

The DermTech Adhesive Skin Collection Kit contains all necessary materials to non-invasively collect and mail a skin sample to the DermTech Gene Lab for molecular pathology analysis.

Each DermTech Adhesive Skin Collection Kit contains a trifold Sample Collector containing four (4) adhesive DermTech Smart Stickers™ in a re-sealable plastic bag, 70% isopropyl alcohol prep pad, gauze pad, Instructions for Use (IFU), Test Requisition Form, re-sealable foil bag with desiccant, and black permanent ultra-fine point marker. Each Sample Collector and Test Requisition Form is labeled with a unique barcode. A patient's skin sample must be collected using all (4) Smart Stickers contained in the trifold Sample Collector.

INSTRUCTIONS

1. Discuss the planned collection procedure with the patient and write the information requested on the front of the Sample Collector. Confirm this information with the patient. **All information is required for the sample to be processed.**
2. Remove contents from the Kit.
3. Carefully review the IFU and quick reference diagrams before using this product.

Use NOT recommended for lesions with the characteristics below:

SIZE	LOCATION	OTHER
Lesions <5mm diameter	Palms, soles of feet, mucous membranes	Ulcerated or bleeding lesions
Lesions >19mm diameter		Patients under 18 years of age

SITE PREPARATION

4. Remove any hairs using small surgical scissors.
5. **BEFORE** applying any adhesive Smart Stickers, thoroughly cleanse the lesion site with the 70% isopropyl alcohol prep pad, ensuring all oils, lotions, makeup, and other surface contaminants are removed (**Figure 1**).
6. Dry the lesion thoroughly by gently pressing the enclosed gauze pad over the lesion (**Figure 2**). **Do not proceed to sample collection until the area is completely dry**

COLLECTION

7. Remove the trifold Sample Collector from the sealed bag.
 - a. Lift the clear front panel and ensure all requested information is filled out and accurate (as noted in step 1)
 - b. Open the interior panel to expose the four (4) adhesive Smart Stickers on the center panel.
 - c. Remove and discard the blue paper liner and the "Remove Before Use" seal (**Figure 3**) to expose the placement areas for Smart Stickers post-collection.
8. Use the Smart Stickers to collect the skin lesion sample:
 - a. Remove the first Smart Sticker by the flap of sticker (see **Figure 4**).
 - b. Center and align the Smart Sticker on the skin lesion (see **Figure 5**).
 - c. Hold the skin tight and **press firmly on the Smart Sticker with your thumb for 10 seconds**, ensuring maximum contact between the Smart Sticker and the lesion. (**Figure 6**).
 - d. Use the provided ultra-fine permanent marker to outline the lesion margin (**Figure 7**). **Ensure the lesion is fully enclosed by the outline.**
 - e. Peel the Smart Sticker slowly and continuously from the skin lesion in one direction.
 - f. Place the Smart Sticker, adhesive side down, directly onto the pre-marked oval area (see **Figure 8**).
 - g. With the next Smart Sticker, repeat the procedure (Steps 8b-8g) on the lesion, until all four (4) Smart Stickers have been used on the same lesion.
 - h. Refold the Sample Collector so that the clear cover is on the outside and re-confirm the subject information is completed and accurate in the space provided.
9. The sample should be shipped as soon as possible, ideally on the same day as the collection, but no more than 5 days post-collection. Do not freeze or refrigerate the collected sample. Store at room temperature until shipment.

Note: One (1) Adhesive Skin Collection Kit and one (1) Test Requisition Form should be completed for each lesion and/or non-lesion to be tested.

SEND SAMPLE

10. Place the completed Sample Collector into the re-sealable foil bag with desiccant. Place this bag and the completed test requisition form and supporting paperwork in a FedEx envelope and mail overnight to the DermTech Gene Lab.

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

Patents: dermtech.com/patents

Figure 1

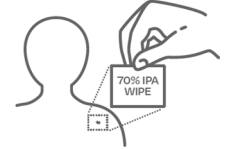


Figure 2

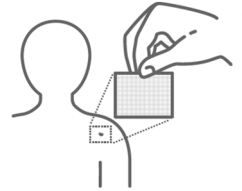


Figure 3

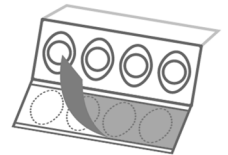


Figure 4

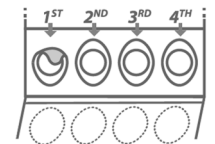


Figure 5



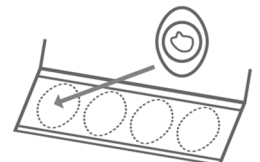
Figure 6



Figure 7



Figure 8



This product is not made with natural rubber latex.

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