

HLA Celiac

- ▶▶ **Celiac disease, also known gluten-sensitive enteropathy, is characterized by an inflammation of the mucosa of the small intestine as a consequence of a permanent immune reaction against ingested gluten.**
- ▶▶ The current diagnosis is based on the following criteria:
 - (1) Typical signs and symptoms (malabsorptive diarrhea);
 - (2) Anti-tissue transglutaminase antibodies, anti-deaminated gliadin peptides and/or positive anti-endomysial antibodies;
 - (3) HLA-DQ2 and/or HLA-DQ8 positive haplotypes;
 - (4) Intestinal damage (eg, villous atrophy and minor injuries);
 - (5) Clinical response to the gluten-free diet.
- ▶▶ **Celiac disease has a strong hereditary component, which can be measured by analyzing the presence or absence of different haplotypes (combination of different alleles) on chromosome 6, which indicate the predisposition to develop this disease.**
- ▶▶ **CerTest Biotec** has developed a Real-Time PCR for the typing of the main HLA haplotypes related to celiac disease in patients with suspected gene susceptibility.
- ▶▶ **This test has the advantage of requiring less time than the routine method.**



“Ready & Easy-to-use” kits.
Lyophilised product



Transport and storage at **room temperature.**
Shelf-life: 24 months



Validated according to **ISO 13485**
and **CE marked**



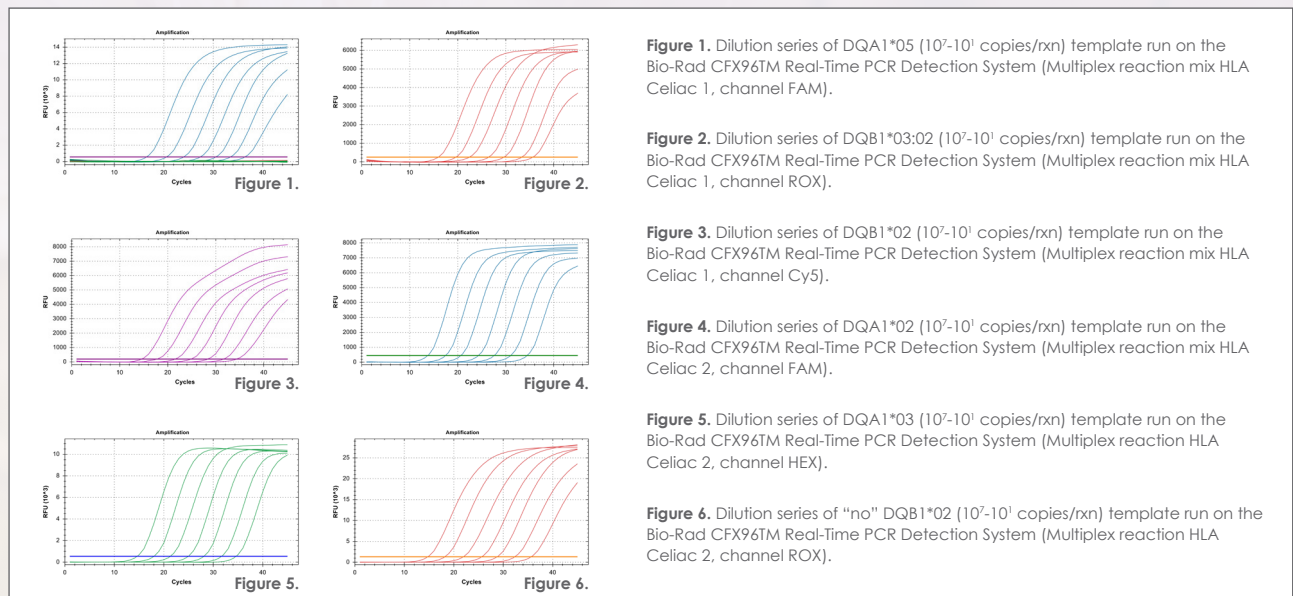
HLA Celiac

VIASURE HLA Celiac Real Time PCR Detection Kit is a real-time RT-PCR multiplexed test designed for the simultaneous qualitative detection and differentiation of the main HLA alleles (DQA1*05, DQB1*03:02, DQB1*02, DQA1*02, DQA1*03 and other alleles DQB1 different from DQB1*02) associated with celiac disease (CD) in blood samples.

This test is intended to be used as an aid in the detection of a genetic predisposition for celiac disease based on genotype identified. The absence of Celiac Disease-associated HLA-DQ2.5, HLA-DQ2.2 and HLA-DQ8 risk factors is an important exclusion criterion for CD. For the HLA-DQB1*02 allele, it can determine the status of a sample as homozygous or heterozygous. DNA is extracted from blood specimens, multiplied using Real Time amplification and detected using specific primers and a fluorescent reporter dye probe for HLA alleles.

►► Analytical sensitivity

VIASURE HLA Celiac Real Time PCR Detection Kit has a detection limit of 50 DNA copies per reaction for HLA alleles DQA1*05, DQB1*03:02, and DQB1*02; and 10 DNA copies per reaction for HLA alleles DQA1*02, DQA1*03 and "no" DQB1*02 (other alleles DQB1 different from DQB1*02)) with a positive rate of $\geq 95\%$.



►► References - VIASURE HLA Celiac Real Time PCR Detection Kit -

6 x 8-well strips, low profile _____ VS-CEL106L

12 x 8-well strips, low profile _____ VS-CEL112L

9 x 4-well strips, Rotor-Gene® _____ VS-CEL136

TUBE FORMAT WITH INTERNAL CONTROL: 4 tubes x 24 reactions _____ VS-CEL148T

6 x 8-well strips, high profile _____ VS-CEL106H

12 x 8-well strips, high profile _____ VS-CEL112H

CerTest
BIOTEC

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For more information and use procedure,
read the instructions for use included in this product.



VIASURE/HLA-0521EN