

The SMARTEST Patch is intended as a collection device for drugs of abuse and/or their metabolites excreted from the wearer's body in perspiration. The patch is then intended to be analyzed by a laboratory authorized by Smartox to test for the presence of cocaine and cocaine metabolites, amphetamines (including methamphetamine), opiates (including synthetic opiates), cannabinoids, barbiturates, benzodiazepine, phencyclidine and ethanol biomarkers (including EtG). **The collection kit is intended solely for use by professionals in nonclinical, employment, and insurance sample collection, and does not include collecting test samples intended for federally regulated workplace drug testing programs [e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT) and the US military].**

## **APPLICATION INSTRUCTIONS FOR SMARTEST PATCH**

**\*\*SMARTEST Patch is ONLY to be applied by individuals certified by Smartox as Authorized Applicators. Applicator training is available on our website by scanning the QR code on the outside of the SMARTEST Patch box or by visiting [www.smartox.com](http://www.smartox.com)\*\***

\*Avoid applying the SMARTEST Patch to any skin surface that suffers from cuts, abrasions, sores, scars, ulcers, infections or any other issue inconsistent with normal, healthy skin. The SMARTEST Patch MAY be applied over skin with tattoos if the tattoos are not so new that the skin has not yet healed from the tattoo process.

\*SMARTEST Patch is not intended to be used as a bandage for the covering of open wounds.

**\*\* A FRESH SET OF GLOVES IS TO BE WORN DURING EACH APPLICATION. Gloves MUST be changed between Donors to avoid potential contamination\*\***

### **Choosing an application site for the SMARTEST Patch**

Site choice is one of the most important components of a successful application. It is imperative that the Applicator choose a site that is free from wrinkles or natural folds in the skin. Additionally, the site should be free from excessive amounts of hair which would decrease contact between the adhesive and the skin. Common areas chosen for application are the upper arm and lower back. Areas that can also be used include the chest, the lower rib area, and the sides of the stomach. Due to the potential "private" nature of some of these secondary sites, consideration should be given if the Applicator and Donor are of a different sex.

### **Site Preparation**

The items necessary for the application of the SMARTEST Patch will be provided by Smartox. They include the patch itself, disposable gloves, alcohol pads, chain of custody forms, and these instructions. Once a satisfactory application site has been chosen for the Donor, the site must be prepared to ensure a successful application. If the Donor is actively perspiring, allow them to stop perspiring and the skin to dry prior to application. The surface of the skin should be free of any blemishes and should be void of dirt. Using one of the supplied 70% isopropyl alcohol wipes, clean the chosen application site firmly for at least 30 seconds. A second 70% isopropyl alcohol wipe may be used if the application area needs additional cleaning. After cleaning the site, allow the area to air dry for 60 to 90 seconds. Ensure that the area has dried completely prior to application as moisture on the skin can reduce the adhesive properties of the SMARTEST Patch during the application process.

### **SMARTEST Patch Application**

As an added precaution against contamination of the SMARTEST Patch, the Applicator should remove the gloves that were worn during the Site Preparation phase and apply a clean, new set of gloves for the Application phase. Remove the SMARTEST Patch from the peel-apart pouch. The skin on the area chosen for application should be taught and free of wrinkles or folds. Have the Donor flex the muscle (in the case of the arm) or have them lean to stretch the skin in the case of the back, lower rib area, and side of the stomach. This will allow the patch to be applied to skin that is stretched so as not to cause discomfort when stretching occurs. The adhesive backing on the SMARTEST Patch has a 3-part release liner designed to be peeled off in a specific order thus exposing the adhesive and making application easy. The center panel of the release liner should be removed first exposing the center of the SMARTEST Patch. While holding the remaining release liners, the SMARTEST Patch should be applied to the selected application site (ensure the area is completely dry after cleaning). Using gloved hands, carefully yet firmly press the middle part of the patch to adhere the exposed adhesive to the skin. It is important to avoid creases in the adhesive ring during application. Once the middle portion of the patch is firmly attached to the skin, remove one of the remaining folded release liners. After the folded release liner is removed, repeat the process of ensuring proper adhesion to the skin by pressing firmly and avoiding creases. Remove the final remaining folded release liner and repeat the above process for adhesion. Examine the SMARTEST Patch to ensure that there are no creases and that the Donor's skin is not restricted during normal motion. While not necessary, a photo may be taken of the applied patch to demonstrate a proper application. Each SMARTEST Patch is printed with a unique identifier number directly over the

collection pad. This number is intended to ensure that the patch applied to the Donor is the same as the one that is being worn when the Donor returns for removal. The SMARTEST Patch unique identifier number should be recorded on the laboratory chain of custody form to compare to the number on the patch at the time of removal. This will ensure that the patch has not been substituted. Advise the Donor that after the SMARTEST Patch has been applied to clean and dry skin that there are no restrictions regarding exposure to moisture. The Donor can perspire, bathe, shower, and swim as they normally would. **After any such exposure to moisture, care should be taken when drying skin as would be with any other adhesive product. The area with the SMARTEST Patch should be patted dry rather than rubbed with a towel. Excessive rubbing of the patch could cause the edges to become dislodged.** The components of the SMARTEST Patch have been developed for direct, prolonged contact with skin. While sensitivities are extremely rare, the Donor should be instructed to contact the Applicator or their office immediately should any sensitivities be noticed. **If extreme irritation occurs, discontinue the use of the SMARTEST Patch on that Donor and instruct them to treat the skin appropriately.** Once the SMARTEST Patch has been applied to the Donor, complete the section of the supplied Chain of Custody form labeled "Application" following the instructions on the form. Ensure that both the Applicator and the Donor sign the appropriate boxes on the chain of custody form. Retain the Chain of Custody form in a secure place so that it will be easily accessible as it will be used again during the removal process.

## **REMOVAL INSTRUCTIONS FOR SMARTEST PATCH**

### **Removal of SMARTEST Patch**

When the Donor returns to have the patch removed and sent to the lab for analysis, the removal technician plays a vital role in the chain of custody process. Particular attention should be paid to the details in this section in order to ensure proper chain of custody procedures are followed. The items necessary for the removal of the SMARTEST Patch will be provided by Smartox. They include disposable gloves, individually wrapped single-use tweezers, pouches for the transportation of the SMARTEST Patch collection pad, chain of custody forms with tamper-evident seals and shipping supplies. These items should be available and ready to avoid skipped steps or any stoppage in the removal process. The person removing the patch should complete the chain of custody form except for the Donor's signature box. The Donor will sign their section attesting that the patch removed is theirs and was worn by them (and only them) the entire time once the collection pad is in the pouch for transportation to the lab. Before removing the patch, the removal technician should compare the SMARTEST Patch Identifier Number that was recorded at the time of application to the number that is being removed by the Donor confirming that they agree. If the numbers are different or the number is absent at the time of removal, the removal technician should make a note on the Chain of Custody and not send the sample collection pad to the lab for analysis as there is no way to attest that the patch is the one that was originally placed on the Donor.

The person responsible for the removal of the SMARTEST Patch should visually inspect the patch while still on the skin to identify any adulteration or removal attempts. There should be no tears or holes in the clear film covering the collection pad. The white adhesive area is designed with tamper-evident features which will easily identify any removal attempt. **When removing the SMARTEST Patch, take extra care to avoid the collection pad falling to the floor or coming into contact with anything other than the provided single-use disposable tweezers or the pouch in which it will be sent back to the lab. In the event that this happens, the pad should not be sent to the lab as contamination could have occurred.** Place the collection pad in the small pouch (labeled Pouch 1) provided in the back-to-the-lab kit. Use the tamper-evident seal, including the specimen barcode from the chain of custody form, to seal the pouch. After the pouch has been sealed, have the Donor initial the tamper seal with their initials and the date. After Pouch 1 has been sealed, place Pouch 1 into Pouch 2 with the white copy of the chain of custody form. After this is done, Pouch 2 (containing Pouch 1 and the white copy of the chain of custody form) can be packaged in the shipping envelope to send to the lab. The yellow copy of the chain of custody form is to be retained by the removal technician and the pink copy may be given to the donor.

**Once the removal of the patch has been completed, the Collector should ensure that all sections of the chain of custody form are completed per the instructions on the chain of custody form. The chain of custody form MUST accompany the collection pad to the lab. Prior to shipment, samples can be kept at room temperature. Refrigeration is not necessary.**