

## Technology Offer

### Novel Peptides for Celiac Disease Diagnosis

Ref. No.: CH462

#### Background

Hypersensitivity to gluten is causing celiac disease, a chronic disease of the small intestinal mucosa. A number of pathogenic peptide fragments of gluten, the so-called gliadins have been identified as one cause so far. The endogenous tissue transglutaminase (tTG) modifies gliadin by transforming the amino acid glutamine in glutamate. In celiac disease patients these tTG-modified gliadins represent the very pathogenic form of gliadin by interacting with increased produced HLA proteins and thereby inducing complex reactions within the small intestine mucosa and the immune system. As a result autoantibodies against the human endogenous tTG as well as antibodies against the gliadins / modified gliadins are produced by the patients. There exist *in vitro* diagnostic approaches for diagnosis of celiac disease which detect patient autoantibodies against tTG or which detect patient antibodies against gliadin or deaminated gliadin. However, the respective test sensitivities are not yet optimal and the tests are not able to detect IgA-deficient celiac disease patients.

#### Technology

A novel artificial 31 amino acid-peptide (CDP) has been generated which is assumed to mimic the natural deaminated pathogenic gliadin in its conformational structure and is able to bind serum antibodies from celiac disease patients. Using this CDP peptide in an ELISA system, 78% of celiac disease patients (cohort N= 91 celiac disease patients identified by histological results, of these were 20% anti-tTG-IgA-serum negative) can be identified (sensitivity: 78%). Furthermore, a fusion protein has been developed consisting of the human transglutaminase and the artificial CDP peptide. Using this fusion protein (tTGCDP) in an ELISA system, the sensitivity of the diagnostic test can be further increased onto 93% (sensitivity: 93%) which is more than 20% higher than the sensitivity of the commercially available anti-tTG-IgA Elisa (4033 Anti-huTransG, Generic Assay) for celiac disease used in this study. Furthermore in contrast to state of the art tests, also IgA-deficient celiac patients can be detected (90% of IgA-deficient celiac disease patients are detectable).

#### Benefits

- ✓ Higher sensitivity (93%) compared to commercial available diagnostics for celiac disease such as gliadin-based or tTG-based ELISA
- ✓ Only one fusionprotein (bi-functional) for detection of anti-tTG and anti-(deaminated) gliadin antibodies at the same time
- ✓ Also IgA-deficient celiac disease patients can be detected

#### Application

Diagnosis of celiac disease patients

#### Commercial Opportunity

Searching for a licensing or developing partner

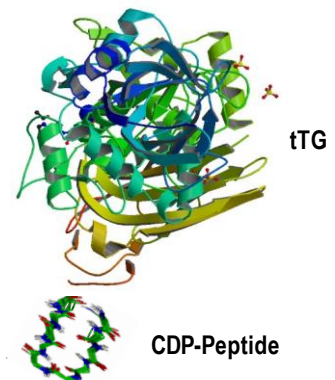


Fig. 1: Fusion protein tTGCDP as a basis for the novel ELISA approach for celiac disease diagnosis. Kindly provided by Dr. Karl Skriner

#### Key words

Celiac disease, diagnostic, gliadin, artificial peptide, tTG, transglutaminase, ELISA, fusion protein

#### Developmental Status

Patient data

#### IP Status

DE priority patent application (10/2009)  
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EP and US patent granted: 12/2015  
EP validated in: DE; GB, F, ES, IT, AT  
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#### Patent Owner

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