Genvinset®

Malattia di Behçet (HLAB* 51/52), ver 5

ISO 13485 Quality Management for Medical Devices CERTIFIED

Molecular determination of the HLA-B*51/52 group of alleles

Kit for detecting the HLA-B*51 and B*52 alleles by Real-Time PCR using TaqMan® probes technology

About Genvinset® Malattia di Behçet (HLAB* 51/52), ver 5

Behçet's disease (BD) is a form of vasculitis that manifests with urogenital ulcers, uveitis, skin inflammation, arthritis, enterocolitis and inflammation in other organs. Despite being a worldwide-distributed illness, BD is more frequent in the area that extends from East Asia to the Mediterranean basin. It is also relatively common in countries such as Turkey and Japan.

According to various scientific studies, there are several genetic factors that partially determine the susceptibility to develop the illness. More specifically, it is known that BD is associated with the HLA-B5 antigen, belonging to the Major Histocompatibility Complex (MCH), encoded by the HLA-B*51/52 group of alleles. Therefore, the HLA-B5 antigen is a risk factor strongly associated with BD.

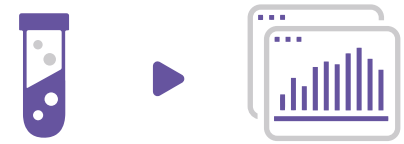
Intended use

Genvinset® HLA Behçet v5 is a semi-automated *in vitro* diagnostic kit for the qualitative detection of the HLA-B*51/52 group of alleles in genomic DNA extracted from whole blood, associated with Behçet's disease predisposition, by Real-Time PCR using TaqMan® probes technology.

The patient referred by the corresponding health specialist (digestive), and taking into account the compatibility of the symptoms presented; several types of skin lesions, inflammation of the joints (arthritis), intestinal inflammation with diarrhea and inflammation of the nervous system, both central (brain, cerebellum, brainstem, spinal cord, meninges) and peripheral nerves (arms and legs) and / or his family history (for example, a direct ascendant diagnosed with Behçet's disease) may be subject to the determination of HLA-B5 alleles group. The results of this test should not be the only ones on which the therapeutic decision is based and should be used as an aid in the diagnosis together with results of other markers of the disease.

The intended user of the kit is technical personnel trained to carry out the protocol and the interpretation of results described in the instructions for use.

Workflow



Product Information

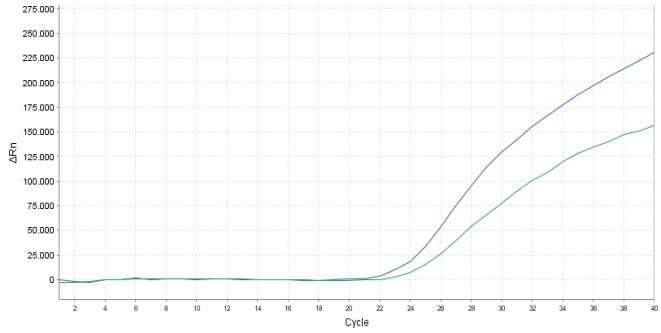
24 tests - CODE: **AA1513/24_V5** UDI-DI: **8437016942659**
48 tests - CODE: **AA1513/48_V5** UDI-DI: **8437016942666**

DE DESCRIPTION: **Genvinset® Malattia di Behçet (HLAB* 51/52), ver 5**

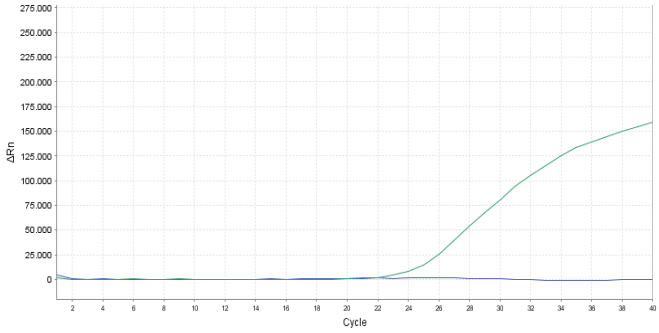
CE-IVD certified **(Notified Body 2797)**

Results

HLA-B*51/52 positive sample



HLA-B*51/52 negative sample



Limitations

- See detected alleles in the updated document "HLA alleles detected_GVS-B5v5" at www.bdrdiagnostics.com.
- Mutations or polymorphisms at annealing primer/probe sites are possible and may result in the lack of allele definition. Other technologies could be necessary to resolve the typing.
- Data and result interpretation should be revised by qualified personnel.
- This product is an auxiliary tool for the diagnosis of patients with suspected HLA-B*51/52-associated disorders. Use these results in conjunction with clinical data and results of other tests performed on the patient.

BDR
BLACKHILLS DIAGNOSTIC RESOURCES S.L.U.
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