



Genvinset[®]

HLA DQA1*05



EUROPEAN UNION
European Regional Development Fund
A WAY TO MAKE EUROPE

Molecular determination of HLA-DQA1*05 alleles

Kit for detecting the HLA-DQA1*05 alleles
by Real-Time PCR using TaqMan[®]
probes technology

About Genvinset[®] HLA DQA1*05 Real Time

Code NLM AA1702/24

Several studies suggested the role of tumor necrosis factor alpha (TNF) in chronic immune-mediated diseases, such as Crohn's disease, inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis. Therefore, anti-TNF therapies were developed and are now the most widely used biological therapies for treating immune-mediated diseases. The most prescribed anti-TNF antibodies are infliximab and adalimumab.

Prolonged use of these anti-TNF antibodies may lead to the formation of anti-drug antibodies (ADA), which can decrease the efficacy of these biologics and promote adverse reactions and treatment failure.

HLA-DQA1*05 alleles were independently associated with a high risk of infliximab antibody formation in addition to the loss of response and treatment discontinuation. Also, a genome-wide significant association between HLA-DQA1*05 and the development of antibodies against anti-TNF agents was found.

Therefore, the screening of the HLA-DQA1*05 allele may be a useful clinical tool that could predict ADA risk and guide the clinical approach of anti-TNF therapies.

Intended use

Genvinset® HLA DQA1*05 is a semi-automated *in vitro* diagnostic kit for the qualitative detection of the HLA-DQA1*05 allele in genomic DNA extracted from whole blood, associated with the immunogenicity of anti-TNF drugs, 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 in conjunction with clinical data and results of other tests performed on the patient.

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

Workflow



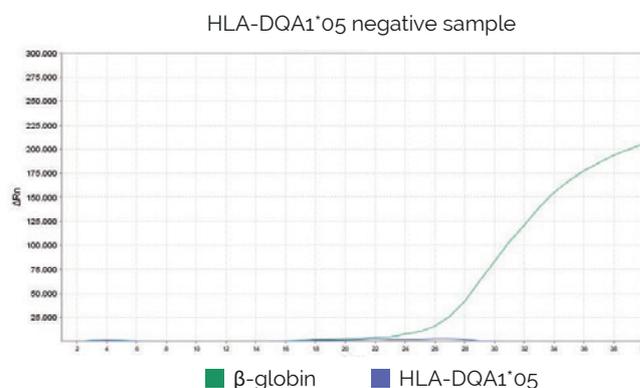
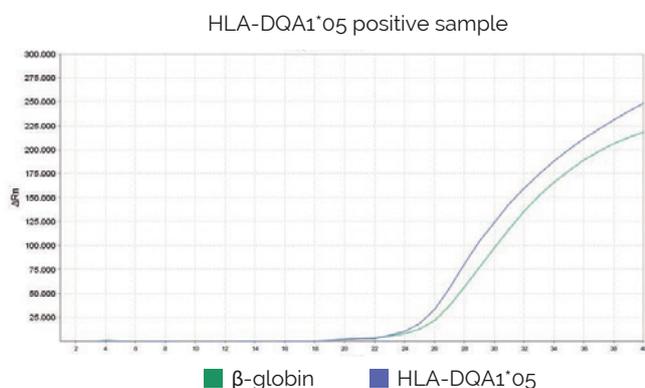
Product Information

24 tests - Code NLM AA1702/24

DESCRIPTION: Genvinset® HLA DQA1*05 Real Time 24 test

CE-IVD certified (Notified Body 2797)

Results



Limitations

- See detected alleles in the document "HLA alleles detected_GVS-DQA5" 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 clinical approach of biological therapies with an associated influence of the HLA-DQA1*05 allele. Use these results in conjunction with clinical data and results of other tests performed on the patient.



BLACKHILLS DIAGNOSTIC RESOURCES S.L.U.
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EXCLUSIVE DISTRIBUTOR

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