

# Analytical test kits to ensure gluten-free food



#### Gluten-free food for gluten intolerant patients

Coeliac disease is triggered by <u>gluten</u> (proteins found in wheat, barley and rye) resulting in damage of the small intestine. The only treatment is a lifelong adherence to a gluten-free or reduced gluten diet.

RIDASCREEN® Gliadin is the most used test kit worldwide to quantify the gluten concentration in food. The

R5-antibody used in the test kit detects the prolamins of wheat, rye and barley, with no cross reactivity to soy and oats. This Mendez ELISA R5 method has been validated in several international collaborative studies and obtained AOAC and AACCI approvals.

# Codex Alimentarius and the Mendez ELISA R5 method



The Codex Standard 118-1979 (revised 2008) sets limit values for gluten-free food (< 20 mg/kg gluten). This method consists of R5 sandwich ELISA (like RIDASCREEN® Gliadin) and the Cocktail (patented) for which R-Biopharm is the exclusive license holder.

The AOECS (Association of European Celiac Societies) is in charge of licensing the "crossed grain" label to help consumers identifying gluten-free food. The AOECS recommends the R5 Sandwich ELISA (Mendez) for natural and heat-processed foods and the R5 competitive ELISA for hydrolyzed food.

## R5 test kits – dip stick or ELISA (competitive/sandwich)



Depending on food processing, different test kits are recommended for gliadin analysis as can be seen in Table 1. The test kits are useable for matrixes like biscuits, bread, chocolate, cereals and also for

hydrolyzed food like beer, starch syrup, starch, malt extract, sourdough and soy sauce. RIDASCREEN® Gliadin is also suitable for automation.

Table 1: Different processed food and the respective gliadin test kit recommended for analysis							
Intended use	All kinds of food samples (e.g. biscuits, bread, chocolate)			Hydrolyzed/fermented food (e.g. beer, starch			
	Surfaces		syrup)				
Test kit	RIDA®QUICK Gliadin	RIDASCREEN® Gliadin	RIDASCREEN®FAST Gliadin	RIDASCREEN® Gliadin competitive			
Method	Dip stick (qualitative)	Sandwich ELISA (quantitative)	Sandwich ELISA (quantitative)	Competitive ELISA (quantitative)			
Antibody used	R5-mAb	R5-mAb	R5-mAb	R5-mAb			
Calibrator material	No calibrator	Calibrated to purified gliadin material of the WG PAT		Prolamin hydrolysate (mixture of wheat, rye and barley)			
Extraction	Ethanol (60 %) or Cocktail (patented)	Cocktail (patented) (RIDA® Extraction Solution only after validation)		Ethanol (60 %)			
Detection	Intact prolamins and large fragments with more than one epitope			Small peptide fragments (and intact prolamins)			
Detection limit	pos. result > 2.5 mg/kg	0.5 mg/kg gliadin	0.5 mg/kg gliadin	1.4 mg/kg gliadin			
Limit of quantification	-	2.5 mg/kg gliadin	5 mg/kg gliadin	5 mg/kg gliadin			
Incubation time	5 min.	90 min.	30 min.	40 min.			
Validation Nev	AOAC-OMA 2015.16 AACCI in process	AOAC-OMA 2012.01 AOAC-RI 120601 AACCI 38.50.01	Internal	AACCI 38.55.01 AOAC-OMA 2015.05			



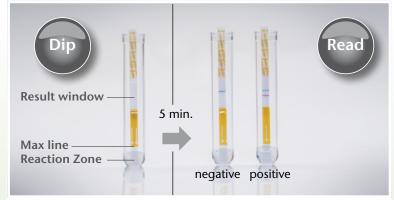
# Direct swabs for hygiene control

A Hazard Analysis of Critical Control Points (HACCP) is necessary to ensure gluten-free products. The dip stick RIDA®QUICK Gliadin is an ideal tool for carrying out surface swabs for hygiene control within

production sites or the laboratory. Low and high gluten concentrations are detected (no hook-effect, no overdose effect). RIDA®QUICK Gliadin is user friendly and currently the only R5 dip stick available worldwide.



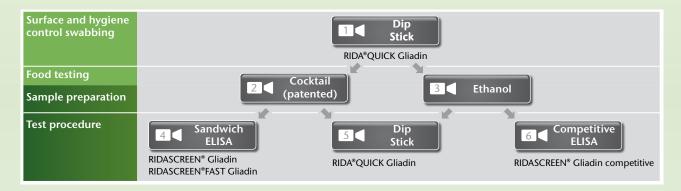
**Figure 1:** RIDA®QUICK Gliadin dip stick can be used directly as a swab test



**Figure 2:** The RIDA®QUICK Gliadin strip is then immersed in the buffer solution and is read after 5 min.

#### Training videos on Gluten analysis

This interactive webbased brochure allows you to watch our training videos if the computer is connected to the internet. Simply click on the small camera icons below to watch and learn all about the different sample preparations and the practical test procedures. Each video takes approximately 5 minutes.



### **Product testing using ELISA and PCR**

Gluten-free products are constantly surveyed for the presence of gluten by manufacturers or by food inspectors. SureFood® Gluten can be used as a confirmatory method for wheat contamination. The positive result for a soy cheese sample obtained by the R5 Mendez ELISA was confirmed by real time PCR (see Table 2).

Table 2: Analysis of soy cheese contaminated with wheat						
Food (declaration)	RIDASCREEN® Gliadin ELISA [Gliadin mg/kg]	SureFood® PCR Gluten	PCR Wheat			
Soy cheese 1 (gluten-free)	49.9	positive	positive			
Soy cheese 2 (gluten-free)	39.6	positive	positive			

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Product	Description	No. of Tests/Amount	Art. No.
Gliadin/Gluten	ELISA Microtiter Plates		No.
RIDASCREEN® Gliadin AOAC-OMA 2012.01 AOAC-RI 120601 AACCI 38-50.01 Codex Method (Type I)	Official R5 Mendez method: Sandwich ELISA to quantify prolamines from wheat, rye and barley in e.g. food declared as gluten-free; sample extraction with R7006 or R7016 (not contained in the kit); the kit is suitable for automation; Detection limit: 0.5 mg/kg (ppm) gliadin or 3.0 mg/kg (ppm) gluten	96 determinations Incubation time: 1 hr 30 min	R7001
RIDASCREEN®FAST Gliadin	R5 sandwich ELISA Detection limit: 0.5 mg/kg (ppm) gliadin or 4.0 mg/kg (ppm) gluten	48 determination Incubation time: 30 min	R7002
RIDASCREEN® Gliadin competitive (2nd generation) AACCI 38-55.01 AOAC-OMA 2015.05	R5 competitive ELISA; sample preparation with an ethanolic solution; the standard material is a hydrolyzate (mixture of wheat, rye and barley);  Detection limit: 1.36 mg/kg (ppm) gliadin or 2.7 mg/kg (ppm) gluten	96 determinations Incubation time: 40 min	R7021
	ELISA – Accessories		
Cocktail (patented)	Developed by Prof. Mendez; officially recommended extraction buffer for all processed e.g. heat treated food samples in conjunction with R7001, R7002, R7003, R7004	105 ml	R7006
Cocktail (patented)	Corresponding to R7006 but larger bottle size	1000 ml	R7016
RIDA® Extraction Solution (colorless)	Alternative to the Cocktail (patented) (use only after extraction comparision with Cocktail): The extraction is faster (35 min compared to 1 h 50 min with the cocktail); it is used in conjunction with R7001, R7002, R7003, R7004	105 ml	R7098
Set of 3 processed Gliadin  Assay Controls	Three assay controls: 3 positive homogenized processed snack samples; produced by Trilogy® Analytical Laboratories	3 x 1.5 g	R7012
	Lateral Flow Test Strips (immunochromatographic tests)		
<u>RIDA®QUICK Gliadin</u> AOAC-OMA 2015.16	The immunochromatographic test is based on the R5 antibody and detects prolamines from wheat, rye and barley; the test strips can be used directly for swabs on surfaces or for analysis of e.g. gluten-free raw materials or processed food extracted with Cocktail (patented) Detection limit: 1 - 2 µg gliadin/100 cm² on surfaces Detection limit: 2.5 mg/kg (ppm) gliadin in food	25 test strips in reclosable tube, 25 plastic pipettes, sample diluent (ready-to-use), 30 vials Incubation time: 5 min	R7003
RIDA®QUICK Gliadin (single packaged)	Corresponding to R7003, test strips are single packaged and no plastic pipettes are included	25 test strips single packaged, sample diluent (ready-to-use), 30 vials Incubation time: 5 min	R7004
RIDA®QUICK Gliadin (ready to swab)	Corresponding to R7003, test strips are single packaged, prefilled vials with ready-to-use sample buffer are included	25 test strips single packaged, 25 prefilled vials with ready- to-use buffer	R7005
	DNA preparation		
SureFood® PREP Advanced	For highly processed matrices (food and feed)	50 preparations	S1053
	Real-time PCR		
SureFood® ALLERGEN ID Gluten	Detection of gluten containing cereals (wheat, spelt, barley, oats, kamut, rye) Detection limit: ≤ 0.4 mg/kg (ppm); using QUANTARD Allergen 40	100 reactions	S3106
SureFood® ALLERGEN QUANT Gluten	Detection of gluten containing cereals (wheat, spelt, barley, oats, kamut, rye) Detection limit: ≤ 0.4 mg/kg (ppm) Quantification limit: 1 mg/kg (ppm); using QUANTARD Allergen 40	100 reactions	S3206
	Laboratory reference material for quantification		
SureFood® QUANTARD Allergen 40	Laboratory reference material for quantitaive real-time PCR. Corn flour contains 12 potential allergens in concentrations of 40 mg/kg (ppm)	2 g	S3301
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