Genvinset® HLA Celiac Product Information

24 tests - CODE: GVS-DQ-24 UDI-DI: 8437016942093
48 tests - CODE: GVS-DQ-48 UDI-DI: 8437016942109

DESCRIPTION: Genvinset® HLA Celiac 24 test
Genvinset® HLA Celiac 48 test
CE-IVD certified

Genvinset® HLA Celiac Plus Product Information

24 tests - CODE: GVS-DQP-24 UDI-DI: 8437016942505
48 tests - CODE: GVS-DQP-48 UDI-DI: 8437016942512

DESCRIPTION: Genvinset® HLA Celiac Plus 24 test
Genvinset® HLA Celiac Plus 48 test
CE-IVD certified

BLACKHILLS DIAGNOSTIC RESOURCES S.L.U.
SRN: ES-MF-000001091 (Spain) · FIC GVS-DQ REV.04

ISO 13485 Quality Management for Medical Devices CERTIFIED

Genvinset®
HLA Celiac & HLA Celiac Plus

Molecular determination of HLA-DQB1*02, DQB1*03:02, DQA1*05 and DQA1*03 alleles

Kits for detecting the HLA-DQB1*02, DQB1*03:02, DQA1*05 and DQA1*03 alleles by Real-Time PCR using TaqMan® probes technology

About Genvinset® HLA Celiac & HLA Celiac Plus

Susceptibility to gluten sensitivity is, in part, genetically determined. The strong predisposition is associated with HLA-DQ alleles, encoding the α and β chains of the Major Histocompatibility Complex (MHC) class II.

In most populations studied, 90-95% of patients carry the HLA-DQ2 heterodimer encoded by the alleles HLA-DQA1*05 and HLA-DQB1*02 in cis or trans position. The remaining patients (5-10%) usually carry a second heterodimer, HLA-DQ8, encoded by the alleles HLA-DQA1*03:01 and HLA-DQB1*03:02. It is estimated that only 0.5% of celiac patients do not carry HLA-DQ2 or HLA-DQ8 heterodimers.

Genvinset® HLA Celiac - Intended use

Genvinset® HLA Celiac is a semi-automated *in vitro* diagnostic kit for the qualitative detection of the HLA-DQB1*02, DQB1*03:02 and DQA1*05 alleles in genomic DNA extracted from whole blood, and the consequent determination of the DQ2 and DQ8 antigens, associated with celiac disease predisposition. The kit is able to determine the homozygosity or heterozygosity status for the DQB1*02 alleles. The analysis is based on Real-Time PCR technology, using TaqMan® probes.

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 the Instructions for Use.

Genvinset® HLA Celiac Plus - Intended use

Genvinset® HLA Celiac Plus is a semi-automated *in vitro* diagnostic kit for the qualitative detection of HLA-DQB1*02, DQB1*03:02, DQA1*05 and DQA1*03 alleles in genomic DNA extracted from whole blood, and the consequent determination of DQ2 and DQ8 antigens associated to celiac disease. The kit is able to determine the homozygosity or heterozygosity status for the DQB1*02 alleles. The analysis is based on Real-Time PCR technology using TaqMan® probes.

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 the Instructions for Use.

Highlights

- The kit resolves the zygosity of the HLA-DQB1*02 allele.

- The Genvinset® Report Viewer software combines all reactions' results to determine the probable genotype and the associated risk to celiac disease.

Workflow

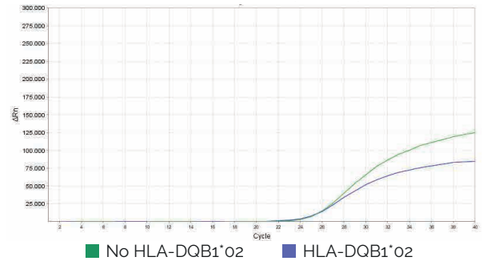
Limitations

- See detected alleles in the updated documents "HLA alleles detected_GVS-DQ" and "HLA alleles detected_GVS-DQP" 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 celiac disease. Use these results in conjunction with clinical data and results of other tests performed on the patient.

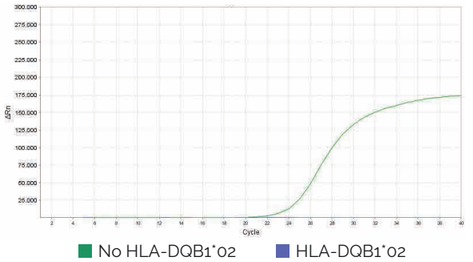
Results HLA Celiac & HLA Celiac Plus

Reaction 1

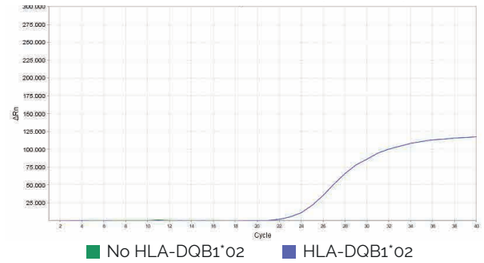
Only one HLA-DQB1*02 allele samples amplification plot



HLA-DQB1*02 homozygous samples amplification plot

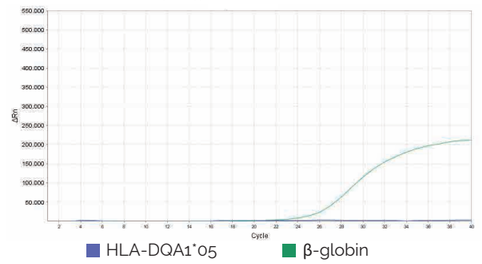


No HLA-DQB1*02 samples amplification plot

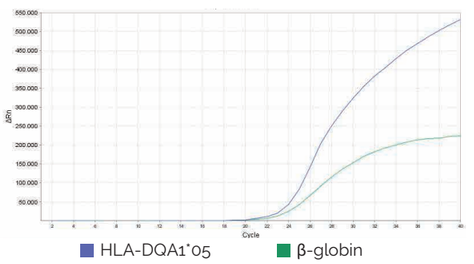


Reaction 2

HLA-DQA1*05 negative samples amplification plot

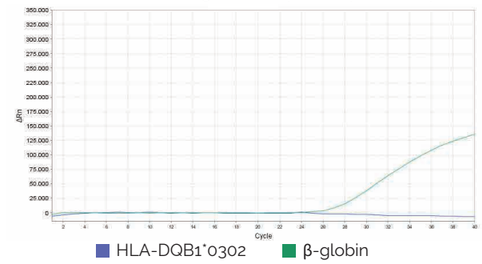


HLA-DQA1*05 positive samples amplification plot

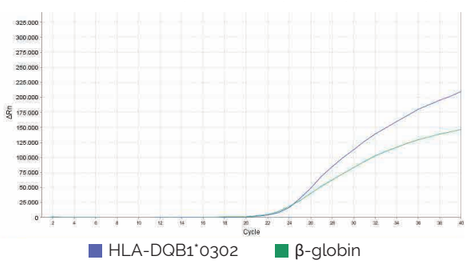


Reaction 3

HLA-DQB1*0302 negative samples amplification plot

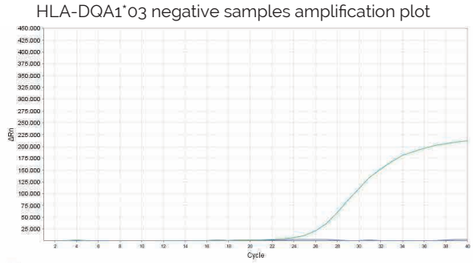


HLA-DQB1*0302 positive samples amplification plot



Results HLA Celiac Plus

HLA-DQA1*03 negative samples amplification plot



HLA-DQA1*03 positive samples amplification plot