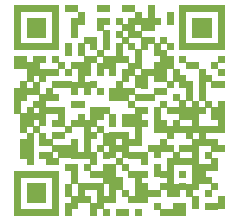




Analytical test kits to ensure gluten-free food

Perfect analysis for all situations

- Tests for protein or DNA detection
- For food analysis and hygiene monitoring (swab tests)
- Methods for protein detection are based on the R5 antibody
- Approved by AOAC/AACCI/ASBC/ICC
- Validated for automation



Dip Stick

PCR

ELISA



Gluten-free food for gluten intolerant patients

Coeliac disease is triggered by *gluten* (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 world-wide 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	Raw material and heat treated food			Hydrolyzed/fermented food (e.g. beer, starch syrup)
	Surfaces			
Test kit	RIDA®QUICK Gliadin (Art. Nr. 7003/R7004/R7005)	RIDASCREEN® Gliadin (Art. Nr. 7001)	RIDASCREEN®FAST Gliadin sensitive (Art. Nr. 7051)	RIDASCREEN® Gliadin competitive (Art. Nr. 7021)
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 %), Cocktail (patented) or RIDA® Cocktail ECO	Cocktail (patented) or RIDA® Cocktail ECO		Ethanol (60 %)
Detection	Intact prolamins and large fragments with more than one epitope			Small peptide fragments (and intact prolamins)
Detection limit*	6.3 mg/kg gluten 1.6 µg gluten/100 cm ²	0.5 mg/kg gliadin or 1.0 mg/kg gluten	0.2 mg/kg gliadin or 0.4 mg/kg gluten	2.3 mg/kg gliadin or 4.6 mg/kg gluten
Limit of quantification*	–	2.5 mg/kg gliadin	1.25 mg/kg gliadin	4.6 mg/kg gliadin
Incubation time	5 min.	90 min.	30 min.	40 min.
Validation	AOAC-OMA 2015.16 AOAC-RI 101702 AACCI 38-60.01	AOAC-OMA 2012.01 AOAC-RI 120601 AACCI 38.50.01	Internal	AACCI 38.55.01 AOAC-OMA 2015.05

* depending on matrix

Automation of R5 ELISA test kits

ELISA automation plays an important role in modern laboratories. Time saving and standardized test conditions are two advantages of automation.

There are evaluations on different devices (e.g. ThunderBolt®) for the RIDASCREEN® ELISA to fulfill optimally the individual needs of a laboratory

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

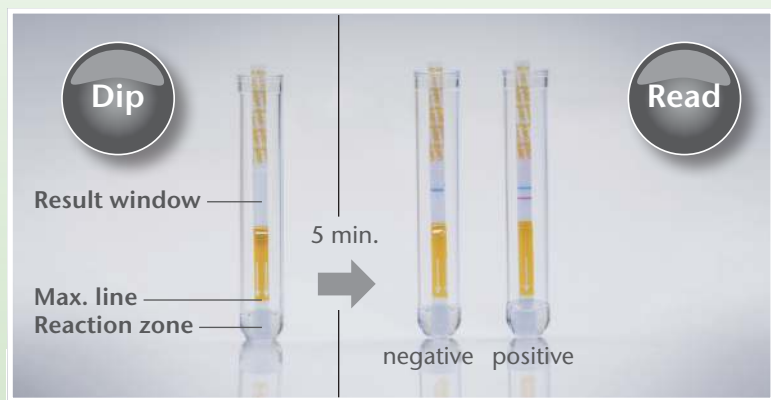
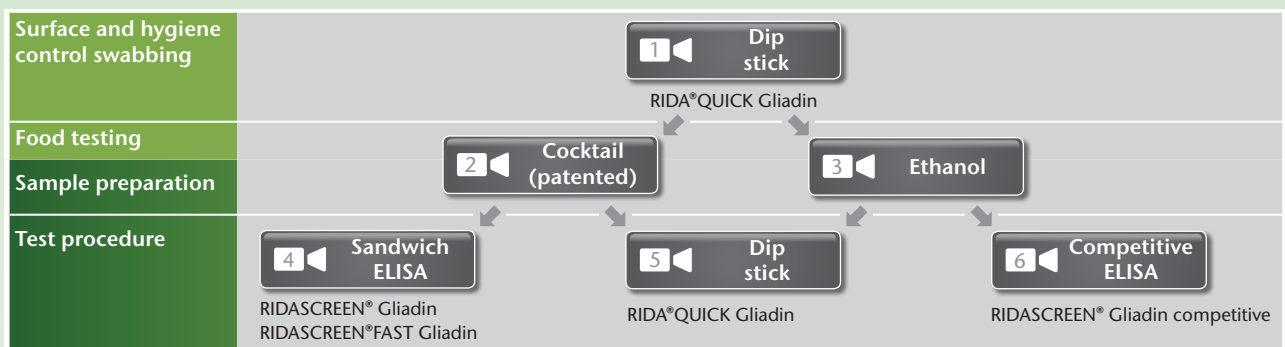


Figure 2: The RIDA®QUICK Gliadin strip is then immersed in the buffer solution and is read after 5 min.

Training videos on gluten analysis

<https://food.r-biopharm.com/media/videos/>
Each video takes approximately 5 minutes.





Product	Description	No. of tests/amount	Art. No.
ELISA microtiter plates			
RIDASCREEN® Gliadin AOAC-OMA 2012.01 "Final Action" AOAC-RI 120601 AACCI 38-50.01 Codex Alimentarius Method (Type I) ICC	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 gliadin (0.1 - 1.2 depending on the matrix) resp. 1.0 mg/kg gluten	96 determinations Incubation time: 1 hr 30 min	R7001
RIDASCREEN®FAST Gliadin sensitive	R5 sandwich ELISA to quantify prolamines from wheat, rye and barley. For example, in food declared as gluten-free; sample extraction with Cocktail (patented) R7006/R7016 or R7080 (not contained in the kit); the kit is suitable for automation Detection limit: 0.2 mg/kg Gliadin (0.19 - 2.1 depending on the matrix) resp. 0.4 mg/kg Gluten	96 determinations Incubation time: 30 min	R7051
RIDASCREEN®FAST Gliadin	R5 sandwich ELISA to quantify prolamines from wheat, rye, barley in e.g. food declared as gluten-free; sample extraction with R7006/R7016 or R7080 (not contained in the kit); the kit is suitable for automation Detection limit: 0.5 mg/kg gliadin (0.14 - 2.1 depending on the matrix) resp. 1.0 mg/kg gluten	48 determination Incubation time: 30 min	R7002
RIDASCREEN® Gliadin competitive (2 nd generation) AACCI 38-55.01 AOAC-OMA 2105.05	R5 competitive ELISA to quantify potential toxic peptide sequences of prolamines from wheat, rye and barley in fermented and hydrolyzed food (e.g. beer, starch, starch syrup, malt extracts); sample preparation with an ethanolic solution; the standard material is a hydrolyzate (mixture of wheat, rye and barley); the results can be related to the limit values of the Codex Alimentarius; Detection limit: 2.3 mg/kg gliadin (1.9 - 2.6 depending on the matrix) resp. 4.6 mg/kg 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, R7051, R7003, R7004	105 ml	R7006
Cocktail (patented)	Corresponding to R7006 but larger bottle size	1000 ml	R7016
RIDA® Cocktail ECO	Alternative to the Cocktail (patented) (use only after extraction comparison with the Cocktail): the extraction is faster (35 min) and more environment-friendly; for all processed e.g. heat treated food tested with R7001, R7002, R7051, R7003, R7004	2 x 115 ml	R7080
RIDA® Extraction solution (colorless)	Alternative to the Cocktail (patented) (use only after extraction comparison with the Cocktail): the extraction is faster (35 min); for all processed e.g. heat treated food tested with R7001, R7002, R7051, R7003, R7004	105 ml	R7098
Set of 3 processed Gliadin Assay Controls	Three assay controls: one negative, two positive homogenized snack samples; in cooperation with Trilogy® Analytical Laboratories	3 x 1.5 g	R7012
Lateral flow test strips			
RIDA®QUICK Gliadin AOAC-OMA 2015.16 "Final Action" AACCI 30-60.01 AOAC-RI 101702	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 Detection limit: 1.6 - 3.0 µg gluten/100 cm ² on surfaces, 4.4 mg/kg gluten in raw materials, 6.3 mg/kg gluten in processed food, cleaning/process water (without cleaner) 10 ng/ml gluten, (with cleaner) 50 - 100 ng/ml gluten	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 packed, sample diluent (ready-to-use), 30 vials	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 packed, 25 prefilled vials with ready-to-use buffer	R7005
Real-time PCR – qualitative and/or quantitative DNA detection			
SureFood® ALLERGEN Gluten	Detection limit: ≤ 0.4 mg/kg; limit of quantification: 1 mg/kg depending on matrix and DNA preparation	100 reactions*	S3606

