Celiac disease (CD) is a lifelong disorder that results in damage to the lining of the small intestine in individuals when foods with gluten such as wheat, rye, and barley are eaten. These individuals are genetically susceptible and when they eat foods containing gluten, their immune system forms antibodies to gluten, which damage the intestinal lining. The disease is therefore known as an autoimmune condition where the body is forming antibodies against its own self.

A recent study has shown that the prevalence of celiac disease in the north Indian community is ~1%.

The disease can affect both children and adults. The disease can manifest with one or more of the following symptoms of prolonged diarrhea, abdominal bloating and/or pain, bulky stools, weight loss, anemia resistant to therapy, failure to grow (in children) amongst other symptoms. These individuals have a higher risk of having other autoimmune diseases like diabetes, thyroiditis, hepatitis. The disease may exist without any symptoms especially in those with diabetes or in family members.

The first step for identifying CD is to detect self-antibodies, known as antiendomyseal and tissue transglutaminase in the blood of individuals suspected to have CD. The diagnosis is further confirmed with an intestinal biopsy, that shows characteristic changes in the small intestine while the individual is on a gluten-containing diet. Complete clinical recovery takes place and the antibodies in the blood disappear once gluten-free diet (GFD) is started.

Correct diagnosis of CD is essential because it requires lifelong adherence to gluten-free diet and long term complications like diabetes, thyroiditis, osteoporosis (thin bones) and malignancies can be prevented if the disease is diagnosed early.

Many hospitals, especially small centres across India do not have access to the conventional expensive laboratory-based tests for identifying antibodies in the blood, required as the first step for identifying CD. Once these individuals are identified in small hospitals/community they can be referred to larger hospitals where facilities for conducting confirmatory intestinal biopsies are available.

It is, therefore, imperative to have easily available, affordable, rapid, sensitive and specific tests that can identify CD correctly and also decrease the time required for the diagnosis of the disease. This highlights the need for simple point-of-care (POC) tests that give rapid results and shorten the time between diagnosis and therapeutic intervention. These can be used effectively as the initial non-invasive CD screening methods in both-people with symptoms suggestive of CD, and in high risk groups such as close family members or those with other autoimmune diseases.

The Department of Biotechnology, Government of India, has sponsored a collaborative program between the Translational Health Science and Technology Institute (THSTI), the International Centre for Genetic Engineering and Biotechnology (ICGEB), the All India Institute of Medical Sciences (AIIMS) and an industrial partner, J. Mitra and Co. for the development of affordable, indigenous, rapid sensitive and specific diagnostic tests for CD.

ICGEB designed and developed a recombinant clone for the production of antigen (human tissue transglutaminase -tTGA protein). This “know-how” was transferred by ICGEB to the J. Mitra and Co, as per DBT guidelines. AIIMS/THSTI screened CD patients and provided well-characterized positive and negative sera samples to J. Mitra and Co. The industrial partner produced this antigen at their site and then used the two components (Protein and Sera samples) and their resources to develop the final test. Testing of the diagnostic kits was done at AIIMS and by THSTI. All procedures were conducted after taking appropriate informed consent from the patients as per the requirements of the respective Institutional Ethics Committees. The whole program was coordinated by THSTI.

ICGEB New Delhi, 28 October 2014