



# Genvinset<sup>®</sup>

## HLA Narcolepsy



EUROPEAN UNION  
European Regional Development Fund  
A WAY TO MAKE EUROPE

## Molecular determination of HLA-DQB1\*06:02 alleles

Kit for detecting the HLA-DQB1\*06:02 alleles  
by Real-Time PCR using TaqMan<sup>®</sup>  
probes technology

## About Genvinset<sup>®</sup> HLA Narcolepsy

Code NLM AA1602/24

Narcolepsy is an autoimmune disorder that affects approximately 0.02 - 0.05% of the population worldwide. Narcoleptic patients frequently have severe sleepiness and fragments of Rapid Eye Movement (REM) sleep that intrude into wakefulness, such as hypnagogic (dream-like) hallucinations as they drift off to sleep, as well as brief episodes of cataplexy (muscle paralysis) triggered by strong emotions.

The importance of the immune system and its potential role in the onset of narcolepsy has been the focus of research and debate for many years. With more than 98% of narcoleptic patients carrying HLA-DQB1\*06:02, frequently in combination with HLA DRB1\*15:01, narcolepsy has one of the strongest known associations with HLA. While nearly all narcoleptic patients express HLA-DQB1\*06:02 alleles, the presence of these are not limited to narcoleptic individuals; between 12% and 38% of the general population are carriers of this group of alleles.

## Intended use

Genvinset® HLA Narcolepsy is a semi-automated *in vitro* diagnostic kit for qualitative detection of the HLA-DQB1\*06:02 group of alleles in genomic DNA extracted from whole blood, associated with narcolepsy predisposition, by Real-Time PCR using TaqMan® probes technology.

Patients who can benefit from this determination are those referred by a specialist. 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 Instructions for Use.

## Workflow



## Product Information

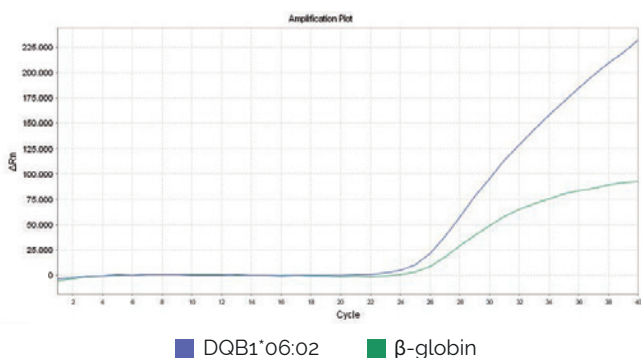
24 tests - Code NLM AA1602/24

DESCRIPTION: Genvinset® HLA Narcolepsy 24 test

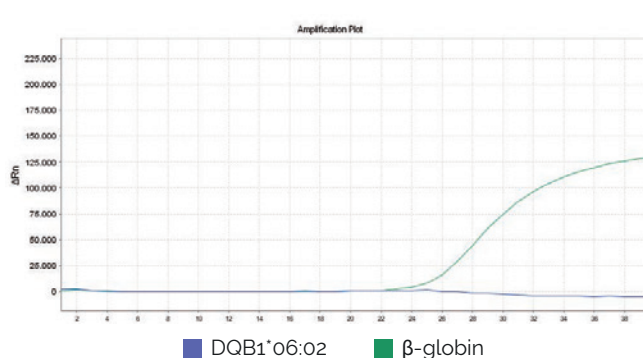
CE-IVD certified

## Results

HLA-DQB1\*06:02 positive sample



HLA-DQB1\*06:02 negative sample



## Limitations

- See detected alleles in the updated document "HLA alleles detected\_GVS-NP" at [www.bdrdiagnostics.com](http://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 narcolepsy. Use these results in conjunction with clinical data and results of other tests performed on the patient.



**BLACKHILLS DIAGNOSTIC RESOURCES S.L.U.**  
SRN: ES-MF-000001091 (Spain) · FIC GVS-NP REV. 02



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