

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.

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 and a black permanent marker-ultra fine point. 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

4. Remove any hairs using small surgical scissors.
5. BEFORE applying any adhesive Patches, cleanse the lesion site with a 70% alcohol prep pad (see **Figure 1**).
6. Allow the site to air dry completely.
7. Use the gauze pad to dry and rough up the lesion (one gauze pad can be used prior to applying each one of four (4) adhesive Patches (see **Figure 3**)).

COLLECTION

8. 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.
 - d. Trim excessive hair, when appropriate.

Use not recommended for biopsies with the characteristics below:

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

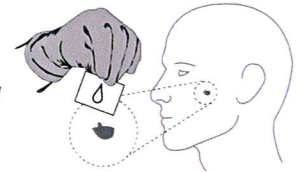
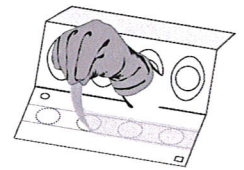
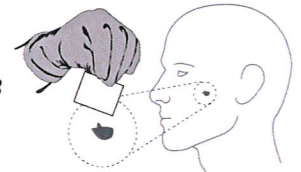
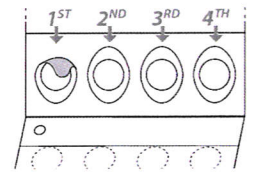
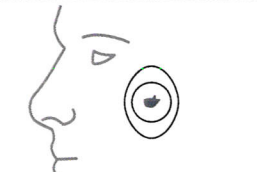
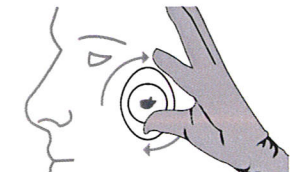
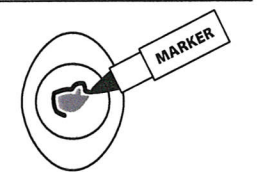
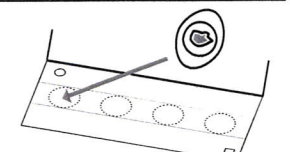
9. Use the adhesive Patches to collect the skin lesion sample:
 - a. Moving from left to right on the Sample Collector, remove the first Patch (see **Figure 4**).
 - b. Center and align the Patch on the skin lesion (see **Figure 5**).
 - c. Hold the skin tight and press firmly while making approximately 5 circular motions on the Patch with your thumb. (see **Figure 6**).
 - d. BEFORE removing the Patch, use the provided permanent marker to outline 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 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 re-fold the Sample Collector so that the clear cover is on the outside and confirm the patient information is noted in the space provided.
10. The sample is stable for 10 days from time of collection. Do not freeze or refrigerate the collected sample.

Note: One (1) Adhesive Skin Biopsy Kit and one (1) Laboratory Requisition Form should be completed for each lesion to be tested.

SEND SAMPLE

11. Place the Sample Collector with the skin tissue sample into its original re-sealable plastic bag and staple it to the completed Laboratory Requisition Form along with any supporting paperwork. Place all in a FedEx envelope. Mail to the DermTech Laboratory in a FedEx envelope. Skin tissue samples, once collected, should be mailed overnight.

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