Cambridge Nutritional Sciences

FOOD INTOLERANCE TESTING

New Insights in Diagnosis of Food Intolerances

Christiane Loose

Regional Sales Director

Omega DIAGNOSTICS GROUP PLC

Omega Diagnostics Group Plc History:

1987

Omega Diagnostics Ltd founded

2006

Public Listing

2007

Acquisition of Genesis Diagnostics and Cambridge Nutritional Sciences.

2010

Acquisition of IVD Division of Allergopharma

2011

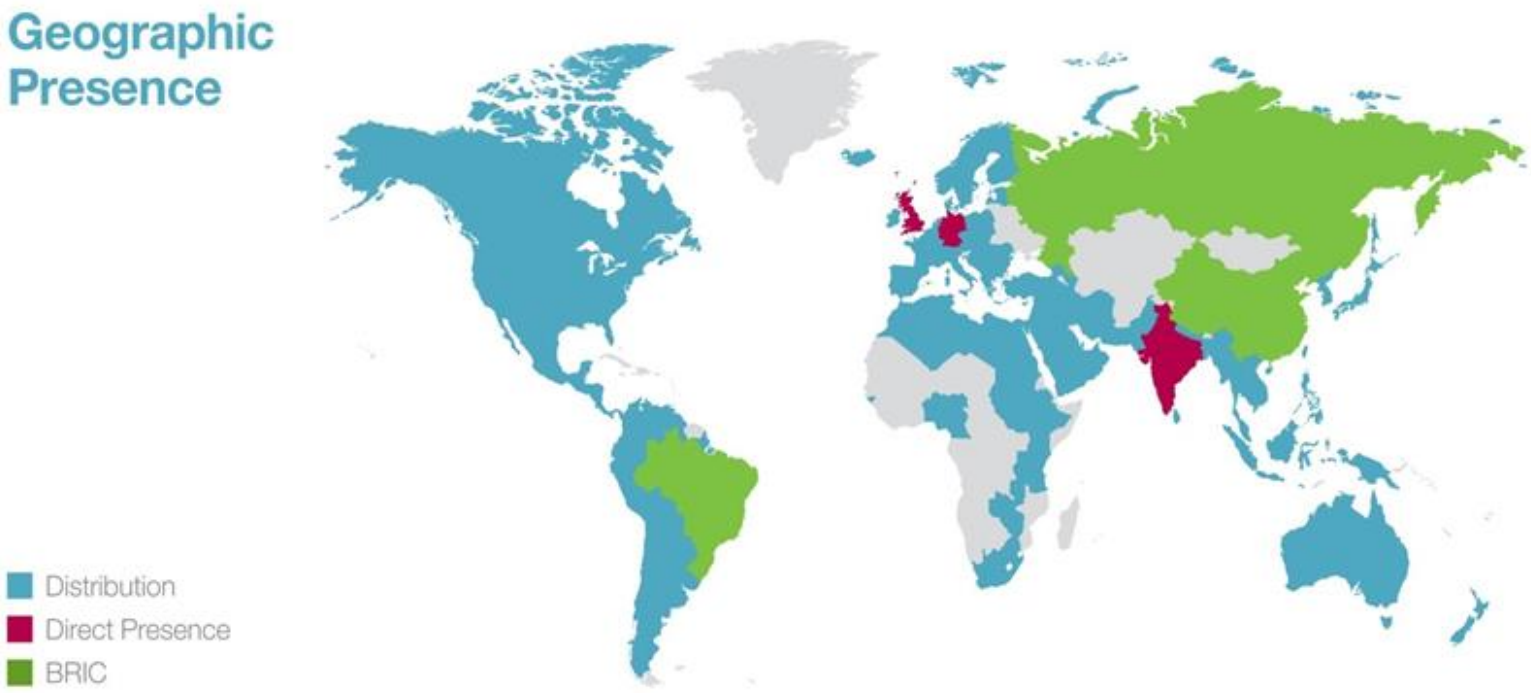
Formation of Indian Subsidiary Omega Dx (Asia) Pvt Ltd.

2012

Partnership with Burnet Institute CD4

Omega DIAGNOSTICS GROUP PLC

Global Presence



> 100 countries

Omega DIAGNOSTICS GROUP PLC

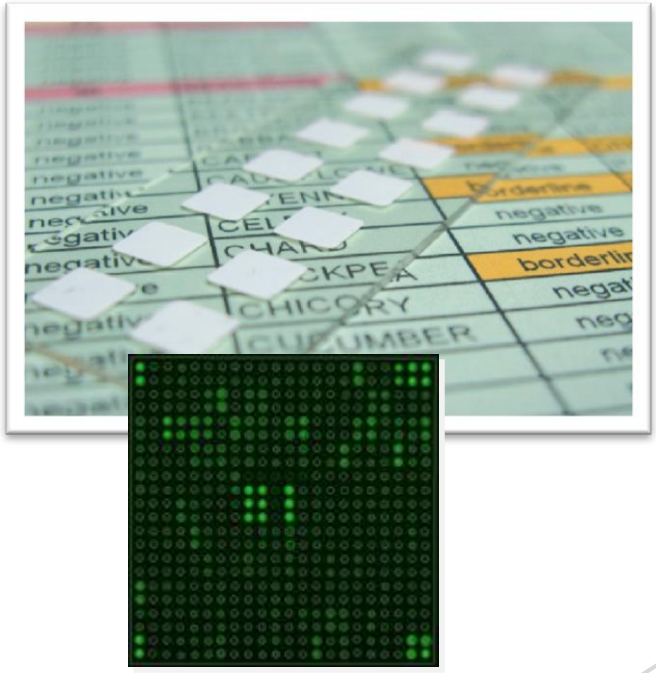
Cambridge Nutritional Sciences

- First ELISA to detect IgG against specific foods
- Food Detective® – POC test, designed for use by patients and health practitioners, based on macroarray technology
- Lab service: various panels of IgG tests and a range of complementary tests for patients suffering from food intolerance
- Support by qualified, BANT registered nutritionists
- ISO certified, accredited and member of the British In Vitro Diagnostics Association (BIVDA)
- CNS branding of Genesis FIT products - Global CNS Brand Franchise

Food Intolerance Product Range

- Food Detective

- Genarrayt / FoodPrint Microarray

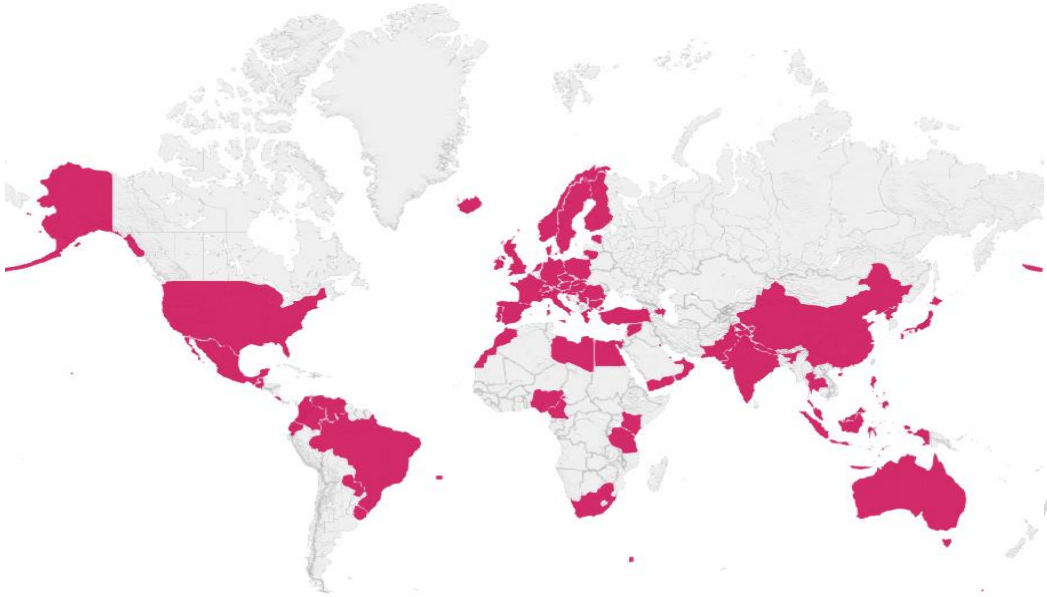


Food Intolerance Product Range

Growing International Coverage

- FD registered and sold into 74 countries worldwide

Year	No. of Countries
2007	2
2008	8
2009	23
2010	42
2011	66
2012	69
2013	72
2014	**74**



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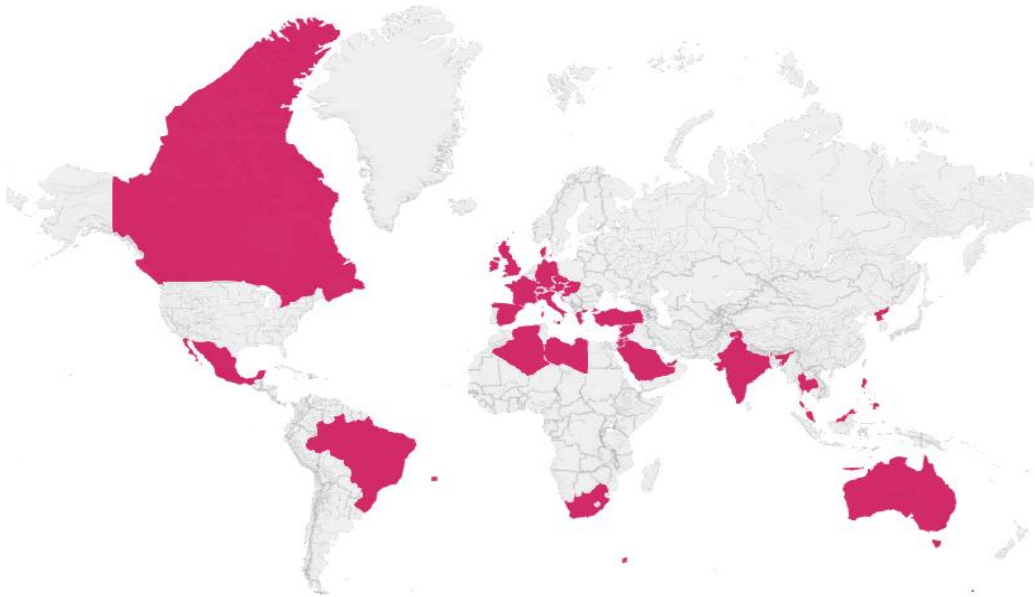
Food Intolerance Product Range

Growing International Coverage

- FoodPrint Microarray registered and sold into 35 countries worldwide

Year	No. of Countries
2007	1
2008	1
2009	10
2010	18
2011	24
2012	28
2013	31
2014	**35**



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Food Intolerance Product Range

Growing Sales since 2008

Food Intolerance (IgG)

Allergy UK

"45% of the British population suffer from a food intolerance"

- Non-specific / multiple symptoms
- Most people are undiagnosed

Symptoms of Food Intolerance

Respiratory:	Asthma, rhinitis, sinusitis, persistent cough, catarrh
Gastrointestinal:	IBS, Crohn's disease, abdominal pain, diarrhoea, constipation, bloating, flatulence
Skin:	Eczema, rashes, spots
CNS:	Headache, migraine, hyperactivity (ADHD)
Cardiovascular:	Heart palpitations
Musculoskeletal:	Joint pain, rheumatoid arthritis, muscle pain, fibromyalgia
Psychiatric:	Chronic fatigue, insomnia, ME, anxiety, depression
Metabolic:	Weight gain / water retention

IgE and IgG Responses to Food

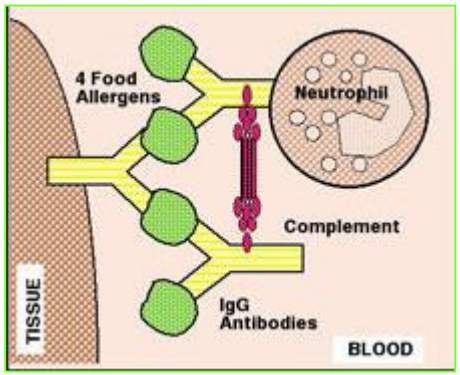
- Immediate onset
  IgE-mediated, skin test positive, often self-diagnosed

- Delayed onset
  IgG-mediated, skin test negative, rarely self-diagnosed

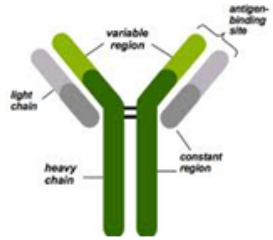
also called: Food Intolerance - UK
Food Sensitivity - US

IgG Response to Food

- Food proteins are recognised as “foreign”
- Food specific IgG production and formation of antigen/antibody complexes
- Complexes are deposited in tissues and activate complement
- Complement and macrophages stimulate inflammation
- Reaction is delayed and may last for days



IgG Antibodies



- Predominantly involved in secondary responses
- There are four sub classes of IgG antibody IgG1, IgG2, IgG3 and IgG4
- Bind to many kinds of ‘foreign substances’ in the body
- IgG protects by agglutination and immobilisation
- Formation of complexes and deposition in tissue

IgG Subclasses

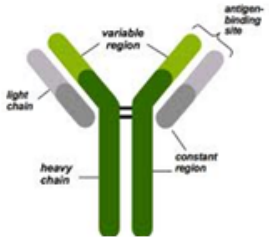
SUBCLASS	ABUNDANCE
IgG1	66%
IgG2	23%
IgG3	7%
IgG4	4%

IgG SUBCLASS PROPERTIES

PROPERTY	IgG1	IgG2	IgG3	IgG4
Neutralisation	++	++	++	++
Activation of complement pathway	**++**	+	**+++**	
Opsonisation	**+++**	+	**++**	
Binding to macrophages	++	+	+++	++
Binding to neutrophils	+		+	

- IgG1 and IgG3 have strong **pro-inflammatory** properties
- IgG4 has protective, **anti-inflammatory** properties

IgG4 FUNCTION



- Acts as a counter part of IgE: Catches and neutralizes the (food) antigen before IgE can bind to it
- IgG4 acts to prevent acute allergic reactions (Type I allergy)
- IgG4 is the only IgG subclass which does not cause inflammatory processes
- No involvement with Type III (IgG-mediated) food intolerance
- CNS FoodDetective® and FoodPrint® Microarray detects total IgG for more accurate results

Food IgG Assays

- Detect the presence of IgG antibodies to specific foods which may be implicated in food intolerance in symptomatic patients
- Do not diagnose food intolerance!
- Provide a means to identify the foods most likely to cause a symptom, provided the symptoms are food related

Link Between IgG Antibodies and Symptoms

Compromised immune system

and / or

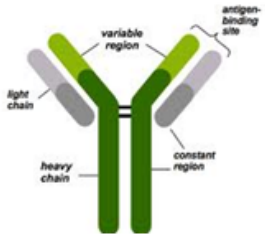
Increased gut permeability

Mechanisms of Food Intolerance

HEALTHY gastrointestinal tract and HEALTHY immune system:

- Foods digested and broken down to glucose, amino acids and fatty acids
- Absorbed through the gut lining
- Partially digested foods will also pass between cells into bloodstream
- Antibodies produced against these partially digested foods
- Form antigen / antibody complexes (normal)
- Efficient immune system will clear these complexes

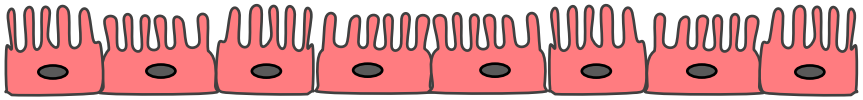
No symptoms despite an immune response occurring



Normal Response to Food

Food

Healthy Gut



Healthy
Immune System

Low level of
Ab/Ag complexes

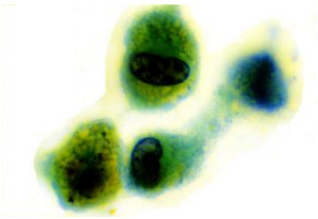
Complexes removed by macrophages

No symptoms

Mechanisms of Food Intolerance

HEALTHY gastrointestinal tract, but COMPROMISED immune system:

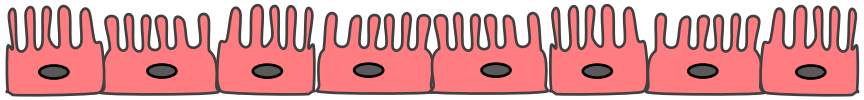
- Partially digested foods pass through the gut lining
- Antibodies produced against these partially digested foods
- Ab/Ag complexes form (normal)
- Compromised immune system - insufficient macrophages produced
- Ab/Ag complexes not cleared and circulate in bloodstream
- Deposited in tissues – causes inflammation



Compromised Immune System

Food

Healthy Gut



Compromised Immune System

Low level of
Ag/Ab complexes

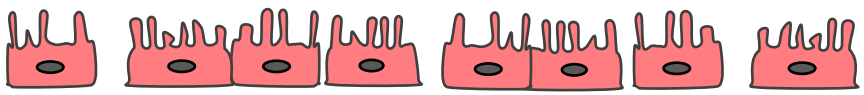
excess complexes
deposited in tissues

Symptoms

Mechanisms of Food Intolerance

LEAKY gastrointestinal tract and NORMAL immune system:

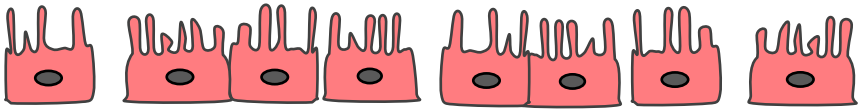
- Gut wall becomes more permeable
- Tight junctions in epithelial layer open up
- Increased number of partially digested foods enter bloodstream
- Ag/Ab complexes form – immune system becomes overloaded
- Complexes cannot be cleared and are deposited in tissues



Leaky Gut

Food

Leaky Gut



Normal
Immune System

High level of
Ag/Ab complexes

excess complexes
deposited in tissues

Symptoms

Factors Linked to Leaky Gut

- Antibiotics
- Medication/Drugs
- Candida overgrowth

Heal gut with supplements and diet

- Alcohol
- Poor diet
- Stress
- Low stomach acid
- Low pancreatic enzymes

Foods commonly associated with Food Intolerance

Cows Milk

Cheese

Nuts

Gluten

Wheat

Egg

Soya

Yeast

FoodDetective

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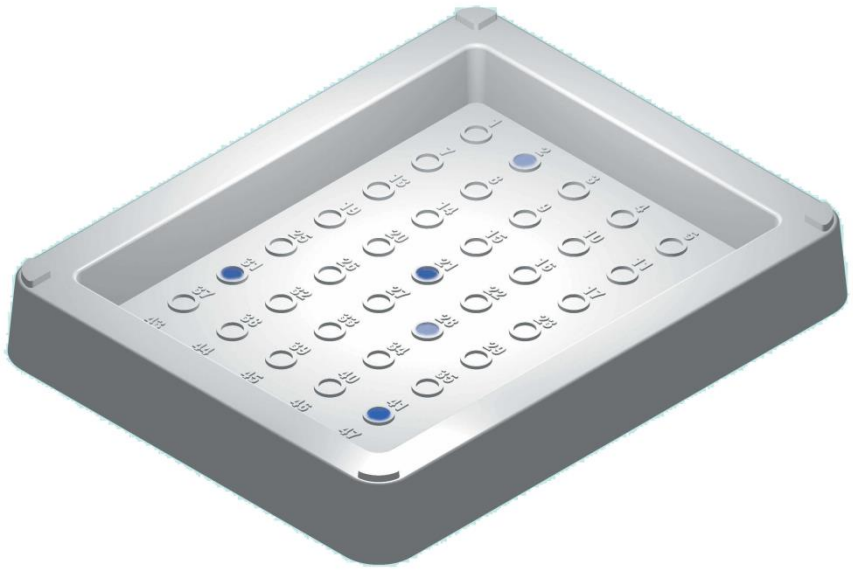
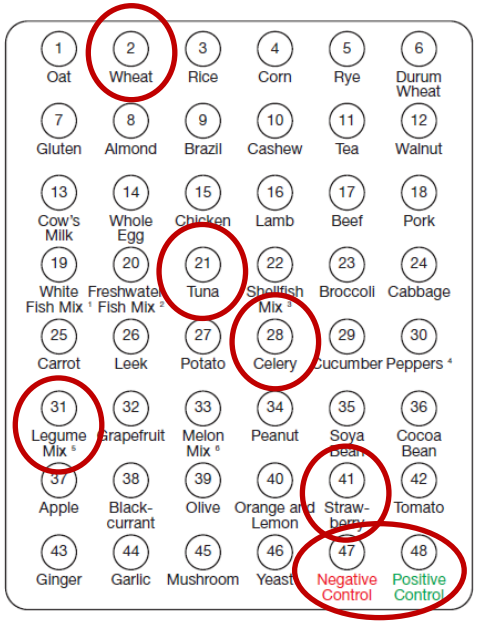
FoodDetective





- Easy procedure
- Visual reading of the results
- Easy identification of the foods

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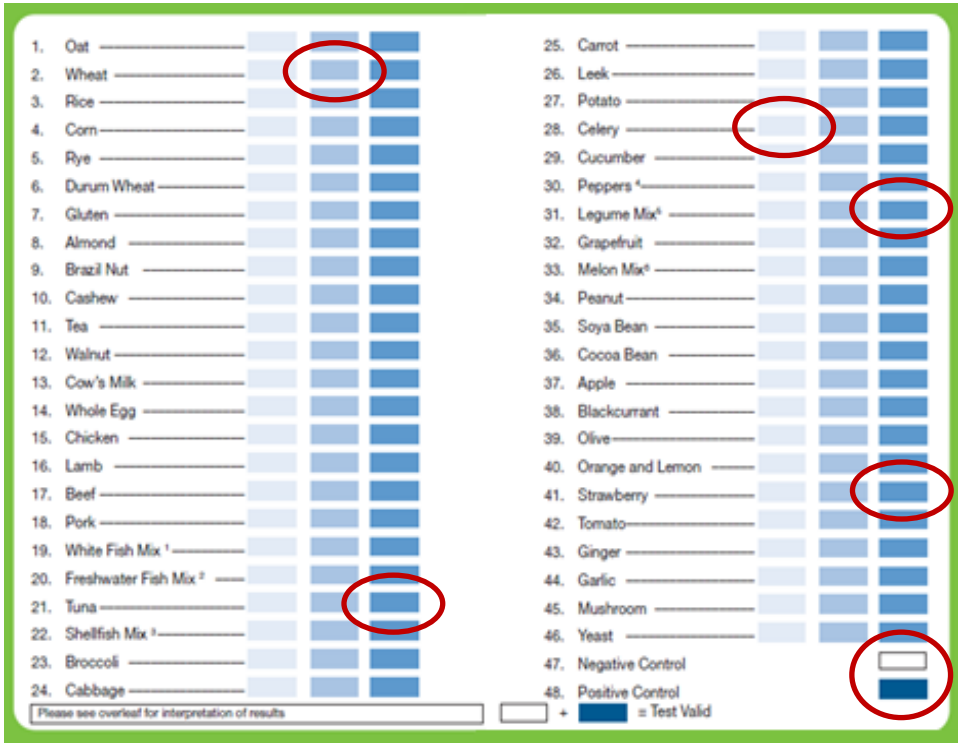
Result Card



CONTROLS

Result Interpretation

White	NEGATIVE	×	IgG
Pale blue	WEAK POSITIVE	✓	IgG
Mid blue	POSITIVE	✓	IgG
Dark blue	STRONG POSITIVE	✓	IgG

Result Interpretation

Ring / halo	INVALID
Negative Control	must be WHITE
Positive Control	must be **BLUE**

59 Foods Tested

GRAINS
Oat
Wheat
Rice
Corn
Rye
Durum Wheat
Gluten

OTHER
Cocoa Bean
Tea
Yeast

DAIRY / EGGS
Cow's milk
Whole egg

FRUIT
Apple
Blackcurrant
Grapefruit
Melon mix
Olive
Orange and Lemon
Strawberry
Tomato

VEGETABLES
Broccoli
Cabbage
Carrot
Celery
Cucumber
Leek
Legume mix
Mushroom
Peppers
Potato
Soya Bean

FISH / SEAFOOD
White fix mix
Freshwater mix
Tuna
Shellfish mix

MEAT
Beef
Chicken
Lamb
Pork

HERBS / SPICES
Garlic
Ginger

NUTS / SEEDS
Almond
Brazil Nut
Cashew
Peanut
Walnut

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FOODPRINT®

IgG Microarray Food Intolerance Test

- Food extracts ‘printed’ onto nitrocellulose pads

FoodPrint Testing Process

Finger-prick sample

Send to Budalab

FoodPrint Microarray

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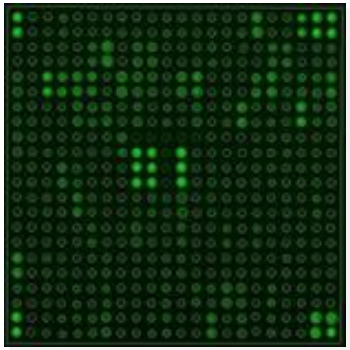
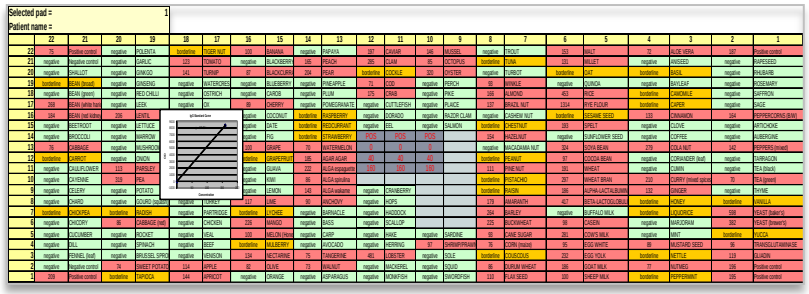
FoodPrint performed in Budalab

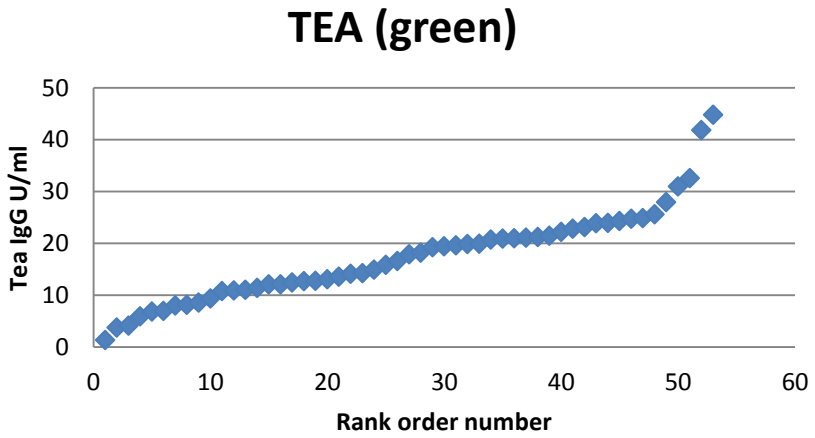




Hi-res optical scan → Data conversion → Test Report

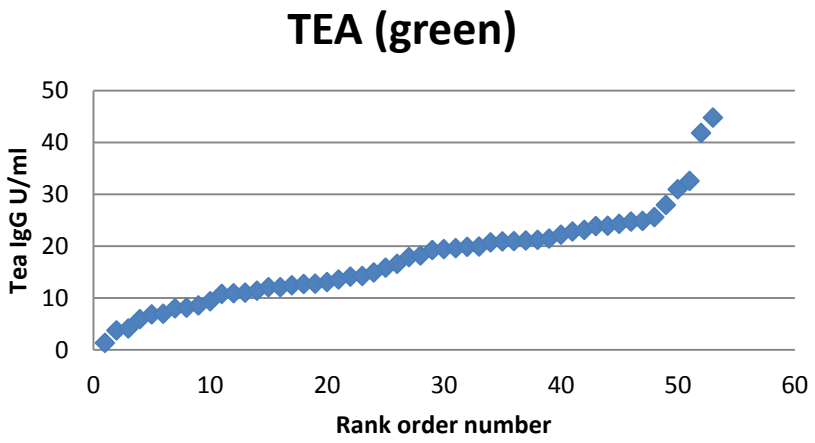
CNS Foodprint® 200+ Food IgG Reference Range Determination

- Samples from a mixed population worldwide assayed, slides scanned and data generated using reporting software
- IgG concentrations U/ml for each food put into rank order e.g. 0 – 45 U/ml
- Scatter plot generated



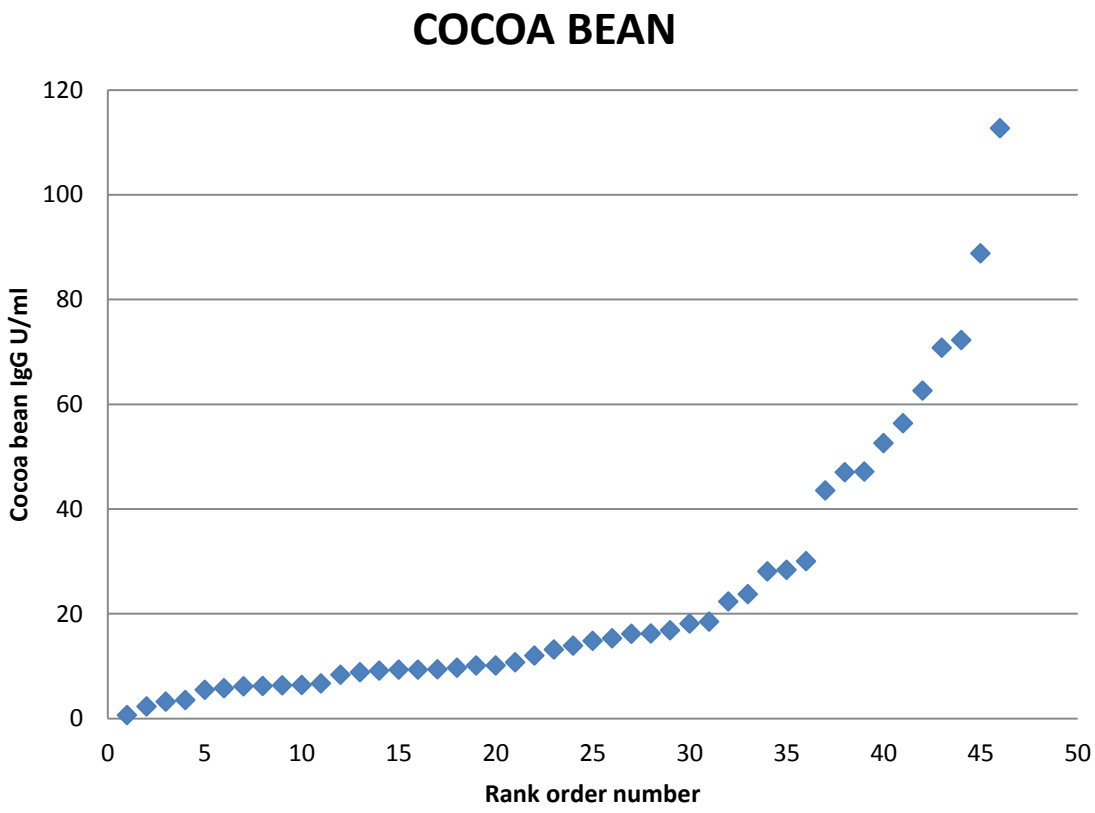
CNS Foodprint® 200+ Food IgG Reference Range Determination

- From the scatter plot, we determine the 'IgG concentration' that identifies the subpopulation with elevated IgG responses to that food

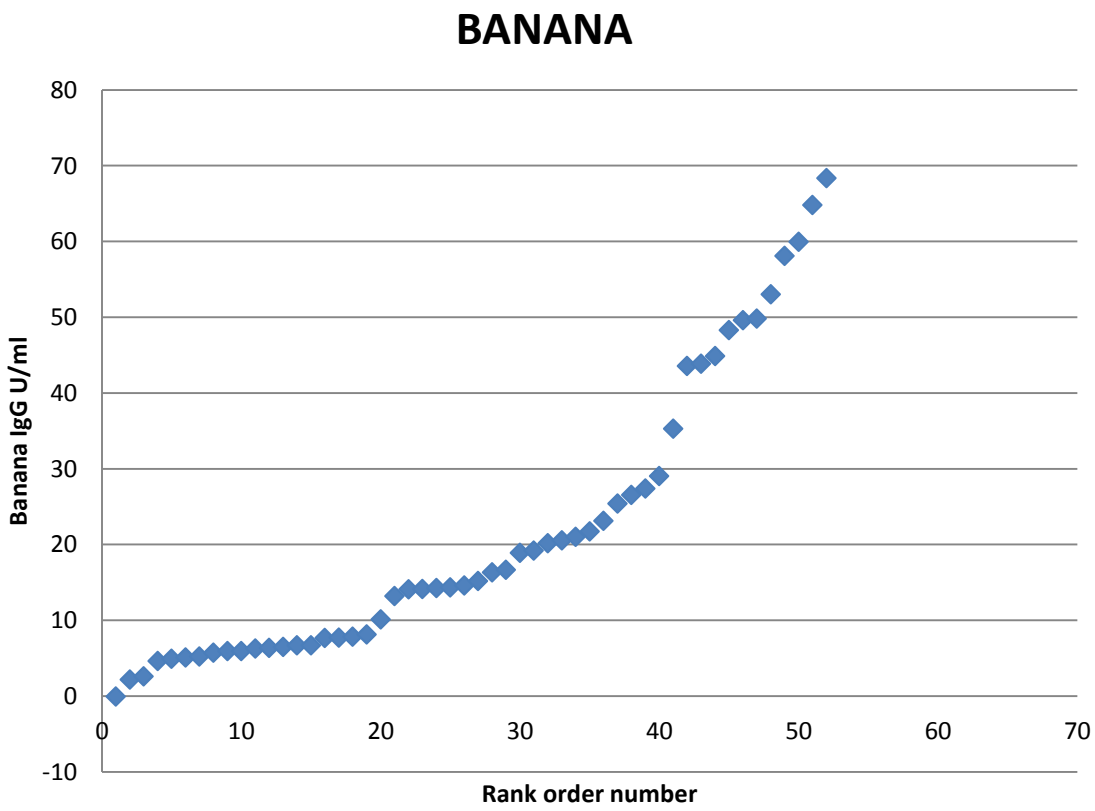


- Concentration corrected in the software to give borderline as 24-30 U/ml and elevated >30 U/ml for all foods

CNS Foodprint® 200+ Food IgG Reference Range Determination



CNS Foodprint® 200+ Food IgG Reference Range Determination



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CNS Foodprint® 200+ Food List

Agar Agar	Black/White Pepper	Clam	Gingko	Marrow	Pike	Sesame seed	Walnut
Alga	Blackberry	Clove	Ginseng	Melon (Honeydew)	Pine Nut	Shallot	Watercress
Alga	Blackcurrant	Cockle	Gliadin	Millet	Pineapple	Sheep Milk	Watermelon
Alga	Blueberry	Cocoa Bean	Goat Milk	Mint	Pistachio	Shrimp/Prawn	Wheat
Almond	Brazil Nut	Coconut	Gourd	Mixed Peppers	Plaice	Sole	Wheat Bran
Aloe Vera	Broccoli	Cod	Grape	Monkfish	Plum	Soya Bean	Wild Boar
Alpha-lactoglobulin	Brussel Sprout	Coffee	Grapefruit	Mulberry	Polenta	Spelt	Winkle
Amaranth	Buckwheat	Cola Nut	Guava	Mushroom	Pomegranate	Spinach	Yeast(bakers)
Anchovy	Buffalo Milk	Coriander	Haddock	Mussel	Pork	Squid	Yeast(brewers)
Aniseed	Cabbage	Corn	Hake	Mustard Seed	Potato	Strawberry	Yucca
Apple	Cabbage (Red)	Couscous	Hazelnut	Nectarine	Quail	Sunflower Seed	
Apricot	Camomile	Cow's Milk	Herring	Nettle	Quinoa	Sweet Potato	
Artichoke	Cane Sugar	Crab	Honey	Nutmeg	Rabbit	Swordfish	
Asparagus	Caper	Cranberry	Hops	Oat	Radish	Tangerine	
Aubergine	Carob	Cucumber	Horse	Octopus	Raisin	Tapioca	
Avocado	Carp	Cumin	Kiwi	Olive	Rapeseed	Tarragon	
Banana	Carrot	Cuttlefish	Lamb	Onion	Raspberry	Tea(black)	
Barley	Casein	Date	Leek	Orange	Razor Clam	Tea(green)	
Barnacle	Cashew Nut	Dill	Lemon	Ostrich	Red Chilli	Thyme	
Basil	Cauliflower	Dorado	Lentil	Ox	Redcurrant	Tiger Nut	
Bass	Caviar	Duck	Lettuce	Oyster	Rhubarb	Tomato	
Bayleaf	Cayenne	Durum Wheat	Lime	Papaya	Rice	Transglutaminase	
Bean(broad)	Celery	Eel	Liquorice	Parsley	Rocket	Trout	
Bean(green)	Chard	Egg White	Lobster	Partridge	Rosemary	Tuna	
Bean(red-kidney)	Cherry	Egg Yolk	Lychee	Pea	Rye Flour	Turbot	
Bean (haricot)	Chestnut	Fennel	Macadamia Nut	Peach	Saffron	Turkey	
Beef	Chicken	Fig	Mackerel	Peanut	Sage	Turnip	
Beetroot	Chickpea	Flax Seed	Malt	Pear	Salmon	Vanilla	
Beta-lactoglobulin	Chicory	Garlic	Mango	Peppermint	Sardine	Veal	
Billy Goat	Cinnamon	Ginger	Marjoram	Peach	Scallop	Venison	

Managing Results – Summary of Advice

- Eliminate foods with strong reaction (**ELEVATED** foods) for at least 3 months
- Reduce / rotate foods with moderate reaction (**BORDERLINE** foods) for at least 3 months
- Eat foods freely from the **NORMAL** group
- Replace foods with a similar food from that food group
- Eat a varied diet
- Repair leaky gut
- Support immune system

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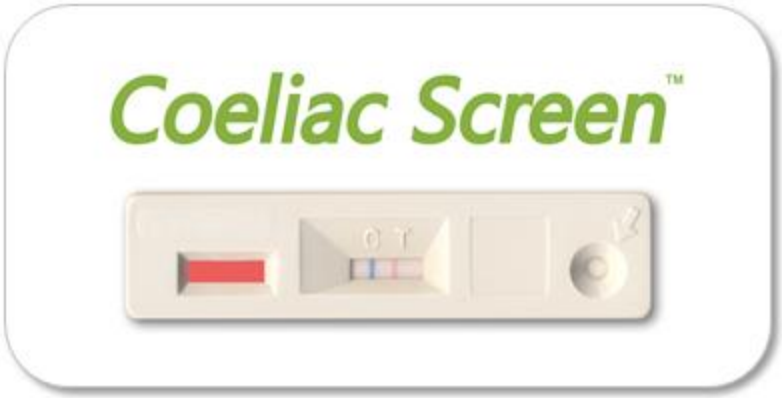
Coeliac Disease

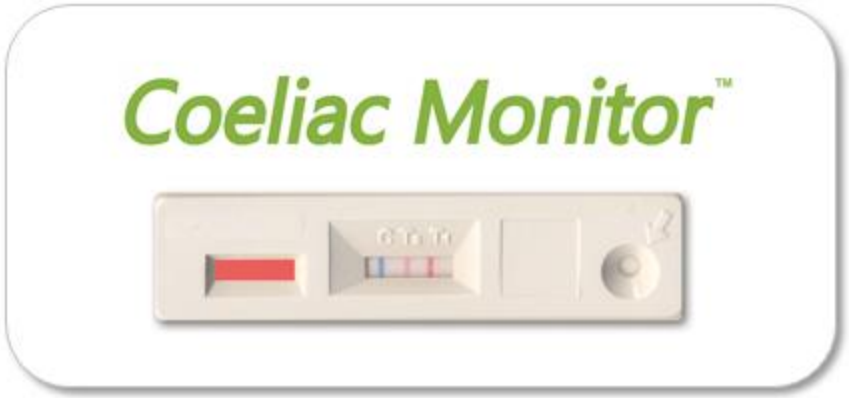
Product Information

Coeliac Disease

- Autoimmune disease caused by a permanent intolerance to gluten
- Gluten found in cereals: wheat, barley and rye
- Gluten consists of Gliadins and Glutenins
- Body's reaction to Gliadin responsible for Coeliac disease
- Immune system produces autoantibodies that attack the lining of the small intestine
- Approximately 1/100 people have Coeliac disease
- Many people are undiagnosed (4/5 cases)

Product Range





- ✓ Rapid, point-of-care tests
- ✓ Lateral flow principle
- ✓ Finger-prick whole blood
- ✓ CE-marked kits

Coeliac Screen™

Detects antibodies against **tissue transglutaminase (tTg)**:

IgA, IgG & IgM

- ✓ IgA antibody – key autoantigen in CD
- ✓ IgG antibody – to also detect IgA-deficient patients (approx. 3%)

SCREENING test

Coeliac Monitor™

Detects antibodies against tissue transglutaminase (tTg) and Gliadin:

tTG IgA + Gliadin IgA

- ✓ tTG IgA antibody – tTG key autoantigen in CD
- ✓ Gliadin IgA antibody – Gliadin associated with consumption of gluten

MONITOR effectiveness of gluten-free diet

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Result Interpretation

Coeliac Screen™

NEGATIVE

tTG IgA/G/M
POSITIVE

INVALID

Cambridge Nutritional Sciences

Result Interpretation

Coeliac Monitor™

NEGATIVE

tTG IgA
POSITIVE

Gliadin IgA
POSITIVE

tTG +Gliadin IgA
POSITIVE

INVALID

Thank you!