

The **DermTech Adhesive Skin Biopsy Kit** contains all necessary materials to non-invasively collect and mail a skin sample to the DermTech Laboratory for molecular pathology gene expression analysis. The steps involved in this procedure reserved for licensed providers are very similar to the ones required for a conventional invasive skin biopsy.

**DO NOT FREEZE OR REFRIGERATE THE COLLECTED TISSUE SAMPLE.**

Each DermTech Adhesive Skin Biopsy Kit contains a tri-fold Sample Collector containing four (4) adhesive Patches in a re-sealable plastic bag, a 70% alcohol prep pad, a gauze pad, Instructions for Use ("IFU"), a Laboratory Requisition Form, a FedEx pouch with a prepaid shipping label, and a black permanent marker. Each Sample Collector and Laboratory Requisition Form is labeled with a unique barcode that is assigned to the patient sample. A patient's skin sample is collected using all (4) Patches contained in the Sample Collector.

**INSTRUCTIONS**

1. Discuss planned biopsy procedure with patient, obtain written informed consent, document procedure.
2. Remove contents from the Kit.
3. Carefully review the IFU and quick reference diagrams before using this product.

**Note: The instructions correspond to the diagrams, as indicated below.**

**SITE PREPARATION - GLOVES SHOULD BE USED AT ALL TIMES**

3. If necessary, remove any hairs using small surgical scissors.
4. BEFORE applying any adhesive Patches, cleanse the lesion site with a 70% alcohol prep pad (see **Figure 1**).
5. Allow the site to air dry completely.

**COLLECTION**

6. Remove the tri-fold Sample Collector from the sealed bag.
  - a. Open the clear front panel and fill out the patient information.
  - b. Open the interior panel to expose the four (4) adhesive Patches on the center panel and liner on the lower panel.
  - c. Remove and discard the lower panel liner (see **Figure 2**) to expose the placement areas for used Patches.
7. Gently swab lesion with gauze pad to ensure the area is dry (one gauze pad can be used to remove moisture prior to applying each one of four (4) adhesive Patches (see **Figure 3**).

**Use not recommended for biopsies with the characteristics below:**

SIZE	LOCATION	OTHER
Lesions < 5 mm diameter	Palms, soles of feet, mucous membranes	Ulcerated or bleeding
Lesions > 16 mm diameter		Patients under 18 years of age

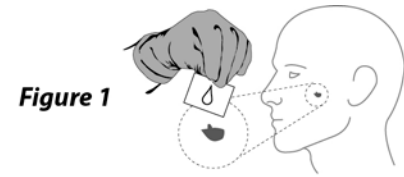
8. Use the adhesive Patches to collect the skin lesion sample:
  - a. Moving from left to right on the Sample Collector, remove the first Patch (see **Figure 4**).
  - b. Center and place the Patch on the skin lesion (see **Figure 5**).
  - c. Hold the skin taut and, using your thumb, press firmly while making approximately 5 circular motions on the Patch (see **Figure 6**).
  - d. BEFORE removing the Patch, use the provided permanent marker to demarcate the lesion margin or tumor margin that is to be analyzed (see **Figure 7**). Make sure that the outline marking is accurate and complete. This area will be macro-dissected from the surrounding tape at the DermTech Laboratory as part of the testing.
  - e. Remove the Patch slowly from the skin lesion in one direction.
  - f. Place the edges of the Patch onto the adhesive strips within the placement areas on the lower panel so that the adhesive side of the Patch is facing down (see **Figure 8**).
  - g. Repeat the procedure (Steps 7 and 8a-8f) on the lesion, consecutively applying the 2nd, 3rd and then 4th Patch from left to right on the Sample Collector until all four (4) adhesive Patches have been used on the same lesion.
  - h. Correctly refold the Sample Collector so that the clear cover is on the outside and confirm the patient information is noted in the space provided.

**SEND SAMPLE**

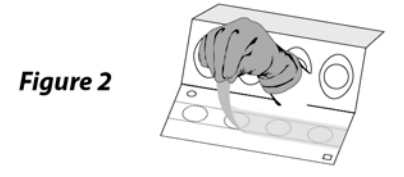
9. Place the Sample Collector with the skin tissue sample into its original re-sealable plastic bag and return it to the Kit box with the completed Laboratory Requisition Form.
 

**Note: One (1) Adhesive Skin Biopsy Kit and one (1) Laboratory Requisition Form are required for each lesion to be tested.**
10. Mail the Kit box to the DermTech Laboratory in the prepaid FedEx pouch included in each Kit. Skin tissue samples, once collected, should be mailed overnight. No more than five (5) Kit boxes can be included in a single FedEx pouch for return to the DermTech Laboratory. Samples collected on Friday should be retained at room temperature at the site over the weekend and mailed on Monday. Post biopsy site care can include application of ointment.

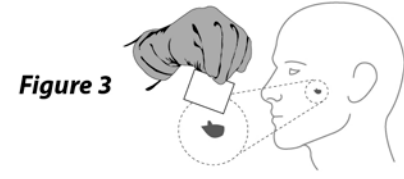
For further information or questions, contact DermTech's client services at 1.866.450.4223.



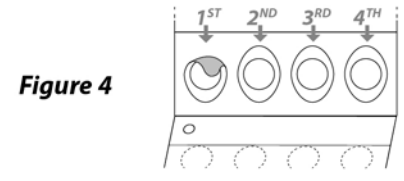
**Figure 1**



**Figure 2**



**Figure 3**



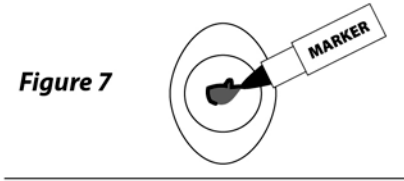
**Figure 4**



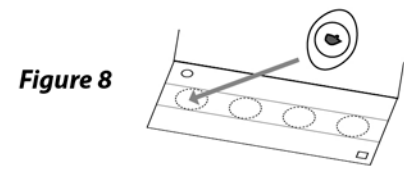
**Figure 5**



**Figure 6**



**Figure 7**



**Figure 8**