absorbed in the patch each week.
- The absorbent pad is tested for the presence of drugs of abuse.
  - Drugs and drug metabolites are stable for days at room temperature and months in the freezer.

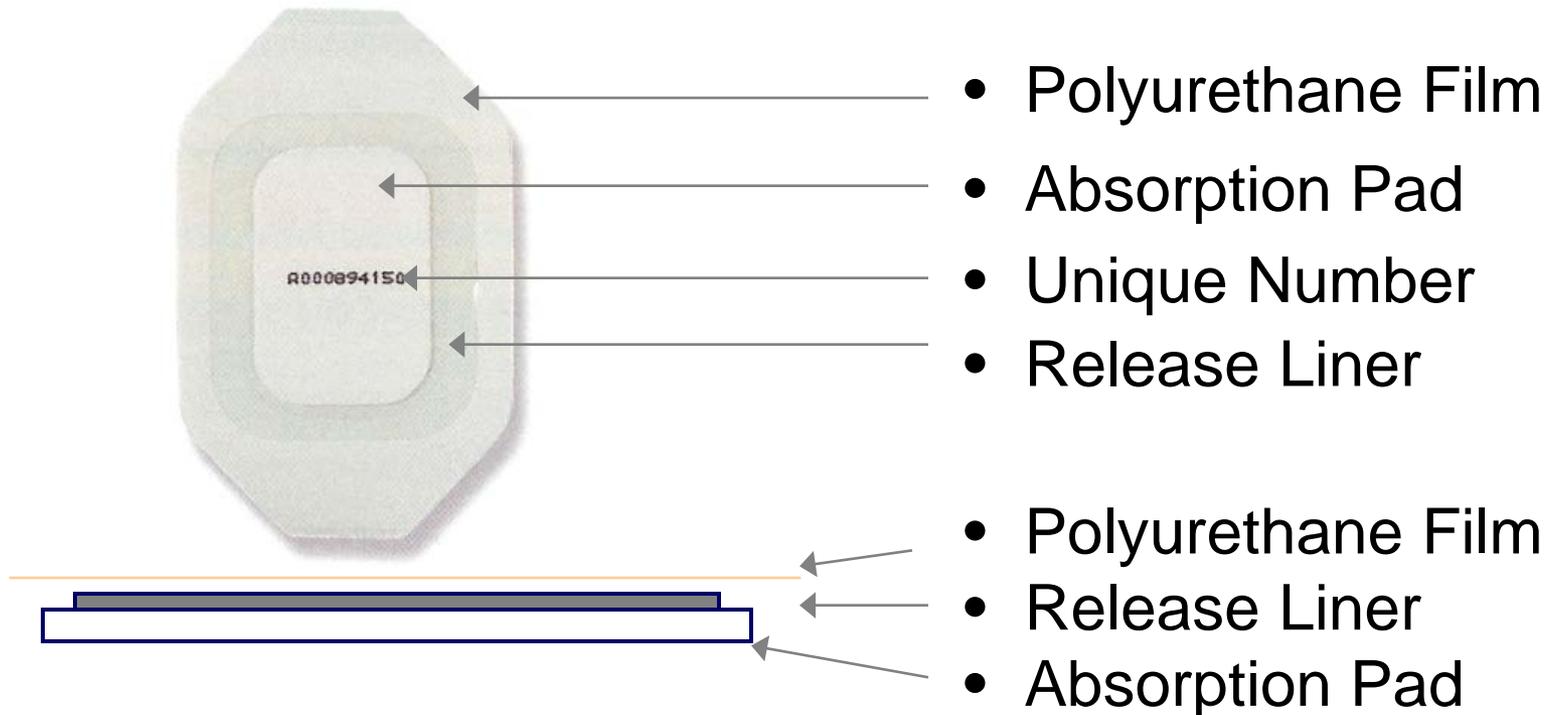
# PharmChek® Drugs of Abuse Sweat Patch

## **How the sweat patch works**

- The transparent film portion of the patch is a semi-permeable membrane that allows oxygen, carbon dioxide and water vapor to pass through the patch leaving the skin underneath healthy and sterile.
- Substances of large molecular weight are trapped in the absorbent pad portion of the patch.

# PharmChek® Drugs of Abuse Sweat Patch

## What is PharmChek?



PharmChek is a Sweat patch, worn on the skin surface, that acts as a specimen container for the non-volatile and liquid components of sweat.

# PharmChek® Drugs of Abuse Sweat Patch

## Understanding Sweat Patch Results

Detection Periods in sweat differ from those in urine, the sweat patch is a collection device designed to retain evidence of drug use.

- Results cannot be used to:
  - reflect the dose of drugs taken.
  - reflect the time of use.
  - determine if multiple small doses or one large dose of drug is ingested.
  - show when drug use occurred.

# PharmChek® Drugs of Abuse Sweat Patch

## Testing Methods & Cutoff levels

Drug or Drug Class Analyte	Patch Screening	Drug or Drug Class Analyte	Patch Confirmation LC/MS/MS
Cocaine	EIA 10 ng/ml	Cocaine Benzoylecgonine	10 ng/ml 10 ng/ml
Opiates	EIA 10 ng/ml	Heroin 6-MAM Morphine Codeine	10 ng/ml 10 ng/ml 10 ng/ml 10 ng/ml
Amphetamines	EIA 10 ng/ml	Amphetamines Methamphetamine	10 ng/ml 10 ng/ml
Marijuana	EIA 1.5 ng/ml	Marijuana	.5 ng/ml
Phencyclidine	EIA 7.5 ng/ml	Phencyclidine	7.5 ng/ml

# Drug Detection in Sweat

## Patch Detects Parent Drug & Metabolites

- Cocaine: cocaine, benzoylecgonine
- Heroin: heroin, 6-MAM, morphine
- Codeine: codeine, morphine
- Amphetamines: methamphetamine, amphetamine
- PCP: PCP
- Marijuana: THC

# PharmChek® Drugs of Abuse Sweat Patch

## Understanding Sweat Patch Results

- A positive result indicates drug use occurred during the time the patch was worn or 24-48 hours before the patch application.
- The metabolite must be present above the limit of detection (LOD) to report a positive result.

# PharmChek® Drugs of Abuse Sweat Patch

## Wear Time

Patches must be worn for a minimum for 24 hours.

- Sweat patches can be worn for up to 7 - 10 days.
  - if the patch is worn longer than 7 – 10 days, the test will be valid as long as there is a clear seal around the pad – see Overlay Section which follows.

# PharmChek® Drugs of Abuse Sweat Patch

## Advantages of PharmChek®

- The distinct advantages:
  - Increased Window of Detection
  - Acts as a Deterrent to Drug Abuse
  - Detects Parent Drug and Metabolites
  - Variable Removal Date
  - Quick Application and Removal
  - No Urine Collections
  - No Sample Substitution
  - No Sample Dilution
  - Gender Indifferent

# PharmChek® Drugs of Abuse Sweat Patch

## Application of PharmChek®

- Applying the Patch
  - Remove patch from envelope.
  - Remove backing (only the white backing with PharmChek logo).
  - Be sure the number on the patch is right side up.
  - Apply the patch onto the cleaned area of the skin (pages 16 & 17).
  - Gently rub the area of film around the absorption pad (page 18).
  - Remove the border and gently rub outside edge of the patch (pages 19 & 20).

# PharmChek® Drugs of Abuse Sweat Patch

## Recommended areas to wear the Patch

- **Select Area to Apply the Patch**
  - Upper or outer arm
  - Lower midriff
  - Lower back
- **Cleaning Application Area**
  - Aggressively clean application area (8cm x 8cm) using the alcohol swabs provided.
  - Let area dry 60 – 90 seconds.

# Application

## Clean Skin With Alcohol Wipe



# Application

## Place Patch Over Skin



# Application

## Rub Around Absorbent Pad



# Application

## Remove Patch “Window Frame”



# Application

## Rub Around Edge Of Patch



# PharmChek® Drugs of Abuse Sweat Patch

## Application Tips & Questions

- Have the donor flex his/her arm before applying the patch.
- The patch should not be placed on skin that has scratches, lesions, or excessive hair.
- The patch can be placed over a tattoo if no other areas are available.
  - Choose the lightest part of the tattoo to apply the patch.

# PharmChek® Drugs of Abuse Sweat Patch

## Chain of Custody

- Complete the application section of the Chain of Custody form:
  - Donor ID Number
  - Donor's name (optional)
  - Treatment Status/Reason
    - Random, Probable Cause, Retest, In Treatment, Medical, Pre-Trial, Surveillance, Other.
  - Patch number
  - Date
  - Observer's Initials
  - Donor's Initials
- Let the donor know when he/she is to return to have the patch removed.

# PharmChek® Drugs of Abuse Sweat Patch

## Donor Instructions

- The donor should be told that if the patch appears to be coming loose, it is his/her responsibility to tell a staff person prior to the patch removal date.
- If the patch is removed early, another patch may be applied to the donor.
- The donor may perform normal activities such as work, bathing, showering and exercising, etc.
- Gently pat the patch area following these activities.

# PharmChek® Drugs of Abuse Sweat Patch Overlay Application

- The modified PharmChek® Overlay is made of the same material as the Sweat Patch which can be used for long term wear. The Overlay has a “window” to make removal of the Patch easier.
- **Who May Need to Wear the Overlay**

Individuals who have had, or are having, difficulty wearing a patch for the recommended length of time may need to wear an Overlay. Difficulty wearing the patch is most common with:

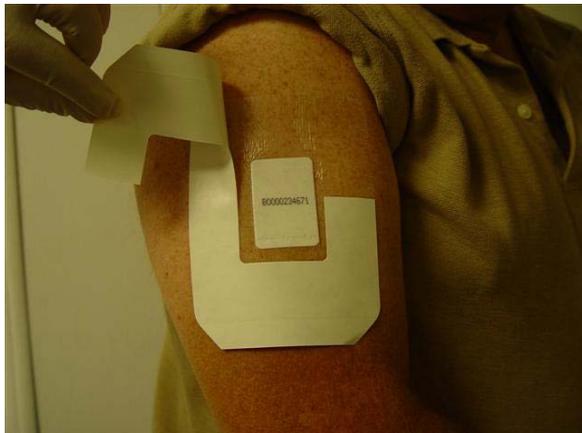
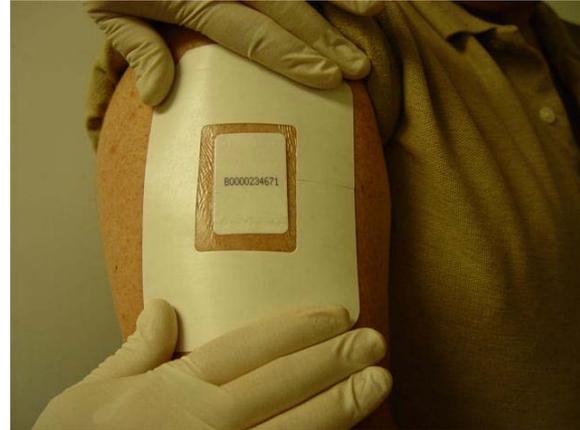
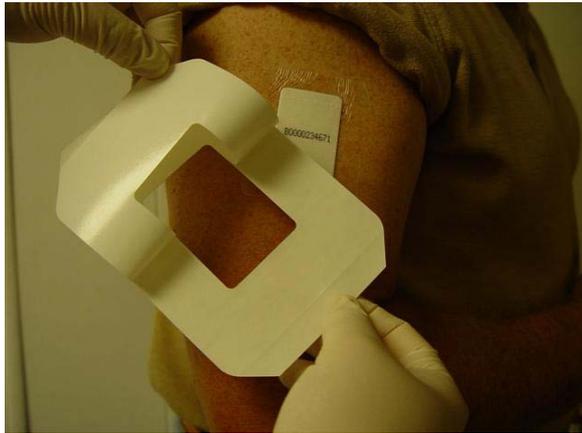
  - Individuals who exercise heavily.
  - Individuals who perform strenuous labor.
  - Individuals who live in hot, humid climates.
- These individuals may produce a large amount of sweat very quickly. Occasionally, the sweat cannot evaporate through the patch fast enough and consequently may cause the adhesive to loosen.
- The Overlay’s construction allows excess sweat that might loosen the patch to evaporate and keep the patch adhered to the skin.

# PharmChek® Drugs of Abuse Sweat Patch

## Overlay Application (Cont'd.)

- **Overlay Application (see page 26).**
- Once the PharmChek® patch is in place, apply an Overlay around the patch.
  - A. Remove the backing from half of the Overlay. The backing has a slit across the center to help with removal.
  - B. Place the part of the Overlay where the backing has been removed around the top of the patch to “frame” the patch. The white absorbent cellulose pad and ¼ inch of the transparent covering of the patch should be showing. Press the Overlay frame against the skin for good adhesion.
  - C. Remove the rest of the backing on the bottom half of the Overlay. Press the bottom half of the Overlay around the bottom half of the patch. Press the Overlay against the skin for good adhesion.

# Overlay Application (Cont'd.)



# PharmChek® Drugs of Abuse Sweat Patch

## Removal Instructions – No Overlay Used

- Supplies necessary for Removal of PharmChek® Sweat Patch
  - Chain of Custody Form
    - The form used when applying the patch.
  - Specimen Bag
  - Disposable Plastic Tweezers and Plastic Gloves
  - Transport Bag

# PharmChek® Drugs of Abuse Sweat Patch

## Removal Tips – No Overlay Used

- Look for puncture holes.
  - For best results, hold patch up to the light after removal.
- Request that the donor pull down the top edge of the patch (page 29).
  - Using the gloved hand, pull the patch half way down.
  - Using the single-use tweezers, **remove the cellulose pad** (page 30) and place the pad in the specimen bag (page 31).
  - Affix a bar-code sticker, from the chain-of-custody form (page 32), to the outside of the specimen bag (page 39).

Removal Tips – No Overlay Used

Donor Peels Outer Cover of Patch Down



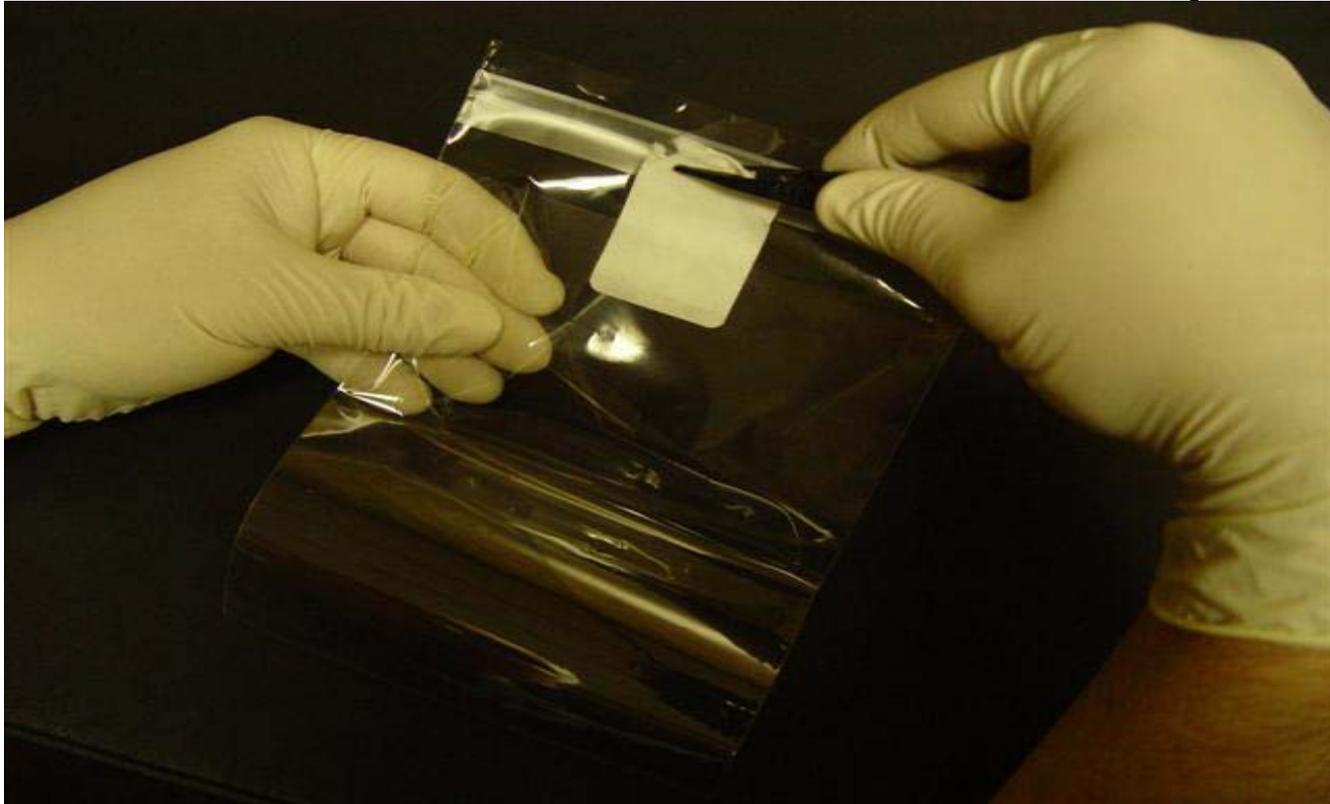
# Removal Tips—No Overlay Used

## Remove Absorbent Pad

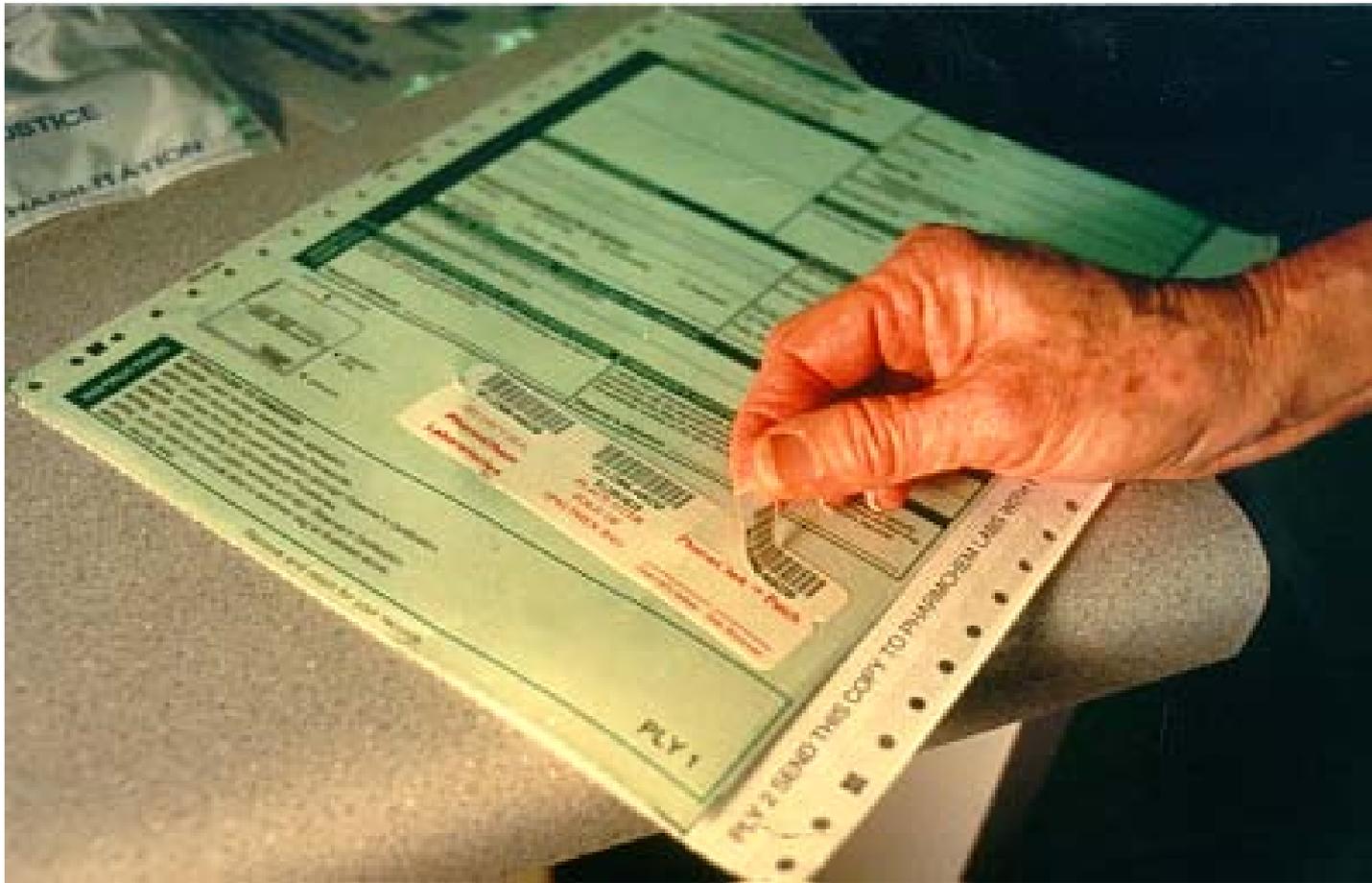


# Removal Tips

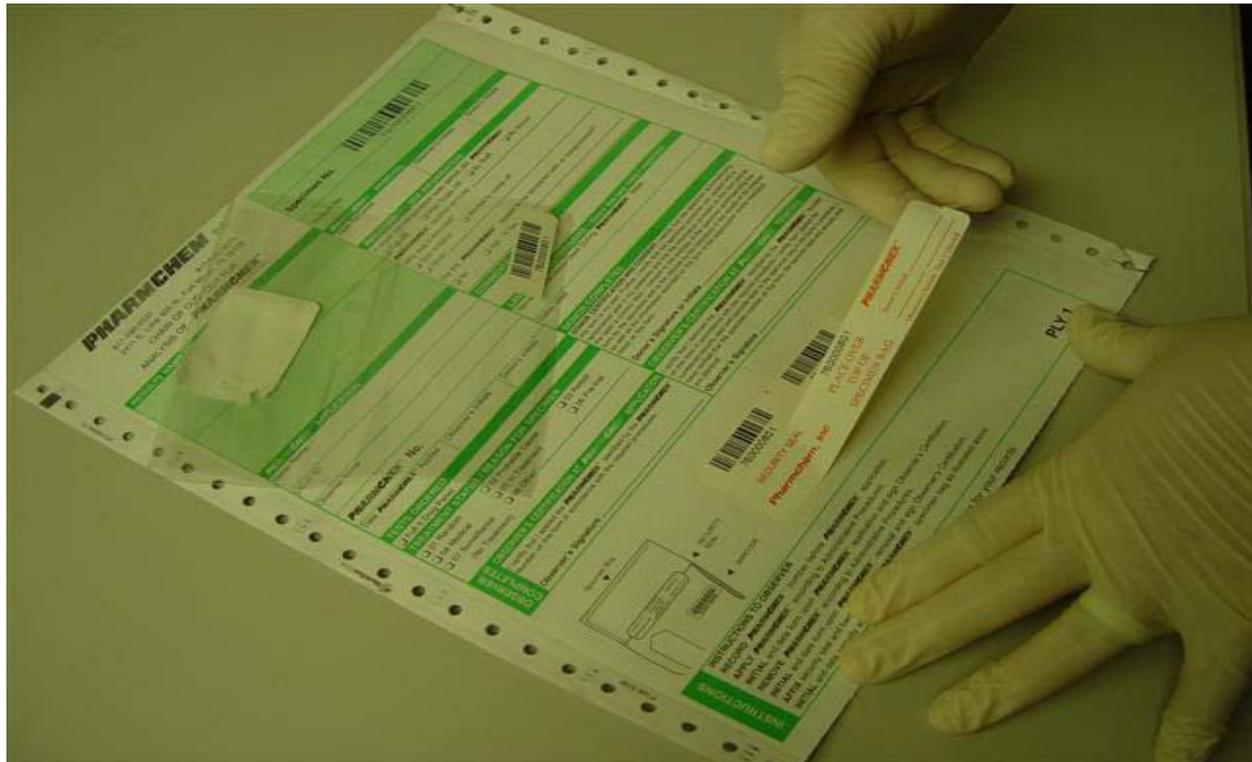
Place Absorbent Pad in Bag



# Remove Barcode Label



# Peel Off Security Seal



# PharmChek® Drugs of Abuse Sweat Patch

## Removal Instructions – If Overlay is Used

- Supplies necessary for Removal of PharmChek®
  - Chain of Custody Form
    - The form used when applying the patch.
  - Specimen Bag
  - Disposable Plastic Tweezers and Plastic Gloves
  - Transport Bag

# PharmChek® Drugs of Abuse Sweat Patch

## Removal Tips –If Overlay is Used

- Look for puncture holes.
  - For best results, hold patch up to the light after removal.
- Have the donor peel the overlay down about halfway from the top. The PharmChek® patch should peel down with the overlay (page 36).
  - Using the gloved hand, pull the patch half way down (page 36).
  - Using the single-use tweezers, **remove the cellulose pad** (page 30) and place the pad in the specimen bag (page 31).
  - Affix a bar-code sticker, from the chain-of-custody form (page 32), to the outside of the specimen bag (page 39).

# Removal Tips –If Overlay is Used Donor Peels Outer Cover of Overlay Down



# PharmChek® Drugs of Abuse Sweat Patch Removal Information – With or Without Overlay

- Complete Chain of Custody.
  - Removal
    - Date removed
    - Observer's Initials
    - Donor's Initials
  - Use Information
    - Indicate whether the patch fell off or was taken off.
    - If the patch was removed before the wear period was completed, indicate the reason.
    - If Patch appears to have been tampered with, check the "Yes" box and indicate how.

# PharmChek® Drugs of Abuse Sweat Patch

## Removal Instructions – With or Without Overlay

- Comments
- Medication Used
- Donor Signature
- Observer's Signature
- Place the plastic specimen bag into the transport bag with the chain-of-custody form (page 39).
- Place the transport bag into the appropriate shipping envelope and send to **CRL** for testing.

# Place Barcode Label on Bag



# PharmChek® Drugs of Abuse Sweat Patch

## Observation After Removal

- Confirm Patch Number.
  - Compare the number on the patch with the number on the Chain of Custody form.
  - The observer must initial the boxes marked “Observer’s Initials.”
- Examine Patch for Tampering
  - Look for signs of attempts to remove and re-apply.
    - An uncompromised patch should have the adhesive still adhering to the skin completely surrounding the absorption pad.

# Drug Detection in Sweat Current Issues

- External Contamination
  - Studies conducted at CHT involved externally applied drugs to the skin followed by 2X isopropyl alcohol wipes and/or soap followed by isopropyl alcohol wipes.
  - These studies indicated depending on the amount of drug applied to the skin, the wipes may not completely remove all the drug.

# Drug Detection in Sweat Current Issues (Cont.)

- In the drug application study, no drug metabolites were detected, regardless of the amount applied to the arm.
- Under PharmChem's (and the proposed HHS) criteria, these samples would have been reported as negative.

# Drug Detection in Sweat Current Issues (Cont.)

- In another study conducted by CHT, sweat patches were exposed to vaporized drugs.
- The concentration of these drugs was equivalent to burning a significant amount of pharmaceutical grade cocaine/methamphetamine.

# Drug Detection in Sweat Current Issues (Cont.)

- Under conditions where the outside of the patch was kept at 37°C, kept at a higher than normal pH, and maintained under these conditions for 24 hours, some drug was observed to penetrate the exterior of the patch.

# Drug Detection in Sweat Current Issues (Cont.)

- No drug metabolite was detected in the vapor exposure study.
- Results would have been reported as negative.
- Also indicated that these were not real world realistic symptoms.

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court

- 07/2006 US District Court-FP Cedar Rapids, IA NDIA-U.S. v. Meyer CR04-0010-Expert Witness P-Kadehjian D-None-Judge Linda Reade-**AUSA Pat Reinart**-COC Positive 8 Patches  
**\*\*\*\*\*CASE WAS APPEALED. FIRST PATCH CASE HEARD IN THE UNITED STATES APPEALS COURT. HEARD BY THE HONORABLE JUDGE SANDRA DAY O'CONNOR (SERVED AS ASSOCIATE JUSTICE OF THE UNITED STATES SUPREME COURT (1981-2006). PATCH RESULTS AND CASE FROM THE DISTRICT COURT UPHELD\*\*\*\*\***
- 05/2006 US District Court-FP Greensboro, NC MDNC-U.S. v. Echard 1:03CR71-Expert Witness P-Kadehjian D-None-Judge Tilley-**AUSA Patrick Auld**-COC Case Positive Patch
- 02/2006 US District Court- FP New York City- U.S. v. Bentham 414 F.Supp.2d472 (SDNY 2006)-  
Expert Witness P-Kadehjian D-Smith-Judge Rakoff-**AUSA Margaret Garnett**-COC  
Case Positive Patch
- (Not given) US District Court – FP Cleveland, OH (ND) – Previous date: 06/2003 – Case#  
402CR00031 – Def Shelva Bell (COC) – Defense Atty Charles Fleming – Judge Peter  
Economus – **Previous AUSA Greg Sasse, Current AUSA Linda Barr**

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court, Cont'd.

- 09/08/04 US District Court – FP Boise, ID – Case# CR02-065-S-BLW – Def Rodney Unger (AMP/METH) – Judge B. Lynn Winmill – Defense Atty Tom Monaghan – **AUSA Kevin Maloney**
- 08/23/04 US District Court – FP Fresno, CA – Case# 1:02CR05229-03, 1:02CR05469-01 – Def Jennifer Rose Abrego (AMP/METH) – Judge Anthony W. Ishii – Defense Atty Eric Kersten – **AUSA Stanley A. Boone**
- 08/2004 US District Court – FP Sacramento, CA (ED) – Case# 2:02CR00556-01 – Def Jason Rooney (AMP) – Judge William B Shubb – Defense Atty Jeffrey Staniels – **AUSA Mary Grad**
- 07/09/04 US District Court – FP Kansas City, MO (WD) – Previous date: Depositions 3/15-16/04 – Case# 00-00239-02-cr-wfjg – Def Michael Dillard (COC, PCP) – Judge Fernando Gaitan – Defense Atty Julian Grouse – **AUSA Linda Marshall**
- 05/26/04 US District Court – FP Gainesville, FL (ND) – Previous date: 03/25-26/04 – Case#1:95CR1007 MMP – Def Gregory Randall (COC) – Judge Maurice Paul – Defense Atty Tom Miller – **AUSA Gregory McMahon**

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court, Cont'd.

- 08/2003 US District Court – FP Kansas City, MO (WD) – Case# 98-00018-04-CR-W-ODS – Def Jacqueline Fenimore (COC) – Defense Atty Scott Turner – Judge Ortrie Smith (opinion to be published) – **AUSA Kate Mahoney**
- 12/02/02 US District Court – FP Los Angeles, CA (CD) – Previous dates: 11/7/02, 11/14/02 – Case# CR 02-983-R – Def Nicholas Mann (AMPH) – Judge Manuel Real – Defense Atty Lara Bazelon – **AUSA Kevin Rosenberg**
- 10/01/02 US District Court – FP Boston, MA – Case# 01-CR-10468-ALL – Def Henry Alfonso (COC/BE) – Defense Atty Matthew Fineberg – **AUSA Laura Kaplan**
- 10/09/02 US District Court – FP Kansas City, MO (WD) – Case# 97-138-03-CR-W-9-1 Def Melinda Zubeck (AMP) – **AUSA David Barnes**
- 12/20/01 US District Court – FP Kansas City, MO (WD) – Case# 99-00160-01-CR-W4 – Def Tucson Redd (COC) – **AUSA Marietta Parker**
- 02/04/03 CASE UPHeld BY 8<sup>th</sup> CIRCUIT**

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court, Cont'd.

- 09/25/00 US District Court – FP Guam – Phone Testimony – (Methamphetamine) – **AUSA Karen Johnson**
- 07/10/00 US District Court – FP Los Angeles, CA (CD) – Case# CR 97-469 SVW – Def Amber Ruth Mayer Turner (COC) - **AUSA Michael Wilner**  
**Judge ruled patch to be reliable, but did not revoke probation. Judge ordered her to stay on the patch.**
- 05/17/00 US District Court – FP Salt City, UT – Case# 2:97 CR 0276S – Def Larry Souza (METH) – **AUSA Leshia M. Lee-Dixon**
- 05/01/00 US District Court – FP Brooklyn, NY (ED) – Case# 00 CR 18 – Def Suzanna Vega (COC) - **AUSA Marshall Miller**
- 04/27/00 US District Court – FP Sacramento, CA (ND) – Case# CR S 97-238 DFL – Def Ronald Mosley (COC) – **AUSA Laurel D. White**
- 04/03/00 US District Court – FP Los Angeles, CA (CD) – Case# CR 92-246- RAP – Def Stanley Medina (COC) – **AUSA Elizabeth Rhodes**

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court, Cont'd.

- 03/29/00 US District Court – FP Little Rock, AR (ED) – Case# LR-CR-89-71 – Def Dwight Watkins (METH) – **AUSA Patrick Harris**
- 06/15/99 US District Court – FP Cleveland, OH (WD) – Case# 5:93CR245 – Def Filmore Lott (COC) - **AUSA Marilyn Bobula**
- 05/31/99 US District Court – FP Las Vegas, NV– Case# CR-95-023-PMP (RLH) – Def Douglas Stumpf, **DAUBERT CASE** (AMP) – **AUSA JOE Sullivan**
- 11/12/99 PATCH WAS REAFFIRMED**
- 02/19/99 US District Court – FP Dallas, TX (ND) – Case# 3:98-CR-352-T (01) – Def Christopher Anthony Seiber (COC) – Judge Robert Maloney – **AUSA Michael Uhl**
- 02/08/99 US District Court – FP Cedar Rapid, IA (ND) – Case# CR 94-5 – Def Tracy Wilcox (COC & THC) – **AUSA Steve Colloton – Patch upheld for the Cannabinoid**
- 02/05/99 US District Court – FP Los Angeles, CA (CD) – Case# CR92-474-R – Def Johnny Solario (COC) – **AUSA Susan Dewitt**

# PharmChek® Sweat Patch - Successful Court Cases

## Patch Cases Upheld in Court, Cont'd.

- 01/15/99 US District Court – FP Las Vegas, NV – Case # CR-S-96-004 PMP (RLH) – Def Steve Denton (AMP) **DAUBERT CASE – AUSA JOE SULLIVAN**
- 12/18/98 US District Court – FP Los Angeles, CA (CD) – Case# 92-00389 – Def Rolando Soto (COC) – **AUSA Robert Dugdale**
- 05/29/98 US District Court – FP Rock Island, ILL (CD) – Case# 95-40014-001 – Def Jason Oliva (COC)
- 04/20/98 US District Court – FP Los Angeles, CA (CD) – Case# CR86-924 GCK – Def William Stallings (COC)
- 04/16/98 US District Court – FP Las Vegas, NV – Case# CRS93-270- PMP – Def Barry Shabansky (METH) – **AUSA Joe Sullivan**
- 04/07/98 US District Court – FP North Carolina – Case# 1:94CR52-4 – Def Leonard Vance Holman (COC)
- 01/30/98 US District Court – FP Los Angeles, CA (CD) – Case# CR96-27DT – Def Hanford Sax (COC)

# PharmChek® Sweat Patch - Successful Court Cases

## Plead While In Court before Testimony

- 06/14/99 US District Court – FP Grand Rapids, MI (WD) – Case# 1-98-PT-07 – Def  
Terrance A. Smith (THC) – **AUSA Donald Daniels**
- 04/16/99 US District Court – FP Memphis, TN (WD) – Case# 90-20065-G – Def  
Barry Fletcher (AMP / METH) – **AUSA Tracy Berry**

# PharmChek® Sweat Patch - Successful Court Cases

## Plead

- 02/19/03 US District Court – FP Kansas City, MO (WD) – Case# 01-05023-01-CR-SW-0DS – Def David Scroggins (METH) – Judge Smith – **AUSA Randall Eggert; AUSA David Barnes** – Original Court Date 2/21/03, Plead out of court 2/19/03
- 09/26/02 US District Court – FP Kansas City, MO (WD) – Def Dixon – **AUSA Mike Greene** – Case was continued to 10/8/02 – **Defendant Plead before case was heard.**
- 06/22/00 US District Court – FP Covington, KY (ED) – Case# 91-2 – Def William Upton (COC) – Judge J. Gregory Werhman – Defense Atty Bill Oldfield – **AUSA Fred Stine – Defendant Plead after testimony heard but before ruling was given.**
- 05/15/00 US District Court – FP San Francisco, CA (ND) – Case# 98-0135-JL – Def Joseph Seelig (COC) – **AUSA Tammy Palamino**
- 04/17/00 US District Court – FP Los Angeles, CA (CD) – Case# CR 97-665 WJR – Def Daniele Desear Ross – **AUSA April A. Christine**
- 04/04/00 US District Court – FP Kansas City, MO (WD) – (COC) – **AUSA David Barnes** – No Case numbers available. **Plead before Subpoena served**

# PharmChek® Sweat Patch - Successful Court Cases

## Plead, Cont'd.

- 02/17/00 US District Court – FP Phoenix, AZ – Case# CR 98-185-PHX-SMM – Def Richard Lane Gueringer (METH) – **AUSA Paul Rood – Plead while in court**
- 01/2000 US District Court – FP Benton, IL (SD) – Case# 94-40009-JPG – Previous date: 07/09/99 – Def Courtney Hurt (COC) – Judge J. Phil Gilbert – Defense Atty Melissa Day – **AUSA George Norwood – Defendant plead out of court in response to positive patch and multiple positive UA's.**
- 04/29/99 US District Court – FP Las Vegas, NV – Case# CR-S-98-028 HDM (RJJ) – Def Marilyn Groveman (AMP) – **AUSA JOE Sullivan**
- 03/25/99 US District Court – FP Los Angeles, CA (CD) – Case# CR-96-57 – Def Jimmy Anderson (COC) – **AUSA Mark Young**
- 03/23/99 US District Court – FP Los Angeles, CA (CD) – Case# CR 98-963-WMB – Def Jose Vera (METH & OPT) – **AUSA Daniel Saunders**
- 04/10/98 US District Court – FP Madison, WI (WD) – Def Anthony Francis Pickens – **Defendant plead before subpoena was served. No Case numbers available.**
- 04/30/98 US District Court – FP Omaha, NEB – Def Taehee Sturderant – **Defendant plead before case went to court. No Case numbers available.**