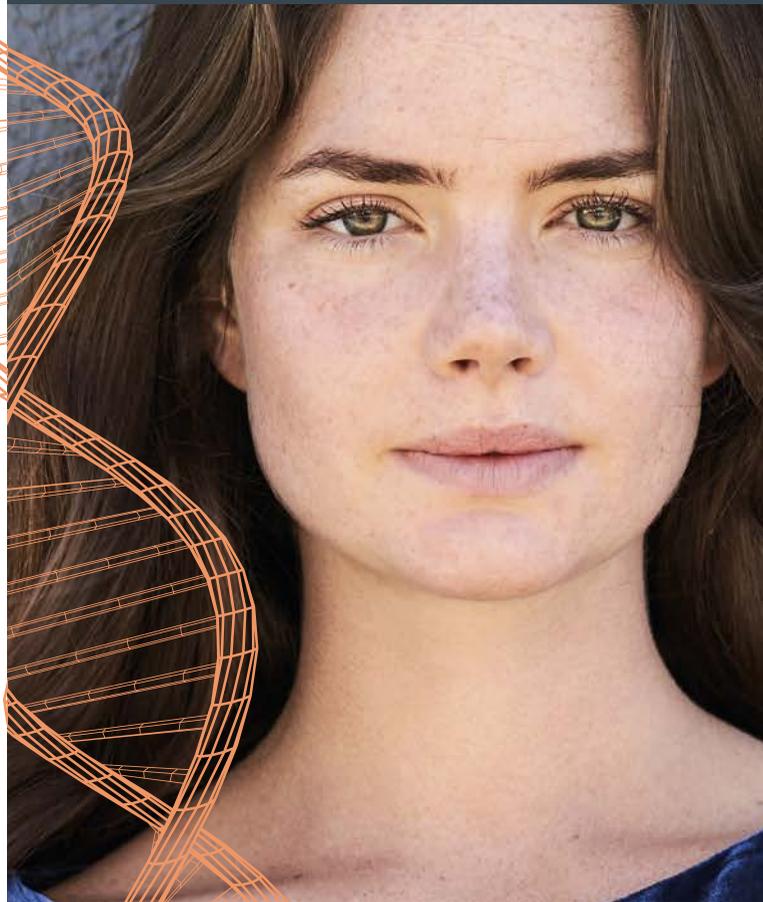




BILHI
SKIN
KELOID

USER MANUAL



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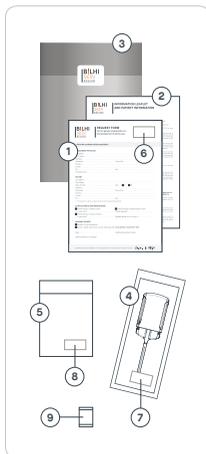
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USER MANUAL - BOX



1. Box packaging
2. Practitioner's Information Leaflet
3. Kits
4. Spare documents: blank documents (order form, information and instruction leaflet)
5. Questionnaire of Patient Refusal

USER MANUAL - KIT



1. Order form (including the Patient Consent Form and the Consultation Slip) to be filled in and inserted into the prepaid envelope for the laboratory
2. Information and Instruction Leaflet for patient use
3. Prepaid outer envelope
4. FTA test
5. Protection envelope for the used FTA test
6. ID label on the order form
7. Repositionable label (ID label (on the protection envelope for the used FTA test)
8. Label with identification number « Envelope for the used FTA test »
9. Desiccant (present in the protection envelope for the used FTA test)

SAMPLING PROCEDURE

1

Remove all the elements from the outer envelope and verify that all 3 labels match.

2

Fill out the consent form and the order form, as well as the consultation slip (document n°1). Do not forget to ask the patient's mode of payment.

3

Provide the patient with the information and instruction leaflet (document n°2), they must read it and keep it safe.

4

Proceed to take the sample: ask the patient to open the FTA test packaging (element n°4), extremely carefully so as to not damage the repositionable label (element n°7).

THE PATIENT TAKES THE SAMPLE, CAREFULLY FOLLOWING THE PROCESS DETAILED BELOW:



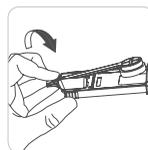
Open the packaging and remove the collector without touching the extremity of the sponge. Use gloves to remove the oral swab from its packaging.



Place the sponge as far as possible into the back of the mouth and rub the inside of the cheek and under the tongue in order to absorb as much saliva as possible. Repeat this process on the inside of the other cheek.



Keep the collector upright (as shown) and slide the protection down to open.



Fold back the swab until the sponge touches the FTA paper. The paper should change colour upon contact with the moist swab.



Close the protection by sliding it up until the arrows are all aligned and it clicks.



Affix the identification tag to the completed kit. Once the FTA card is dry, place the kit in the protection envelope and then the prepaid envelope with the consultation slip and prescription. If the payment has been carried out by cheque, it must also be included in the pre-paid envelope.

Verify that the patient has correctly placed the repositionable label where indicated on the FTA test.

Once the procedure has been completed, the patient must insert the used FTA test into the protection envelope provided for this purpose (element n°5), reseal the envelope, and insert this envelope into the outer prepaid envelope (element n°3).

Insert the order form, accurately and completely filled out, along with the payment (if the patient has chosen to pay by cheque) into the outer prepaid envelope. **Post it back!**