



Gluten DQuick DResolution v4

(REF: RT-59v4)

Advanced HLA Typing for
Celiac Disease Risk Assessment

WHAT IS CELIAC DISEASE?

Celiac disease is a chronic autoimmune disorder triggered by gluten ingestion in genetically predisposed individuals. The condition primarily affects the small intestine, leading to inflammation, villous atrophy, and malabsorption. The genetic predisposition is strongly associated with specific **HLA class II molecules**, particularly **HLA-DQ2** and **HLA-DQ8**, which are found in more than **95% of patients** with celiac disease.

WHY PERFORM GENETIC TESTING FOR CELIAC DISEASE?

HLA typing is a valuable tool in the diagnostic work-up of celiac disease, especially when:

- Serology and biopsy results are inconclusive
- The patient is already on a gluten-free diet
- There is a family history of celiac disease
- Early risk stratification is required. HLA genotyping enables early identification of high-risk subjects, even before symptoms or serological markers appear.

Clonit's **Gluten DQuick DResolution test v4** identifies individuals who carry the HLA-DQ2 and/or DQ8 haplotypes, which are necessary but not sufficient to develop the disease.

Its clinical value lies mainly in its negative predictive power:

Individuals who do not carry HLA-DQ2 or DQ8 have a very low risk of developing celiac disease, making further diagnostic follow-up unlikely.

WHY CHOOSE GLUTEN DQUICK DRESOLUTION V4?

- ☐ Safe and non-invasive, can be used with pediatric patients
- ☐ Comprehensive risk stratification with only 4 amplification mixes per sample
- ☐ Total resolution of DQ2 and DQ8 homozygous status
- ☐ Fast and reliable Real-Time PCR workflow



Gluten DQuick DResolution v4

Molecular diagnostic assay for the detection of HLA haplotypes associated with celiac disease predisposition, by Real-Time PCR.

KEY FEATURES

- **Starting samples:** DNA extracted from Blood EDTA and Buccal Swab
- **Manual DNA extraction:** QIAmp DNA mini kit (QIAGEN)
- **Automatic DNA extraction with:** QIAasympphony SP Robotic Workstation and CloNext12/CloNext24
- **Validated Real-Time PCR Systems:**
 - Applied Biosystems 7500 Fast (ThermoFisher SCIENTIFIC)
 - Rotor-Gene Q MDx (RG-Q MDx - QIAGEN)
 - CFX96 Real-Time PCR Detection System (Bio-Rad)
- **Software DQuick DResolution:** allows a fast and accurate automatic identification of the haplotypes
- **The kit includes all reagents for the Real-Time PCR amplification:** Internal Control (β -Globin), Positive Controls and Negative Controls
- **Package:** 48/96 tests

The Gluten DQuick DResolution v4 kit has been developed according to the AIC (Italian Celiac Association) clinical recommendations on HLA genetic testing for celiac disease (Congia M., 2022).

GENETIC TARGETS

- The test amplifies and detects the following HLA class II alleles:
- DQA1*02, DQA1*03, DQA1*05
 - DQB1*02, DQB1*03:01, DQB1*03:02
 - DRB1*03, DRB1*04, DRB1*05, DRB1*07
 - Includes two DQB1 allele groups for the precise detection of DQ2 and DQ8 homozygosity

CLINICAL RELEVANCE

- Identification of HLA haplotypes:
- DQ2 (DQ2.2, DQ2.5), DQ8, DQ7.5, DQ2.3 and in linkage disequilibrium DR3, DR4, DR7, DR5

These haplotypes are strongly associated with celiac disease and can help in risk stratification and patient management

ORDERING INFORMATION

DESCRIPTION	REF.	REGULATORY	TESTS
Gluten DQuick DResolution v4	RT-59v4	CE IVDR 0123	48
Gluten DQuick DResolution v4	RT-59v4-96	CE IVDR 0123	96
Software DQuick DResolution	PL-01	CE-IVD	