GLUTEN SENSITIVE ENTEROPATHY
CELIAC DISEASE
DERMATITIS HERPETIFORMIS

DIAGNOSTIC KITS AND COMPONENTS

A complete range of assays for diagnosis of CELIAC DISEASE and DERMATITIS HERPETIFORMIS

REFERENCES

7. Ferreira M et al.
8. Chorzelski TP et al. Serologic Diagnosis of Celiac Disease.
21. US Patent Number 5707,204 B1

Gluten Sensitive Enteropathy (GSE) is an autoimmune disorder that may occur in genetically susceptible individuals triggered by the ingestion of gluten containing grains such as wheat, barley and rye. Patients experience an immune response against gluten as it passes through the intestines. GSE incorporates Celiac Disease (CD), a condition characterized by malabsorption resulting from inflammatory injury to the small intestinal mucosa, and Dermatitis Herpetiformis (DH), characterized by blistering of the skin and itchy rash on the head, elbows, knees, lower back and buttocks. Of the two conditions, CD is more common, with prevalence as high as 1 in 130, however, studies have found that the prevalence of CD to be highly variable from non-Hodgkin’s.

Histological examination of the small intestine biopsy remains the gold standard for diagnosing CD. However, certain patients with latent or even active CD may have normal histopathology. Serological methods of diagnosis are commonly used to screen and support diagnosis of CD and DH. The revised European Society of Paediatric Gastroenterology and Nutrition (ESPGAN) criteria for diagnosis of CD include only a single biopsy with clear cut remission of clinical symptoms on GFD. Positive serology at an early stage has deleterious effects on quality of life and may pre-dispose an individual to long term complications such as spastic atrophy and intestinal lymphoma. One study has shown incidence of lymphoma associated with the gastrointestinal tract in patients with CD to range from 3.6 percent to 40 percent. In another recent study, CD was found to be associated with significantly elevated risk for intestinal lymphoma, especially non-Hodgkin’s.

focus on celiac disease and dermatitis herpetiformis

CODE DESCRIPTION DETERMINATIONS
1114 ImmuLisa™ Endomysial antibody kit 48
1114A* ImmuLisa™ Endomysial antibody kit 48
1114A-PDE ImmuLisa™ Endomysial antibody kit 48
1114A-PE ImmuLisa™ Endomysial antibody kit 48
1115 ImmuLisa™ Reticular antibody kit 6 well
1115-18 primate distal esophagus substate slide
2153-18 primate distal esophagus substate slide
2153 primate esophagus substate slide
2160 primate smooth muscle substate slide
2621 primate kidney substate slide
2621-8 primate kidney substate slide
2200 EMA positive control
2201 ARA positive control
2000 IgG conjugate with counterstain
2000 IgG conjugate
2007 IgA conjugate
2007 IgA conjugate
2131 IgA/IgG conjugate with counterstain
2133 IgA/IgG conjugate
2222 rat kidney substrate slide
2251 ARA positive control 0.5ml
1115G ImmuLisa™ Celiac G+ (Gliadin) IgG ELISA 96
5144A Celiac tTG IgA Enhanced ELISA 96
1144 ImmuLisa™ hu tTG Ab IgA/IgG ELISA 96
1144G ImmuLisa™ hu tTG Ab IgG ELISA 96
1114G ImmuLisa™ hu tTG Ab IgA/IgG ELISA 96
1117A ImmuLisa™ Glutamin Ab IgA ELISA 96
1117G ImmuLisa™ Glutamin Ab IgG ELISA 96
1117S* ImmuLisa™ Glutamin Ab (AGA) Screen ELISA 96
1144 ImmuLisa™ hu tTG Ab IgA ELISA 96
5159A ImmuLisa™ Celiac G+ (Gliadin) IgG ELISA 96
5159G ImmuLisa™ Celiac G+ (Gliadin) IgM ELISA 96
5144A Celiac tTG IgA Enhanced ELISA 96
5144G Celiac tTG IgG Enhanced ELISA 96
5159A Celiac G+ (Gliadin) IgA ELISA 96
5159G Celiac G+ (Gliadin) IgM ELISA 96

*For research use only in the US
Serology offers a less invasive alternative to biopsy when considering a diagnosis. Since 1983, IMMCO has specialized in ENDOMYSA L ANTIBODIES [EMA]. A number of studies have noted the presence of anti-reticulin antibodies in patients with CD and DH. The detection of ARA is performed primarily by indirect immunofluorescence: primatesubstrates for EMA detection by such substrates for EMA. In 1973, Rizzetto and Doniach identified five different ARA reaction patterns. Of these, the R1 pattern, characterized by peri-glomerular, peri-tubular, and peri-vascular staining of mouse or rat kidney is associated with GSE. This typical ARA staining pattern appears in the image array above.

EMMA are detected on primate smooth muscle tissues. IMMCO offers two such substrates for EMA detection by indirect immunofluorescence: primate smooth muscle (bladder) and primate distal esophagus. These tissues have been selected for optimal reactions, providing a balance of maximum sensitivity and minimum background.

RETICULIN ANTIBODIES [ARA]
A number of studies have noted the presence of anti-reticulin antibodies in patients with CD and DH. The detection of ARA is performed primarily by indirect immunofluorescence. ARA by definition are detected in rodent tissue.

In 1973, Rizzetto and Doniach identified five different ARA reaction patterns. Of these, the R1 pattern, characterized by peri-glomerular, peri-tubular, and peri-vascular staining of mouse or rat kidney is associated with GSE. This typical ARA staining pattern appears in the image array above.

Both IgG and IgA immunoglobulin class ARA occur in GSE. IgA ARA are the more specific and sensitive marker. Specificity of IgA ARA has been reported from 59% - 100% with sensitivity ranging from 30-95%. IgG ARA occur less frequently, either in conjunction with IgA class ARA or in CD patients who are IgA deficient.

IMMCO Correlation with Biopsy

<table>
<thead>
<tr>
<th>EMA</th>
<th>IgA EMA</th>
<th>IgG EMA</th>
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<tbody>
<tr>
<td>133</td>
<td>132</td>
<td>129</td>
</tr>
</tbody>
</table>

*NO SECOND BIOPSY IN 11 CASES*

Tissue Transglutaminase (TG) Antibodies
Tissue Transglutaminase (tTG) has been identified as the endomysial autoantigen in CD. tTG belongs to a Ca²⁺ dependent acyl transferase that catalyze the cross-linking of proteins post translationally. Antibodies to tTG are present in over 95% of celiac patients and antibody levels seem to correlate with the presence or absence of gluten in the diet. The advantage of the anti-tTG antibody assay is that it is easily automatable and less subjective than EMA. For this reason, many laboratories have opted to use tTG antibody methods for high volume testing.

The Immulisa human tTG assays incorporate a patented technology to enhance sensitivity and specificity. These methods allow detection of both IgA and IgG antibody isotypes, facilitating proper diagnosis of CD even in cases of IgA deficiency. A total tTG (IgA/IgG) antibody assay is also available for screening applications. The correlation between well standardized tTG and EMA results is quite strong as indicated in the table below.

Table 1: Comparative Study of tTG ELISAs

<table>
<thead>
<tr>
<th>HUMAN tTT ANTIBODY ELISA</th>
<th>CD PATIENTS</th>
<th>CHILDREN</th>
</tr>
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<tbody>
<tr>
<td>IG A</td>
<td>SENSITIVITY</td>
<td>SPECIFICITY</td>
</tr>
<tr>
<td>IGG</td>
<td>97%</td>
<td>95%</td>
</tr>
<tr>
<td>IMMCO New Kit</td>
<td>97%</td>
<td>95%</td>
</tr>
<tr>
<td>Competitor</td>
<td>97%</td>
<td>95%</td>
</tr>
</tbody>
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Table 2: Comparative Study of Gliadin Peptide ELISAs

<table>
<thead>
<tr>
<th>GLIADIN ELISA</th>
<th>IgA</th>
<th>SENSITIVITY</th>
<th>SPECIFICITY</th>
<th>91%</th>
<th>97%</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMCO Celiac G+</td>
<td>84%</td>
<td>96%</td>
<td>91%</td>
<td>97%</td>
<td></td>
</tr>
<tr>
<td>Competitor</td>
<td>64%</td>
<td>92%</td>
<td>90%</td>
<td>98%</td>
<td></td>
</tr>
</tbody>
</table>

IMMCO has developed next generation assays for detection of gliadin antibodies: the Immulisa Celiac G+ IgA and IgG ELISAS. Celiac G+ incorporates proprietary gliadin peptides that significantly improve sensitivity and specificity. In combination with Immulisa tTG antibody assays, the Celiac G+ systems provide the total solution in CD diagnosis.