BILHI SKIN KELOID

Product Sheet BILHI SKIN KELOID

DESCRIPTION

The genetic test bilhi skin keloid is a genetic test carried out by Bilhi genetics and a biomedical laboratory. The genetic test is based on the bilhi genetics in vitro diagnostic medical device, bilhi skin keloid software.

Product

BILHI SKIN KELOID SOFTWARE is an in vitro diagnostic medical device, which determines the genetic predisposition to developing a keloid scar, based on genetic data obtained from human biological sampling. It has been designed and developed by BILHI GENETICS; its concept is the software.

USE

The genetic test is based on a saliva sample taken at the doctor's practice, under medical presciption and with the patients informed consent.

A box containing saliva sample kits has been given to medical practitoners. This box contains 25 envelopes with all necessary elements to carry out the test. Once the test has been taken by the patient, the kit must be inserted intended for this purpose, and sent back, at room temperature, to the biomedical laboratory using the prepaid postage envelopes.

The BILHI SKIN KELOID genetic test is based on the research on 14 genetic markers in the patient's genome. The scanning technique used is SNaPshot® micro sequencing.

The software results then make up the medical report given by the biomedical laboratory to the medecin who gave the prescription.

Software desciption

This software uses genetic data to generate a numerical result in order to evaluate the genetic predisposition to developing a keloid scar.

The software has been designed and developed by the teams at BILHI GENETICS and Pr Dessein's public research laboratory, INSERM on « Genetic Parasitic illnesses ». The software has been developed based on over 30 years of genetic studies in Brazil, Africa, China and Europe.

USE OF SOFTWARE RESULTS

WARNING: The results generated by the software are neither for diagnostic purposes, nor should be used to predict the appearance of a pathology or symptoms, nor to detect or identify any specific treatment.

The results are given in the form of a patient classification within two distinct groups:
-A reduced average risk group than in the general population risk group – lower risk group
-An increased average risk group than in the general population – higher risk group
Based on an average prevalence of 5% across all ethnic groups, patients in the higher risk group are 8 times more likely to develop a keloid scar than the general population, and the patients in the lower risk group are 2 times less likely to develop a keloid scar than the general population. In addition, patients in the higher risk group are 16 times more likely to develop a keloid scar than those in the lower risk group.
WARNING : A result deeming the patient to be at a higher risk does not necessarily mean that he/she will develop a keloid scar following a surgical procedure. Conversely, a result deeming the patient to be at a lower risk does not mean that he/she will not develop a keloid scar following a surgical procedure. Low risk does not imply that the risk not present, just as high risk does not imply that the risk is certain.

INVOICE

The genetic test is charged to the patient, who may settle the invoice by credit or debit card directly via GenBio's website: (same address as indicated on the patient documents).

DELIVERY TIME

The average time period for the delivery of results (excluding postal delays) is 7 working days.

INDICATIONS, CONTRE-INDICATIONS ET EFFETS INDESIRABLES POTENTIELS :

<u>Indications</u>

The use of the results from the software is indicated as part of a post-cosmetic surgery planned procedure. The patient must be aged over 15 years in order to undergo the BILHI SKIN KELOID test.

Contre-indications
The (non-exhaustive) contraindications are the following:

1. Mental Illness
2. Signs of oral or dental inflammation
3. Child aged under 15 years
4. All patients who do not wish to comply with the recommendations of the post-test medical practitioner
5. Any other medical complication that would compromise a successful saliva sample and/or the results of the device
6. Patients of Asian ethnic origin

Software results are not designed, intended or sold for any other purpose than those listed above.

Potential side effects:
A list of undesirable effects related to the use of the software results, although not exhaustive, is the following:

1. Behavioural change in the patient regarding his/her decision whether or not to undergo the planned surgical operation

WARNINGS AND PRECAUTIONS:
Every evaluation made by the software will not necessarily lead to a result. It is possible that the software is not able to determine the genetic predisposition, especially if the procedures for collecting and preparing the genetic data have not been respected. In this case, a new sample will be taken free of charge to confirm the previous result.
Compliance with sampling procedures, including sample submission and identification as well as the preparation of genetic data files, are important factors towards the success of the software. In addition, patient cooperation during the sampling will greatly influence the results. Patients who smoke prior to specimen collection have been shown to be at risk of DNA destruction on the FTA card. These patients should be made aware of this fact and informed of the consequences.

IVD The results of the test for a genetic predisposition to keloid scars have been generated by an In Vitro Diagnostic Medical Device.

CE This In Vitro Medical Device has been evaluated according to 98/79. The results were deemed compliant. The device has CE: 10/2018.
For more information, contact BILHI GENETICS via email: contact@bilhigenetics.com.