RIDASCREEN®EASY Gluten

Brief information

RIDASCREEN®EASY Gluten (Art. No. RAE7071) is an R5-based sandwich enzyme immunoassay for the quantitative analysis of gluten from wheat, rye, and barley in food validated for the method (see chapter 1).

All reagents required for the enzyme immunoassay, including standards, are contained in the test kit. The test kit is sufficient for a maximum of 96 determinations (including standards). A microtiter plate spectrophotometer is required for quantification.

Sample preparation:	homogenization, extraction and centrifugation
Time requirement:	sample preparation (for 10 samples) . approx. 20 min test implementation (incubation time) ..... 30 min
Standard material:	PWG-Gliadin in buffered, aqueous solution; expressed as mg/kg gluten (wheat); for more information: http://www.wgpat.com/handling.html
Limit of detection: (depending on matrix)	0.8 mg/kg (ppm) gluten (average of wheat, rye, barley)
Limit of quantification:	3 mg/kg (ppm) gluten; RSD_i 16.6 % (average of wheat, rye, barley)
Specificity:	The monoclonal antibody R5 reacts with the gliadin fractions from wheat and corresponding prolamins from rye and barley. The test kit detects the gluten containing cereals einkorn and khorosan-wheat with recovery rates of approx. 35 % to 50 %. Other gluten containing cereals such as wheat (*triticum aestivum*), rye, barley, spelt, emmer, triticale, and durum wheat show recovery rates within the AOAC specifications of 50 % to 200 %. No cross-reaction was detected in 108 tested foods. Further information can be found in the validation report.

Cross reactivities of the antibodies used for this test kit have been determined for the pure food (e.g. corn flour). In composed / processed food (e.g. maize bread) cross reactivities might be different. Interfering substances (e.g. polyphenols) can be detected by spike experiments (see chapter 13).

To increase the quality of assessment when performing ELISA procedures, we refer additionally to our Good ELISA Practice brochure. It lists minimum standards and conditions that are required when using test kits of R-Biopharm AG to perform ELISA analysis. The brochure can be retrieved, printed and downloaded from the website https://food.r-biopharm.com/media/technical-guides/.

Related product and accessories for gluten / gliadin determination

RIDASCREEN® Gliadin (Art. No. R7001)
RIDASCREEN®FAST Gliadin (Art. No. R7002)
RIDASCREEN® Gliadin competitive (Art. No. R7021)
RIDASCREEN® Total Gluten (Art. No. R7041)
RIDASCREEN®FAST Gliadin sensitive (Art. No. R7051)
RIDA®QUICK Gliadin (Art. No. R7003 / R7004 / R7005)
RIDA®QUICK Gluten quant. (Art. No. RAL7073)
Cocktail (patented) (Art. No. R7006 / R7016)
RIDA® Extraction Solution (colorless) (Art. No. R7098)
RIDASCREEN®EASY Extraction Tablets (Art. No. RAA0008)
Set of 3 processed Gliadin Assay Controls (Art. No. R7012)
SureFood® Allergen 4plex Cereals (Art. No. S7006)
SureFood® Allergen Gluten (Art. No. S3606)
SureFood® QUANTARD Allergen 40 (Art. No. S3301)

1. Intended use

RIDASCREEN®EASY Gluten (Art. No. RAE7071) is an R5-based sandwich enzyme immunoassay for the quantitative analysis of contaminations by prolamins from wheat (gliadins), rye (secalins), and barley (hordeins) in foods. Due to the large number of different foods, the following products were examined representatively within the scope of the test development: baked good, sauce, chocolate containing dessert, and spices.

It can be assumed that the test is also suitable for the analysis of other foodstuffs; this is to be checked by the user himself.

For detailed results and further information on validation data with other food matrices, please refer to the validation report.

2. General information

The use of wheat flour and gluten in foodstuffs is extremely common because of their heat stability and useful effects on e.g. texture, moisture retention and flavour. Gluten is a mixture of prolamin and glutelin proteins present in wheat, rye and barley. The prolamin content (e.g. gliadin) of gluten is per definition generally assumed to be 50 % (CODEX STAN 118-1979) [1]. Hence, a factor of 2 is used for calculation of gluten from a measured gliadin concentration. However, recent research has shown that the real conversion factor from gliadin to gluten is approx. 1.5 [2], [3], [4]. The RIDASCREEN®EASY Gluten is not calibrated against gliadin, but against an exemplary wheat flour [2] and indicates the result in gluten. Therefore, the calculation factor is omitted. Hereby, lower values are determined being in better agreement with new research findings for the gluten content in comparison to an assay, which calculates the gluten content from a measured gliadin concentration by the factor 2.

Coeliac disease is a permanent intolerance to gluten that results in damage to the small intestine and is reversible when gluten is avoided by diet.

According to the Codex Alimentarius „Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten” (CODEX STAN 118/1979) two categories for labelling of food according to the gluten content exist:

1) Food products which contain less than 20 mg/kg can be labeled as **"gluten-free"**.
2) Food products labeled as **"very low gluten"** can have a gluten content above 20 and up to 100 mg/kg.

The threshold of 20 mg/kg has been adopted by many national legislations in many countries.

3. Test principle

The principle of the test is the antigen-antibody reaction. The wells of the microtiter strips are coated with specific R5 antibodies against the gliadin and prolamin components of gluten. By adding the standard or sample solution to the wells, gliadin or related prolamins present in the sample will bind to the specific capture antibodies resulting in the formation of an antibody-antigen-complex. Components not bound by the antibodies are then removed in a washing step. Following the washing step, a solution containing R5 antibody conjugated to peroxidase is added. This conjugate is bound to the Ab-Ag-complex and an antibody-antigen-antibody (sandwich) complex is formed. Any unbound conjugate is then removed in another washing step. A substrate/chromogen solution is added to the wells and incubated. Bound conjugate converts the colorless chromogen into a blue end product. A stop solution is added which results in a color change from blue to yellow. The measurement is made photometrically at 450 nm. The absorbance of the solution which is proportional to the gluten concentration in the sample is measured photometrically at 450 nm and expressed as mg/kg gluten.

4. Reagents provided

Each kit contains sufficient materials for a maximum of 96 measurements (including standard analyses). Each test kit contains:

Component	Cap color	Format		Volume
Microtiter plate	-	Ready to use		96 wells
Extraction tablets	White	Ready to use		50 pcs.
Standard 1*	Transparent	Ready to use	0 mg/kg	1.3 mL
Standard 2*	Transparent	Ready to use	3 mg/kg	1.3 mL
Standard 3*	Transparent	Ready to use	6 mg/kg	1.3 mL
Standard 4*	Transparent	Ready to use	12 mg/kg	1.3 mL
Standard 5*	Transparent	Ready to use	24 mg/kg	1.3 mL
Standard 6*	Transparent	Ready to use	48 mg/kg	1.3 mL
Wash buffer	Brown	**Concentrate**	**10x**	50 mL
Conjugate	Red	Ready to use	11x	11 mL
Substrate/Chromogen Red Chromogen Pro	Brown	Ready to use		13 mL
Stop solution	Yellow	Ready to use		14 mL

*) The concentration values of the standards already consider the **dilution factor of 500** coming from sample extraction as described in this IFU. Therefore, the gluten concentration of samples can directly be read from the standard curve.

5. Reagents required but not provided

5.1 Equipment

- Gloves
- Scale (measurement range at least up to 50 g and precision of ± 0.01 g)
- Laboratory mincer / grinder, mortar, ultra-turrax or homogenizer
- Centrifuge (at least 2,500 x *g*) + centrifugal vials with cap (e.g. 50 mL centrifuge tubes from Greiner Art. No. 227261)
- Shaker
- Water bath (60 °C / 140 °F; for fluctuation range please refer to the instructions of the water bath manufacturer)
- Fluted filter (pore size 8 - 12 µm)
- Graduated pipettes
- Measuring cylinder
- Variable 20 - 200 µL and 200 - 1000 µL micropipettes
- If necessary: a further microtiter plate (e.g. universal binding, breakable MTP from Thermo Fisher Scientific Art. No. 95029390 or low binding Greiner bio-one Art. No. 655901)
- If necessary: 8-channel pipette for 100 µL
- Microtiter plate spectrophotometer (450 nm)
- Optional: RIDASOFT® Win.NET Food & Feed (Art. No. Z9996FF)

5.2 Reagents

- Distilled water (dist. water) or deionized water
- 60 % ethanol (e.g. add 150 mL reagent grade ethanol (99 %) to 100 mL dist. water)
- If further extraction tablets are needed: RIDASCREEN®EASY Extraction Tablets (Art. No. RAA0008)

6. Warnings and precautions for the users

The product / test is only suitable within the scope of its intended use.

This test should only be carried out by trained laboratory personnel. The instruction for use must be strictly followed.

This kit may contain hazardous substances. For hazard notes on the contained substances please refer to the appropriate material safety data sheets (SDS) for this product, available online at www.r-biopharm.com.

Do not reuse wells of the microtiter strips (coated microtiter plate and pre-plate if necessary, see chapter 10.2). Use separate pipette tips for each standard and each sample extract to avoid cross contamination.

All reagents and materials must be recovered or disposed after use at customers own responsibility according to the protection of human health and the environment. Please observe the applicable national regulations concerning waste disposal (e.g. Waste Management Act, Regulations on Dangerous Chemicals, etc.).

7. Storage instructions

Store the kit at 2 - 8 °C (36 - 46 °F). Do not freeze any test kit components. Consider also the following advice for the extraction tablets.

To avoid moisture at the extraction tablets, open the container only after having reached room temperature (20 - 25 °C / 68 - 77 °F). The extraction tablets can be also stored in the closed container at room temperature (20 - 25 °C / 68 - 77 °F) until the expiry date printed on the label.

To avoid moisture inside the wells, open the foil bag for withdrawal of microwells only after having reached room temperature (20 - 25 °C / 68 - 77 °F).

Return any unused microwells to their original foil bag, reseal them together with the desiccant provided and further store at 2 - 8 °C (36 - 46 °F).

The reddish substrate/chromogen is light sensitive. Therefore, avoid exposure to direct light.

Do not use the test kit after the expiration date (see test kit label).

The extraction tablets and the wash buffer are not lot-specific. They can be used also with EASY allergen ELISA of different lot numbers. Beyond that, do not interchange other individual reagents between kits of different lot numbers.

8. Indication of instability or deterioration of reagents

- Bluish coloration of the reddish substrate/chromogen prior to test implementation.
- Value of less than 1.2 absorbance units ($A_{450\ nm} < 1.2$) for standard 6.

9. Sample preparation

Wear gloves before starting and during the assay. Airborne allergens and dirty laboratory equipment lead to contamination of the assay. Therefore, please notice the following recommendations:

- Clean surfaces, glass vials, mincers and other equipment before and after each sample preparation.
- Carry out the sample preparation in a room isolated from the ELISA procedure.
- Check for gluten contamination of reagents and equipment with the test strips RIDA®QUICK Gliadin (R7003 / R7004 / R7005).

The samples should be stored in a cool place, protected against light.

Note about extraction tablets:

The RIDASCREEN®EASY Allergen ELISA contain extraction tablets with all needed chemicals for extraction instead of a liquid extraction buffer concentrate. A tablet is added to each sample. Then, a defined volume of 60 % ethanol is added and the sample will be suspended by mixing until the tablet is decomposed. The 60 % ethanol should be pre-heated to 60 °C (140 °F). This eases decomposition and guarantees the ideal extraction temperature from the beginning. **Caution:** Do not heat the 60 % ethanol solution more than 3 times or store it for longer times at 60 °C (140 °F) as the ethanol can evaporate. Use vials with a tight-closing lid and close the vial immediately after usage.

Due to their high ethanol content, sample extracts must be diluted 1:50 with buffer before testing in ELISA. One extraction tablet is solved in 20 mL of pre-heated (60 °C / 140 °F) dist. water for preparation of the dilution buffer. Tablets contain insoluble, inert additives, which are needed for tablet pressing. The additives sediment usually with sample particles during centrifugation. For preparation of the dilution buffer, the additives must be separated by filtration or centrifugation (5 min at 2,500 x *g*). In case of centrifugation, it is recommended to decant the supernatant into a fresh vial. The prepared dilution buffer has a limited stability and its efficacy declines. Hence, the buffer must be freshly prepared each day.

9.1 Sample extraction

Preheat 60 % ethanol solution in a water bath to 60 °C (140 °F).

Homogenize a representative, adequately big amount of a solid sample (e.g. 50 g; grind it thoroughly to powder and mix well) or mix well a sample in case of liquid foods.

- Weigh 1 g of the homogenized sample (or 1 mL from a liquid sample) into a sufficiently large vial (see chapter 5.1.), add one extraction tablet and 10 mL of preheated 60 % ethanol solution.
- Close vial and mix thoroughly for 30 s (e.g. vortexer) until the extraction tablet is fully decomposed and a homogeneous suspension has formed.
- Incubate for 10 min at 60 °C (140 °F) in a water bath.
- Centrifuge for 5 min at a minimum of 2500 x *g*.
  (Alternatively, or for samples that sediment slowly:
  Transfer 2 mL of the extract into a fresh vial and centrifuge at high speed (> 10,000 x *g*) for 10 min in a microcentrifuge.)
- Filter extract additionally if no particle-free supernatant is obtained by centrifugation.

Note

The particle-free extract can be stored in a tightly closed vial in the dark at room temperature (20 - 25 °C / 68 - 77 °F) up to two weeks. Extracts must be diluted 1:50 (see chapter 10.2) before testing in ELISA.

10. Test procedure

10.1 Test preparation

Bring all reagents to room temperature (20 - 25 °C / 68 - 77 °F) before use.

The **wash buffer** is provided as a 10-fold concentrate. Before use, the buffer must be diluted 1:10 (1 + 9) with dist. water (e.g. 50 mL buffer concentrate + 450 mL dist. water).

The diluted buffer is stable at 20 - 25 °C (68 - 77 °F) for 4 weeks or for 3 months at 2 - 8 °C (36 - 46 °F).

Components should be stored immediately at 2 - 8 °C (36 - 46 °F) when no longer required.

10.2 Test procedure

For ELISA testing, the extracts (supernatant of centrifugation step or filtrate) must be diluted 1:50 (e.g. 40 µL + 1960 µL) with sample dilution buffer (see 9. Sample preparation; note about extraction tablets). The diluted extracts have a shelf life of approx. 24 hours at 20 - 25 °C (68 - 77 °F).

Carefully follow the recommended washing procedure to obtain unambiguous results. Do not allow microwells to dry between work steps.

Do not use more than three microtiter plate strips (24 wells) at a time. If more than three strips are needed, a second uncoated plate (see chapter 5.1) should be used as a pre-plate to avoid a time shift over the microtiter plate due to pipetting. All standards and samples are pipetted into the uncoated plate (at least 150 µL per well) and then exactly 100 µL are quickly transferred to the coated microtiter plate with an 8-channel pipette.

It is recommended to pipette the conjugate, the substrate/chromogen and the stop solution with a multi-channel or stepper pipette to avoid a time shift over the plate.

Avoid direct sunlight during all incubations. Therefore, cover the microtiter plates.

1. Insert a sufficient number of wells into the microwell holder for all standards and sample extracts to be run in duplicate. Record standard and sample positions.
2. Add 100 µL of each standard or diluted extract in duplicate to the wells and incubate for 10 min at room temperature (20 - 25 °C / 68 - 77 °F).
3. Pour out the liquid of the wells and tap the microwell holder upside down vigorously (three times) on absorbent paper to ensure complete removal of liquid from the wells. Fill all the wells with 250 µL diluted wash buffer (see chapter 10.1) and pour out the liquid as before. Repeat three more times (a total of four wash cycles).
4. Add 100 µL of the conjugate to each well and incubate for 10 min at room temperature (20 - 25 °C / 68 - 77 °F).
5. Pour out the liquid of the wells and tap the microwell holder upside down vigorously (three times in a row) on absorbent paper to ensure complete removal of liquid from the wells. Fill all the wells with 250 µL diluted wash buffer (see chapter 10.1) and pour out the liquid as before. Repeat three more times (a total of four wash cycles).
6. Add 100 µL of substrate/chromogen to each well, mix gently by shaking the plate manually and incubate for 10 min at room temperature (20 - 25 °C / 68 - 77 °F) in the dark.

7. Add 100 µL of stop solution into each well. Mix gently by shaking the plate manually and measure the extinction at 450 nm. Read within 30 min after addition of stop solution.

11. Evaluation

A special software, **RIDASOFT® Win.NET Food & Feed (Art. No. Z9996FF)**, is optional available for evaluation of the RIDASCREEN® enzyme immunoassays. The evaluation should be done using the 4-parameter function. This enables result calculation even above standard 6 by extrapolation. However, results being significantly higher than standard 6 show a higher uncertainty.

For exact determination of the gluten content, samples with an absorption (A_{450nm}) > standard 6 can be higher diluted and measured again. For a higher dilution, the undiluted extract should be diluted adequately with freshly prepared dilution buffer (see chapter 9: Note on extraction tablets). The additional dilution factor must be considered when calculating the result.

It must be clarified that all quality criteria are met for the current test run. The course of the standard curve can be taken from the quality assurance certificate (certificate of analysis, CoA), which is available via the QR code on the test kit. As the absorbance values in the laboratory may differ from those stated on the certificate, it is recommended to compare the ratios of the standards to each other with those on the certificate. For this purpose, the B/B_{max} values (the ratio of the absorbance values of the standards to the highest standard) are compared with each other. In the current test run, these should be similar to the ratios of the standards on the certificate.

The test is calibrated against gluten. The result therefore indicates the amount of gluten in mg per kg of food (**gluten in mg/kg**).

When working according to these instructions for use, the samples are diluted 1:500 during extraction and ELISA procedure. The sample dilution factor of 500 is already considered in the concentration data of the standards (see chapter 4*). The concentration of gluten protein in the sample can therefore be read directly from the standard curve.

The assay can also be evaluated when running in single determinations. This has no influence on the function of the test kit. A special assay evaluation must be written in the RIDASOFT® Win.NET Food & Feed software for this purpose. It is not present by default. Each laboratory may decide to perform the test in single determinations after a qualified risk management analysis. However, it is not consistent with the standards EN 15633-1 and EN 15842. It should be

noted that this increases the risk of overlooking errors in the performance of the test (e.g. pipetting errors). Moreover, a higher result variation will occur when pipetting in single determinations.

12. Result interpretation

Compared to the certificate, higher absorbance values ($A_{450\,nm}$) for the standard curve, especially for the zero standard, may be a result of insufficient washing or gluten contamination.

Results between LoD (Limit of Detection) and LoQ (Limit of Quantification) indicate a low gluten concentration in the sample. Depending on the matrix tested, values below the LoQ can still be determined with sufficient precision (CV < 30 %). However, values in this range are generally subject to greater uncertainty due to the higher fluctuation range of the test. If the precision of the test has not been validated with a specific sample matrix, therefore, results below the measuring range should not be reported with a quantitative value, but qualitatively "< LoQ". Further information on this can be found in the current validation report.

A result below the LoD does not exclude a gluten contamination below the detection limit of the assay, or that other cereal components, such as lipids, may be present in a sample. The result should be reported accordingly.

13. Limits of the method

Test results may vary depending on the sample matrix, the actual test procedure and the laboratory environment.

Detection and quantification limits depend on the respective sample matrix, the degree of processing and the extraction method.

Technical limits of the test method are approached outside the designated measurement range resulting in higher variation. This may cause a switch of results between the different areas of the calibration curve especially at the test characteristic boundaries (LoD, LoQ, upper limit of measurement range).

An incorrect weight of the sample to be analyzed will have a 1:1 effect on the measurement result (e.g. a 10 % higher concentration is measured with a weigh in of +10 %). A sufficient accuracy is given with a fluctuation of max. ±1 %.

For detailed results and further information for other food matrices, please refer to the current validation report. In addition, data on individual foods may be available from comparative laboratory tests and inter-laboratory comparisons.

For the present ELISA, only individual, exemplary foods from different product categories could be validated due to the large number of foods. When analyzing a non-validated matrix, it is recommended to verify the results obtained by means of spike experiments. If necessary, a validation of the sample matrix of interest will need to be performed.

Due to the multitude of food types, matrix effects cannot be excluded. These can lead to false-positive / increased results, but also reduce or suppress a correct reaction. Such matrix effects are independent of the specificity of the antibody used in the test and can be made visible by spiking experiments.

By using 60 % ethanol during extraction, unspecific reactions with soy are suppressed. However, a soy drink used during the assay's validation showed a non-specific reaction with the system of approx. 4 mg/kg gluten. This non-specific reaction can be suppressed below standard 1 by using 70 % ethanol. For investigation of soy drinks, extraction with 70 % ethanol instead of 60 % ethanol is therefore recommended.

The addition of foreign protein (depending on the test e.g. BSA, gelatine, skim milk powder) during extraction or test procedure may suppress matrix effects.

In processed foods (e.g. heat treatment, dehydration, etc.), proteins may be altered or fragmented and this may have an impact on the recovery and assay results.

Cross reactivities are side reactions of the antibody used for preparing the test kit with antigen showing similar epitopes as the investigated analyte. These appear especially with antigens from closely related species. In contrast to matrix effects, it is a specific reaction of the antigen with the used antibody. The antigen structures are subject to similar influences (e.g. by heating or drying) as the actual analyte. Therefore, cross reactivities may also appear after food processing in single case or are lost.

For evaluation of the cross reactivity only one representative sample was analyzed, other samples may show a different result. All analyzed cross reactivities are described in the validation report.

The protein content and protein composition of wheat, rye and barley cultivars may differ. Varying results are thus to be expected for different cultivars.

The main epitope of the R5 antibody is the amino acid sequence QQPFP which is part of many celiac-toxic sequences. The sequence occurs repeatedly in the

prolamins from wheat, rye and barley. However, rye and barley contain a higher number of replicates of this sequence, which leads to an overestimation of rye and barley compared to the wheat standard.

14. Recommendation

In order to ensure a high analytical performance we recommend:

- To comply with the general quality assurance requirements for laboratories as listed in standards like EN 15633-1 and EN 15842 (e.g. performing duplicate determinations).
- Pre-flush pipette tips with standard or sample extract prior to pipetting.
- Carry along test controls for quality control. Gluten-free and gluten-containing (spiked) samples should be used (e.g. Art. No. R7012).
- To do spike experiments to ensure an accurate and correct test procedure. An example of a spiking experiment is given in the validation report.
- In case of extremely acidic or basic samples, adjustment of the sample's pH value to neutral (pH 6.5 to 7.5) prior to extraction may be necessary.
- To perform a PCR (e.g. SureFood®) for confirmation of the result.
- During the production of foods such as beer or sourdough, proteins are fragmented. In sandwich ELISAs, **protein fragments** lead to a reduced recovery. Such samples should be analyzed with a competitive ELISA like the **RIDASCREEN® Gliadin competitive** (Art. No. R7021).
- To contact sales@r-biopharm.de if automates (e.g. ThunderBolt® / Bolt™) are used.

15. Further application notes

Further application notes are available on request.

For further product information and applications, please contact your local distributor or R-Biopharm at this address: sales@r-biopharm.de.

Literature

[1] Lacorn, M., Dubois, T., Weiss, T., Zimmermann, L., Schinabeck, T. M., Loos-Theisen, S. & Scherz, K.. (2022). Determination of Gliadin as a Measure of Gluten in Food by R5 sandwich ELISA RIDASCREEN® Gliadin Matrix Extension: Collaborative Study 2012.01, J. AOAC Int (publication in progress).

[2] Schall, E., Scherf, K.A., Bugyi, Z., Hajas, L., Török, K., Koehler, P., Poms, R.E., D'Amico, S., Schoenlechner, R., & Tömösközi, S. (2020). Characterisation and comparison of selected wheat (*Triticum aestivum L*.) cultivars and their blends to develop a gluten reference material. Food Chem. 313, 126049. https://doi.org/10.1016/j.foodchem.2019.126049.

[3] Wieser, H., Koehler, P. & Konitzer, K. (2014). Celiac Disease and Gluten: Multidisciplinary Challenges and Opportunities. Elsevier Inc. Amsterdam, ISBN 978-0-12-420220-7, page 107.

[4] Wieser, H. & Koehler, P. (2009). Is the calculation of the gluten content by multiplying the prolamin content by a factor of 2 valid? Eur. Food Res. Technol. 229, 9-13.

Version overview

Version number	Chapter and title
2024-08-27	Release version

Explanation of symbols

General symbols:

	Follow the instructions for use
	Batch number
	Expiry date (YYYY-MM-DD)
	Storage temperature
	Article number
	Number of test determinations
	Manufacturing date (YYYY-MM-DD)
	Manufacturer + address

Patent Marking:

The extraction means in this product contains sulfite. Food inspection methods using a sulfite-containing extractant as in this product and/or corresponding detection kits are subject to the following patents of MORINAGA & Co., Ltd.: European Patent EP 2 224 239 B1, Australian Patent AU 2008 330 507 B2, United States Patent US 8 859 212 B2, Japanese Patent JP 5 451 854 B2. The patent holder has granted R-Biopharm AG a license to use, and sell products that employ, said protected technology in the above-mentioned territories.

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