# Revolutionizing Gluten Analysis

## Speed & precision

BioSystems
Y15

Food & Beverage analysis

human - centred biotech

# What is gluten

Gluten is found in certain cereal grains as a group of structural proteins, primarily composed of prolamins and glutelins.

Grains containing gluten include all species of wheat, barley, rye, and some cultivars of oat; moreover, cross hybrids of any of these cereal also contain gluten, e.g. triticale. Gluten constitutes around 80% of total protein in bread wheat and it is a key compound in bakery and related technological processes in food industry.

## Why is it analysed?

Certain of these proteins trigger celiac **disease, allergies**, or **intolerances** in some individuals, which can only be avoided in a gluten-free diet.

Gluten analysis is frequently tested using immunoassays based on antigen-antibody bond to detect and sometimes quantify the amount of gluten in a particular matrix. Proper and thorough labelling is essential and mandatory in most countries.

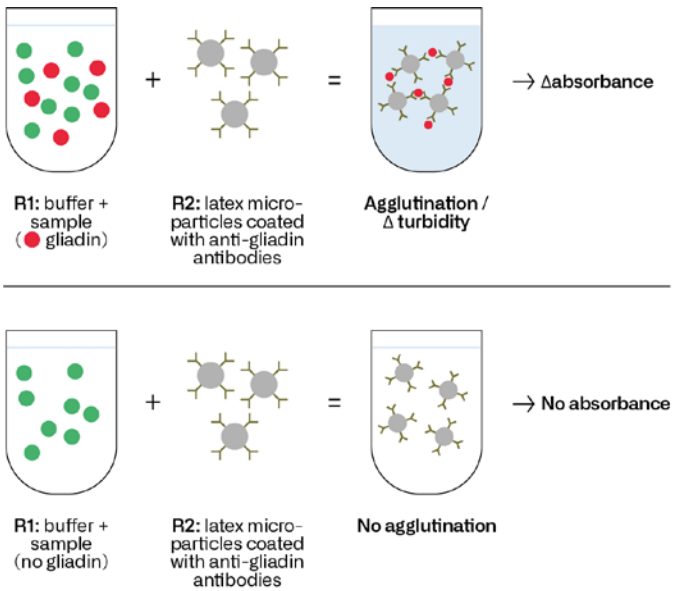
Regulations (EU) 1169/2011 and 828/2014 in the European Union, as well as similar ones in other countries, ensure appropiate gluten labelling and indicate the maximum permitted level (generally 20 ppm).

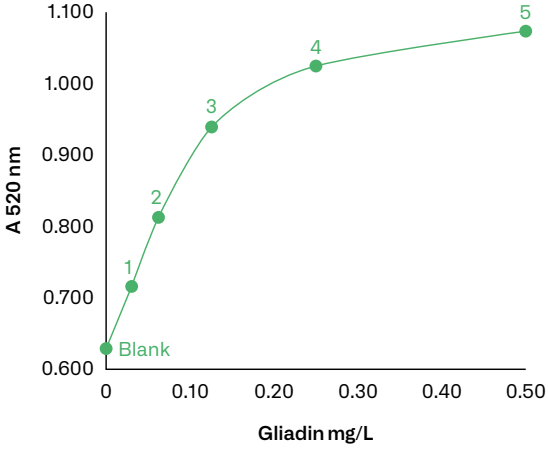
# Our gluten analysis

We present a **new method** for quantifying gluten, based on an **immunoturbidimetric reagent automated in BioSystems Y15 analyser**. This method has the advantages of rapid tests (speed) while accurately quantifying Gluten (like ELISA) in automated way. Other analytes of interest in food industry can be done in the same platform like sugars, organic acids or histamine.

The Gluten test employs **immunoturbidimetry** with latex nanoparticles coated with a monoclonal antibody. This antibody specifically recognises the 33-mer fragment known for its high toxicity. This fragment is present in prolamins like gliadin.

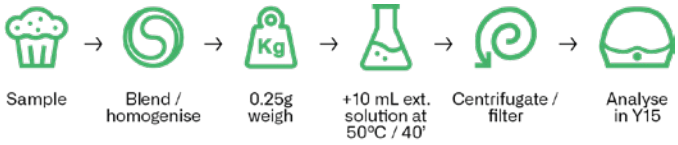
When the coated nanoparticles react with gliadin in the sample, the turbidity of the medium increases, which is measured using spectrophotometry. The increase in absorbance is proportional to the gluten concentration in the sample. Calibrators are supplied in the kit and are traceable to gliadin from Prolamin Working Group (PWG).



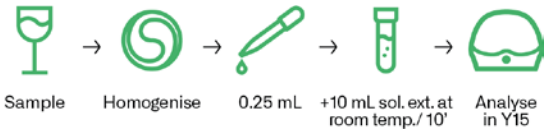




Gliadin/Prolamin in the sample is extracted in a single step with a user-friendly Gluten Extraction Solution (Ref. 31003), in a faster and safer way than other methods.

## Solids extraction:




## Liquids extraction:




Once extracted, the liquid sample is placed into the autoanalyser, delivering results in ppm within 10 minutes for the first sample, with a throughput of up to 60 tests per hour.

We have also developed a Spike Solution (Ref. 31002) to create internal controls. It contains 250 mg/L of gluten and is traceable to PWG standards. The Gluten Spike Solution can be used either diluted in the Gluten Extraction Solution (Ref. 31003) or added directly to the matrix to evaluate recovery rates.

## Gluten performance characteristics | Ref. 31000:

- Limit of quantification: 2.5 mg/kg (mg/L) gluten
- Measurement interval: 2.5 - 40 mg/kg (mg/L) gluten
- Limit of linearity can be extended up to 200 mg/kg (mg/L) gluten with an automated predilution.

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 072503

The scope of **AOAC Performance Tested Method℠ certification** (PTM #072503) includes rice flour, corn flour, sausage, rice cookies, cornbread and post-fermentation wine samples for automated procedure with BioSystems analysers.

## Precision:

| Matrices | Gluten contamination | | Result mg/kg | Recovery (%) | RSDi (%) |
|---|---|---|---|---|---|
| | Source | mg/kg | | | |
| Corn flour | Wheat flour | 5 | 4.89 | 97.8 | 16.1 |
| | | 20 | 19.5 | 97.7 | 10.3 |
| Rice flour | Wheat flour | 5 | 8.01 | 160.2 | 5.91 |
| | | 20 | 20.7 | 103.7 | 10.7 |
| Red wine (post-fermentation) | Wheat flour | 5 | 5.006 | 100.1 | 3.15 |
| | | 10 | 9.61 | 96.1 | 4.08 |
| Sausage | Wheat flour | 5 | 7.64 | 152.8 | 9.38 |
| | | 20 | 20.4 | 101.9 | 8.54 |
| Instant cacao powder | Gluten Spike Solution | 5 | 4.47 | 87.4 | 7.1 |
| | | 10 | 8.75 | 86.5 | 3.6 |
| Cookies | Gluten Spike Solution | 2.5 | 2.50 | 94.1 | 4.1 |
| | | 10 | 10.1 | 99.3 | 2.0 |

The reagent has been **validated according to the new Association of Official Analytical Collaboration (AOAC) guidelines** and has demonstrated excellent performance compared to the official method (R5 antibody, Category I, Codex Alimentarius).

| FAPAS. Quality Control Material | | R5 antibody kit | | BioSystems Y15 Gluten | | |
|---|---|---|---|---|---|---|
| Reference | Matrix | Assigned value. Xa (range for lzl ≤2) | Nº of data points Xa | Mean (n=5) mg/kg | Bias. mg/kg | Bias (%) |
| T27247BQC | Cake mix | 19.3 (9.6 - 28.9) | 100 | 12.1 | -7.20 | 63 |
| T27252AQC | Oat based foodstuff | 16.6 (8.3 - 24.9) | 61 | 18.3 | 1.70 | 110 |
| T27262QC | Cooked biscuit | 76 (38.0 - 114.0) | 73 | 90.2 | 14.20 | 119 |
| T27264BQC | Infant soya formula | 24.8 (12.4 - 37.2) | 52 | 36.8 | 12.00 | 148 |
| T27271AQC | Cake mix | 39.2 (19.6 - 58.8) | 68 | 38.2 | -0.98 | 97 |
| T27275AQC | Cake mix | 14.9 (7.5 - 22.4) | 94 | 17.8 | 2.87 | 119 |
| T27301BQC | Cake mix | 16.0 (8.0 - 24.0) | 78 | 17.0 | 0.95 | 106 |
| T27314QC | Cooked Biscuit | 56.3 (28.1 - 84.1) | 58 | 55.1 | -1.22 | 98 |
| T27331AQC | Cake mix | 13.9 (6.9 - 20.8) | 88 | 16.6 | 2.70 | 119 |
| T27331BQC | Cake mix | 5.53 (2.76 - 8.29) | 48 | 4.1 | -1.46 | 74 |
| FAPAS. Reference Material | | R5 antibody kit | | BioSystems Y15 Gluten | | |
| Reference | Matrix | Reference value (U) | Nº of data points RV | Mean (n=5) mg/kg | Bias. mg/kg | Bias (%) |
| TYG001RM | Cake mix | 14.4 (1.7) | 95 | 14.7 | 0.3 | 103 |
| TGY002RM | Cake mix | 28.8 (2.4) | 103 | 28.0 | -0.8 | 97 |

# BioSystems Gluten kit

Our gluten quantification method enables fully automated analysis via immunoturbidimetry, providing fast, accurate, and reliable results.

**Key features include:**

- Immunoassay: quantitative and direct method.
- Ready-to-use reagents and standards.
- No calibration required before each run.
- No washing steps required.
- Easy to use, no specialized training required.
- Single-step extraction without the need for a fume hood.

| Product | Code |
|---|---|
| Gluten | 31000 |
| Gluten Spike Solution | 31002 |
| Gluten Extraction Solution | 31003 |

# BioSystems Y15

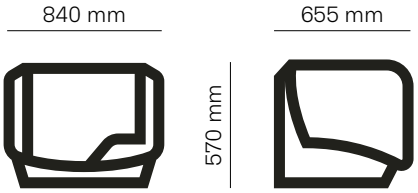
## Automatic Random Access Analyser

## Highlights

- 150 cycles/hour (60 results/hour).
- Continuous sample loading.
- Dedicated reagents with minimal handling.
- Automated pre- and post-dilution steps.
- User-friendly, adaptable software with direct result output.

| Item | Quantity | Code |
|---|---|---|
| BioSystems Y15 analyser | - | 83106 |
| BioSystems Y15C analyser | - | 83106C |
| Reaction rotor | 10 units | AC11485 |
| Concentrated Washing Solution | 500 mL | BO13416 |
| Concentrated System Liquid | 1000 mL | 12889 |
| Sample wells (pediatric cups) | 1000 units | AC10770 |
| Reagent bottles 50 mL + caps | 10 units | BO11493 |
| Reagent bottles 20 mL + caps | 10 units | BO11494 |
| Amber reagent bottles 50 mL + caps | 10 units | BO13442 |
| Halogen lamp Y15 6V/10W | 1 unit | LA10429U |

## Dimensions



Intended use: automated analyser for the measurement of various types of food and beverage samples.
For professional use in analytical laboratories only.

BioS/08-25 ZSM00005

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