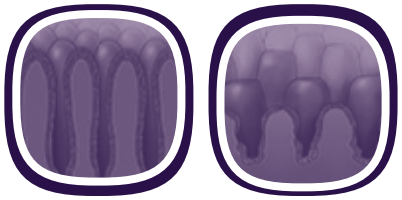
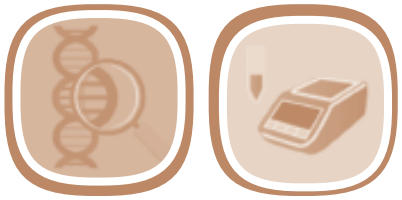
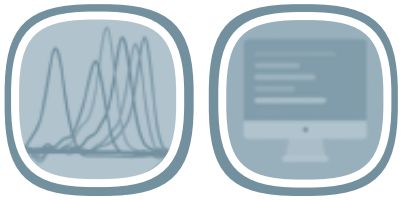
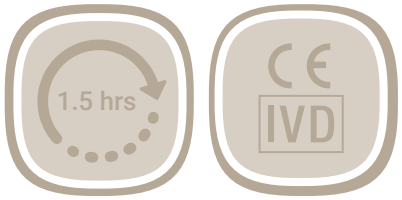
CeliaSCAN Factsheet

Celiac Disease

- Celiac disease (CD) is an autoimmune disease, where individuals develop an intolerance to gluten (wheat, barely, rye), presenting with or without symptoms such as chronic diarrhoea, nutritional malabsorption, weight loss, unexplained iron deficiency anaemia, osteoporosis or neurological symptoms
- Worldwide diagnostic prevalence ~1%, however, since most CD cases go undetected, the expected worldwide prevalence ~8%
- Treatment with strict and lifelong gluten-free diet (GFD)

Current Methods

- Sequence Specific Primers (SSP) like the Olerup HLA kit
- Sequence Specific oligonucleotide (SSO) like the Luminex
- Sequencing
- These tests are often labour intensive and require expertise to interpret the complicated results, for this reason most of these tests are relatively expensive
- Many of these tests are for research use only (RUO) and therefore not suitable for diagnostic purposes

CeliaSCAN

- Multiplex real-time PCR and Melting Curve assay
- 32 tests per kit
- Simultaneous amplification of allele specific parts in exon 2 of both the HLA-DQA1 and HLA-DQB1 genes
- 6 primer pairs detect 6 alleles in 3 reactions
- Two additional primer pairs detect monomorphic parts of the HLA-DRA and HLA-F genes and serve as amplification controls
- Detection by SYBR Green

Unique Features

- Fast (1.5 hours Assay including Analysis & Reports)
- In-house comparison with SSCP method (n=166):
  - Sensitivity ~100%
  - Specificity ~100%
- Distinguishes : HLA-DQ2.2 from HLA-DQ2.5, HLADQ2.5 homozygotes from HLA-DQ2.5 heterozygotes
- Automated analysis of results by online analysis software
- CE-IVDD Certified since July 2017, CE-IVDR expected in 2026, Indian FDA granted in October 2025

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