



foodproof[®] GMO RR Soya Quantification Kit

Revision A, January 2024

PCR kit for the quantitative detection of genetically modified Roundup Ready Soya using real-time PCR Instruments.

Product No. KIT230046

Kit for 128 reactions for a maximum of 48 - 60 samples

Store the kit at -15 to -25 °C

For GMO testing purposes.

FOR *IN VITRO* USE ONLY



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1. What this Product Does

1.1 Number of Tests

The kit is designed for 128 reactions [i.e., 64 reactions with the GMO Gene Master Mix, (vial 1, yellow cap) and 64 reactions with the Reference Gene Master Mix, (vial 2, green cap)] with a final reaction volume of 25 µL each.

Note: The maximum number of samples that can be analyzed per experiment depends on the chosen quantification procedure:

Procedure A Including Relative Standard Curves	Procedure B Importing External Relative Standard Curves
Quantification of up to 48 samples (single sample preparation) in two runs plus calibration curves, one negative control reaction, and one calibrator in each run.	Quantification of up to 60 samples (single sample preparation) in two runs plus calibrator and one negative control reaction in each run.

1.2 Storage and Stability

The kit is shipped on dry ice.

- Store the kit at -15 °C to -25 °C through the expiration date printed on the label.
- Once the kit is opened, store the kit components as described in the following Kit Contents table below:

Keep the GMO Gene Master Mix, (vial 1, yellow cap) and Reference Gene Master Mix, (vial 2, green cap) away from light. Avoid repeated freezing and thawing!

1.3 Kit Contents

Vial	Label	Contents / Function / Storage
1 yellow cap	foodproof GMO Soya - GMO Gene Master Mix -	<ul style="list-style-type: none"> • 2 × 600 µL • Ready-to-use primer and 5'-nuclease probe mix, specific for the 35S-promoter and the chloroplast transit signal sequence of genetically modified Roundup Ready Soya. • For amplification and detection of the 35S-promoter and the chloroplast transit signal sequence. • Store at -15 to -25°C • Avoid repeated freezing and thawing! • Protect from light!
2 green cap	foodproof GMO Soya - Reference Gene Master Mix -	<ul style="list-style-type: none"> • 2 × 600 µL • Ready-to-use primer and 5'-nuclease probe mix, specific for the lectin gene (<i>Le1</i>) of native soya. • For amplification and detection of the <i>Le1</i> gene. • Store at -15 to -25°C • Avoid repeated freezing and thawing! • Protect from light!
3 red cap	foodproof GMO Soya - Enzyme Solution -	<ul style="list-style-type: none"> • 4 × 32 µL • Contains Taq DNA Polymerase and Uracil-DNA Glycosylase (heat labile) for prevention of carry-over contamination. • Store at -15 to -25°C.



Vial	Label	Contents / Function / Storage
4 black cap	foodproof GMO Soya - Dye solution -	<ul style="list-style-type: none"> • 4 x 32 µL • Contains a yellow dye for better visualization of the PCR mix in white PCR plates.
5 purple cap	foodproof GMO Soya - Calibrator DNA -	<ul style="list-style-type: none"> • 2 x 50 µL • Contains a stabilized solution of plasmid DNA. • For use as a PCR run calibrator and positive control. • Store at -15 to -25°C. • Store at 2 to 8°C for up to 1 month after thawing.
6 blue cap	foodproof GMO Soya - Dilution Buffer -	<ul style="list-style-type: none"> • 4 x 1 mL • For dilution of calibrator and sample DNA. • Store at -15 to -25°C.
7 colorless cap	foodproof GMO Soya - H ₂ O, PCR-grade -	<ul style="list-style-type: none"> • 2 x 1 mL • Nuclease-free, PCR-grade H₂O for dilution of reaction mixtures. • For use as a PCR run negative control. • Store at -15 to -25°C.

2. Product Overview

2.1 Product Description

The foodproof® GMO Soya Quantification Kit provides PCR primers and hydrolysis probes (5'-nuclease probes), and convenient premixed reagents for sequence specific amplification and detection. A Calibrator DNA is also provided to ensure accurate determination of the content of genetically modified Roundup Ready soya relative to native soya content. Template DNA is added to the final reaction mixes, thus minimizing contamination risk. Results are obtained within 90 minutes. Optimized PCR conditions allow analysis of Roundup Ready soya and native soya PCR in a single run. The Calibrator DNA provided with the kit serves as positive control and as a reference to normalize the relative Roundup Ready soya content. Normalization corrects for differences in GMO content values, resulting from the combined variation in the quantity and quality of DNA samples and the efficiency of PCR. The foodproof GMO Soya Quantification Kit is specifically adapted for PCR using real-time PCR instruments. Sequence-specific primers and hydrolysis probes (5'-nuclease probes) provide specific detection of DNA of Roundup Ready soya and native soya (serving as a reference):

- The GMO Gene Master Mix, (vial 1, yellow cap) allows the amplification and detection of a fragment of the 35S-promoter sequence of the cauliflower mosaic virus and the downstream located chloroplast transit signal sequence of *Petunia hybrida*, using specific primers. Both sequences have been inserted into the genome of the Roundup Ready soya.
- A fragment of the native soya specific lectin gene (*Le1*) is amplified and detected with the Reference Gene Master Mix (vial 2, green cap). The reaction product serves both as a control for DNA integrity and as a reference for relative quantification.

Note: The kit described in this Instruction Manual has been developed for real-time PCR instruments.



2.2 Test Principle

Roundup Ready soya is identified by detecting a DNA fragment of the 35S-promoter sequence of the cauliflower mosaic virus, and the chloroplast transit signal sequence of *Petunia hybrida*. To detect native soya, a fragment of the soya-specific lectin gene (*Le1*) is amplified and detected with the Reference Gene Master Mix, which serves as both a control for DNA integrity and as a reference for relative quantification. Both amplicons are detected in separate reactions with specific pairs of primers and hydrolysis probes (5'-nuclease probes) using a real-time PCR instrument.

2.3 Product Overview, continued

The basic steps of the test are as follows:

Step	Description
1	Using the kits supplied sequence-specific primers in a polymerase chain reaction (PCR), the real-time PCR instrument and its associated reagents amplify and simultaneously detect fragments of genetically modified Roundup Ready Soya and native soya, respectively.
2	The PCR instrument detects these amplified fragments in real time through fluorescence generated by cleavage of the hybridized probe due to the 5'-nuclease activity of the Taq DNA polymerase. The probe is labeled at the 5'-end with a reporter fluorophore and at the 3'-end with a quencher.
3	During the annealing/elongation phase of each PCR cycle, the probe hybridizes to an internal sequence of the amplicon downstream from one of the primer sites and is cleaved by the 5'-nuclease activity of the Taq DNA polymerase. This cleavage of the probe separates the reporter dye from the quencher dye, increasing the reporter dye signal.
4	The real-time PCR instrument measures the emitted fluorescence of the reporter dye.
5	Determination of the relative ratio of Roundup Ready Soya content. This can be performed using one of the following alternative procedures: <ul style="list-style-type: none"> • Procedure A: Including relative standard curves into the run. • Procedure B: Importing external relative standard curve from a previous run.

2.4 Application

The foodproof GMO Soya Quantification Kit is intended for GMO testing purposes only.

The foodproof GMO Soya Quantification Kit is used to determine the relative content of genetically modified Roundup Ready soya in food by monitoring the threshold values for GMO in soya raw material and food products. Relative quantification is performed by comparing the amplification of a specific gene of Roundup Ready soya with a specific gene of native soya. For calculation purposes, included or external (imported) standard curves can be used.

Note: The foodproof GMO Soya Quantification Kit has been validated to quantify up to 5% GMO content.



2.5 Product Characteristics

Specificity	The primers and hydrolysis probes (5'-nuclease probes) provided in the GMO Gene Master Mix, (vial 1, yellow cap) and in the Reference Gene Master Mix, (vial 2, green cap) are sequence-specific for Roundup Ready soya and native soya, respectively.
Sensitivity	Detects the relative amount of 0.1% genetically modified Roundup Ready soya content in raw material.
Measuring Range	The kit can measure the relative content of Roundup Ready soya in a range of 0-5% (for standard material containing 0.1% GMO the coefficient of variation is equal to or less than 50%; for standard material containing 1-5 % GMO the coefficient of variation is equal to or less than 35%).

2.6 Quality Control

The foodproof GMO Soya Quantification Kit is function tested according to the protocol described below, using sample material with up to 5% GMO content.

2.7 Background Information

The genetically modified soybean "GTS40-3-2", better known as Roundup Ready soya, was the first GMO crop approved in the EU (1). Roundup Ready soya carries a gene that codes for the enzyme CP4 EPSPS (5-enol-pyruvylshikimate-3 phosphate synthase from *Agrobacterium* sp. strain CP4), which confers tolerance to herbicides with the active ingredient glyphosate (*e.g.*, Roundup). According to Swiss and EU law (2-3), foods and additives with more than 1% and 0.9% (in Switzerland and in Europe, respectively) relative amount of genetically modified organisms must be labeled as GMO products.

3. Procedure

3.1 Before You Begin

3.1.1 Precautions and Warnings

Quantification of the relative GMO content using the foodproof GMO Soya Quantification Kit requires DNA amplification by PCR. The kit provides all required reagents in a ready-to-use master mix for the performance of PCR. However, in order to achieve reliable results, the entire assay procedure must be performed under nuclease-free conditions:

Prepare appropriate aliquots of the kit solutions and keep them separate from other reagents in the laboratory.

- Use nuclease-free labware (*e.g.*, pipettes, pipette tips, reaction vials).
- Wear gloves when performing the assay.
- To avoid cross-contamination of samples and reagents, use fresh aerosol-preventive pipette tips.
- To avoid carry-over contamination, transfer the required solutions for one experiment into a fresh tube, rather than directly pipetting from stock solutions.
- Do not touch the surface of the capillaries. Always wear gloves when handling the capillaries.
- Physically separate the workplaces for DNA preparation, PCR setup, and PCR to minimize the risk of carry-over contamination. Use a PCR hood for all pipetting steps.
- In order to avoid cross-contamination, close all capillaries that contain sample DNA and negative controls before pipetting positive controls.



Note: Protect the GMO Gene Master Mix, (vial 1, yellow cap) and the Reference Gene Master Mix, (vial 2, green cap) from light.

3.1.2 Additional Equipment and Reagents Required

- Real-time PCR instruments with a FAM detection channel
- Real-time PCR compatible tubes, strips or plates with optical cap or foil specific for the PCR cycler used
- Standard benchtop microcentrifuge containing a rotor for 2.0 ml reaction tubes.
- Standard swing bucket centrifuge containing a rotor for multiwell plates with suitable adaptors.
- foodproof Sample Preparation Kit III (Product No. KIT230174)
- Nuclease-free, aerosol-resistant pipette tips
- Pipettes
- Sterile reaction tubes for preparing PCR mixes and dilutions

The kit must not be used in diagnostic procedures.

The kit described in this Instruction Manual has been developed for real-time PCR instruments with a FAM detection channel. The performance of the kit was tested with the following real-time PCR instruments: LightCycler® 480 II (Roche Diagnostics) and Mx3000P® QPCR System (Stratagene).

3.1.3 Sample Material

Use any sample material suitable for PCR in terms of purity, concentration, and absence of inhibitors. For preparation of genomic DNA from raw material of plant origin or from food, refer to the corresponding product package inserts of a suitable sample preparation kit (see Additional Equipment and Reagents Required).

Note: In order to quantify the relative amount of genetically modified Roundup Ready soya in a sample of interest, the sample DNA must be diluted at least 1:10 in the Dilution Buffer, (vial 6, blue cap) provided with the kit. This dilution step is essential to compensate for the different ion concentrations of the Calibrator DNA and the sample DNA. The latter depends on the buffers used for the sample preparation procedure. This dilution step also reduces the risk of inhibitory effects.

3.1.4 Assay Time

Procedure	Time
PCR Setup	15 min
PCR run	90 min (e.g., LC 480 II)
Total assay time	105 min

3.1.5 Positive Control

Always run a positive control with the samples. To prepare a positive control, replace the template DNA with the Calibrator DNA, (vial 5, purple cap) or with a positive sample preparation control [e.g., Roundup Ready soya IRMM Certified Reference Material (4)].

3.1.6 Negative Control



Always run a negative control with the samples. To prepare a negative control, replace the template DNA with PCR-grade water (vial 7, colorless cap). Include a negative control during sample preparation to monitor reaction purity and cross-contamination. This extraction control can be used as an additional negative control reaction.



3.2 Program Setup

Program the PCR instrument before preparing the reaction mixes. The amplification is carried out according to the following temperature-time-program (for details on how to program the experimental protocol, see the operation manual of your real-time PCR cycler):

Program for the Roche LightCycler 480:

Pre-incubation 1 cycle

Step 1: 37°C for 4 minutes

Step 2: 95°C for 10 minutes

Amplification 50 cycles

Step 1: 95°C for 5 seconds

Step 2: 60°C for 60 seconds

Fluorescence detection in step 2

Program for other real-time PCR instruments:

Pre-incubation 1 cycle

Step 1: 37°C for 4 minutes

Step 2: 95°C for 10 minutes

Amplification 50 cycles

Step 1: 95°C for 15 seconds

Step 2: 60°C for 60 seconds

Fluorescence detection in step 2

For some real-time PCR instruments, the type of the probe quencher as well as the usage of a passive reference dye has to be determined. The foodproof GMO Soya Quantification Kit contains probes with TAMRA as the quencher and no passive reference dye.

Note for users of the Agilent Mx3005P instrument:

Click 'Instrument → Filter Set Gain Settings' to open the Filter Set Gain Settings dialog box in which the gain settings may be viewed and modified. For FAM, the Filter Set Gain Setting has to be modified to 'x1'.

Note: The kit can also be used with the protocol of the foodproof GMO Screening Kit (Product No. KIT230045).

3.3 Experimental Setup

3.3.1 General Remarks

Determination of the relative ratio of Roundup Ready soya content can be performed using one of the following alternative procedures:

- Procedure A: Quantification using included (in-run) relative standard curves
- Procedure B: Quantification using external (imported) relative standard curves

Thoroughly read the software instructions prior to performing this assay.

3.3.2 Procedure A - Quantification Using Included (in-run) Relative Standard Curves

Each individual real-time PCR run consists of:

- Six dilution steps of the Calibrator DNA for both the Roundup Ready soya and the Reference Gene PCR in order to generate the respective calibrator curves (see table below)
- A variable number of sample preparations to be analyzed for genetically modified Roundup Ready soya DNA amplification



- At least one negative control reaction to control for contamination of the Roundup Ready soya- and the Reference Gene PCR Master Mix, respectively
- One positive reaction with the Calibrator DNA each for the Roundup Ready soya and the Reference PCR to compensate for constant differences between the PCR performance of the Roundup Ready soya and the reference gene

Therefore, a typical experiment consists of 16 wells needed for controls plus $2 \times (n)$ wells needed for the samples of interest, where (n) indicates the number of food samples of interest. Since a multiwell plate has 96 wells, 40 food samples can be analyzed during one PCR run if the Roundup Ready soya and the reference gene are analyzed in the same run.

3.3.3 Dilution of Calibrator DNA

Quantification of the GMO content via Procedure A requires the stepwise dilution of the Calibrator DNA (vial 5, purple cap) in the Dilution Buffer (vial 6, blue cap) as shown below:

Dilution step	Dilution	Concentrations to be Entered as Standards for the Reference or the Roundup Ready Soya PCR
1	Undiluted	100
2	1:4	25
3	1:16	6.25
4	1:64	1.56
5	1:256	0.39
6	1:1,024	0.098

3.3.4 Procedure B - Quantification Using External (imported) Relative Standard Curves

Each individual real-time PCR run consists of:

- One positive reaction with the Calibrator DNA each for the Roundup Ready soya- and the Reference PCR to compensate for constant differences between the PCR performance of the Roundup Ready soya and the reference gene
- A variable number of sample preparations to be analyzed for genetically modified Roundup Ready soya DNA amplification
- At least one negative control reaction to control for contamination of the Roundup Ready soya and the Reference Gene PCR Master Mix, respectively

Therefore, a typical experiment consists of 4 wells needed as controls plus $2 \times (n)$ wells needed for the samples of interest, where (n) indicates the number of food samples of interest. Since a multiwell plate has 96 wells, 46 food samples can be analyzed during one PCR run if the Roundup Ready soya- and the reference gene are analyzed in the same run.

Note: Procedure B is only applicable if the real-time PCR instrument used allows importing external standard curves generated in a previous run.



3.4 Preparation of the PCR Mixes

Proceed as described below to prepare a 25 μL standard reaction. The PCR mixes for the Soya GMO Gene and the Reference Gene must be set up separately, using the respective Master Mixes.

Do not touch the upper surface of the PCR plate.

1. Thaw the solutions and, for maximal recovery of contents, briefly spin vials in a microcentrifuge before opening. Mix carefully but thoroughly by pipetting up and down.
2. In a 1.5 mL reaction tube, prepare the PCR Mix by adding the following components in the order mentioned below, then mix gently but thoroughly by pipetting up and down:

The volumes indicated below are based on a single 25 μL standard reaction. Prepare the PCR mix by multiplying the amount in the “Volume” column by the number of reactions (sample and control reactions) to be cycled plus one or two additional reactions to cover pipetting losses.

Mix for the GMO Gene:

Component	Volume
GMO Gene Master Mix, (vial 1, yellow cap)	18 μL
Enzyme Solution, (vial 3, red cap)	1 μL
Dye solution, (vial 4, black cap)	1 μL
Total volume	20 μL

Mix for the Reference Gene:

Component	Volume
Reference Gene Master Mix, (vial 2, green cap)	18 μL
Enzyme Solution, (vial 3, red cap)	1 μL
Dye solution, (vial 4, black cap)	1 μL
Total volume	20 μL

3. Mix carefully but **thoroughly** by pipetting up and down. Do not vortex.
 - Pipet 20 μL PCR mix into each well.
 - For the samples of interest, add up to 5 μL sample DNA (if less than 5 μL , add H_2O to 5 μL) to a well.
 - For the negative control, add 5 μL PCR-grade H_2O (vial 7, colorless cap).
 - Procedure A: For the included (in-run) relative standard curves, add 5 μL of each dilution of Calibrator DNA (vial 5, purple cap) to the wells.
 - Procedure B: For the positive control, add 5 μL Calibrator DNA (vial 5, purple cap) to a well.
4. Seal the plate accurately with an optical sealing foil.
5. Place the plate in a swing bucket centrifuge and centrifuge at 1,500 x g for 30 s.
6. Cycle the samples as described above.



3.5. Calculation of Relative Amount of Roundup Ready soya

3.5.1 Procedure A – Quantification using included (in-run) relative standard curves

The use of calibration curves results in two values for every sample analyzed (i.e., one for the Roundup Ready soya and one for the reference gene).

Note: Since the calibration curves are specific for the Roundup Ready soya- and Reference PCR, respectively, it is important that the generated values for the Roundup Ready soya- and Reference PCR are distinguishable. The percentage of Roundup Ready soya relative to the total soya content within the sample of interest must be calculated manually, with a spreadsheet program or with the analysis software of the used real-time PCR instrument (e.g., LightCycler 480 instrument, Mx3005p). Please refer to the manual for the real-time PCR instrument used for more detailed information. The calculation of the relative GMO content is based upon the resulting crossing points or Ct-values of one particular sample and the efficiency of the PCR. In brief, the crossing point or Ct value is the cycle at which PCR amplification begins its exponential phase and is considered the point that is most reliably proportional to the logarithm of the initial concentration. The efficiency of the PCR describes the kinetics during the reaction. The overall reaction efficiency is represented by the slope of the calibration curve. Since primers and hydrolysis probes (5'-nuclease probes) for both parameter-specific components (Roundup Ready soya and reference gene) have individual PCR efficiencies, a calibration curve for each gene must be generated.

Notes:

- Quantify two independent sample preparations of each food sample and take the mean value as the final result.
- The ratio of GMO:reference in the Calibrator DNA provided with the kit is 1.00.
- For statistical reasons, the Roundup Ready soya detection and quantification becomes less reliable at low copy numbers, (i.e., results obtained from sample material with crossing points or Ct values greater than 36 for either the Roundup Ready soya and/or the reference gene). Crossing points or Ct values greater than 29 in the Reference PCR indicate there is not enough soya DNA in the sample to reliably quantify 1% Roundup Ready soya content.
- DNA degradation during food processing may affect GMO quantification.

3.5.2 Procedure B – Quantification Using External (imported) Relative Standard Curves

For some real-time PCR instruments, it is possible to import external relative standard curves from a previously generated PCR run with the same instrument (e.g., LightCycler 480 instrument)

3.6 Related Procedures

3.6.1 Prevention of Carry-over Contamination

The heat-labile Uracil-DNA Glycosylase (UNG) is suitable for preventing carry-over contamination between PCRs. This technique relies on the incorporation of deoxyuridine triphosphate (dUTP) during all amplification reactions and the pretreatment of all successive PCR mixtures with the heat-labile UNG. The UNG cleaves DNA at any site where a deoxyuridine residue has been incorporated. The resulting abasic sites are hydrolyzed due to the high temperatures of the initial denaturation step and can no longer serve as PCR templates. The heat-labile UNG is inactivated during the initial denaturation step. Native DNA (e.g., the isolated genomic DNA from food or plant material) does not contain uracil and is therefore not degraded by this procedure. Since dTTP is replaced with dUTP and UNG is included in the foodproof GMO Soya Quantification Kit, decontamination can be achieved with the provided reagents.



4. Appendix

4.1 Troubleshooting

Observation	Possible Reason	Recommendation
No signal increase is observed, even with positive controls.	Incorrect detection channel has been chosen.	<ul style="list-style-type: none"> Set Channel settings to FAM
	Pipetting errors or omitted reagents.	<ul style="list-style-type: none"> Check for correct pipetting scheme and reaction setup. Repeat the PCR run. Always run a positive control along with your samples.
	No data acquisition programmed.	<ul style="list-style-type: none"> Check the cycle programs. Select acquisition mode “single” at the end of each annealing segment of the PCR program.
	Inhibitory effects of the sample material (e.g., caused by insufficient purification).	<ul style="list-style-type: none"> Use the recommended DNA sample preparation kit to purify template DNA. Dilute samples. Always run a positive control along with your samples.
Fluorescence intensity is too low.	Inappropriate storage of kit components.	<ul style="list-style-type: none"> Store the GMO Gene Master Mix (vial 1, yellow cap) and the Reference Gene Master Mix (vial 2, green cap) as indicated in Kit Contents Table; protect from light. Avoid repeated freezing and thawing.
	GMO Gene Master Mix or Reference Gene Master Mix are not homogeneously mixed.	<ul style="list-style-type: none"> Mix the GMO Gene Master Mix (vial 1, yellow cap) and the Reference Gene Master Mix (vial 2, green cap) thoroughly before pipetting.
	Low initial amount of target DNA.	<ul style="list-style-type: none"> Increase the amount of sample DNA. Depending on the chosen DNA isolation method, Inhibitory effects may occur.
Negative control samples are positive.	Carry-over contamination.	<ul style="list-style-type: none"> Exchange all critical solutions. Repeat the complete experiment with fresh aliquots of all reagents. Always handle samples, kit components and consumables in accordance with commonly accepted practices to prevent carry-over contamination.
Fluorescence intensity varies.	Insufficient centrifugation of the plate.	<ul style="list-style-type: none"> Always centrifuge the plate as described.
	Surface of the sealing foil is dirty (e.g., by direct skin contact).	<ul style="list-style-type: none"> Always wear gloves when handling the plate.



4.2 References

1. Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified soya beans (*Glycine max* L.) with the combined modification for insecticidal properties conferred by the Bt endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC. *Official Journal L 031*, 01/02/1997 p. 0069–0070.
2. REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 22 SEPTEMBER 2003; on genetically modified food and feed.
3. REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 22 SEPTEMBER 2003; concerning the traceability and labeling of genetically modified organisms and the traceability and labeling of food and feed products produced from genetically modified organisms.
4. Lipp M, Brodmann P, Pietsch K, Pauwels J and Anklam E. 1999. IUPAC Collaborative trial study of a method to detect the presence of genetically modified soybeans and maize dried powder. *Journal of AOAC International* 82, 923-928.

5. Supplementary Information

5.1 Ordering Information

Hygiena Diagnostics is offering a broad range of reagents and services. For a complete overview and for more information, please visit our website at www.hygiena.com.

5.2 License Notice

The purchase price of this product includes limited, nontransferable rights under U.S. Patent No. 7,687,247 owned by Life Technologies Corporation to use only this amount of the product to practice the claims in said patent solely for activities of the purchaser for bioburden testing, environmental testing, food testing, or testing for genetically modified organisms (GMO) in accordance with the instructions for use accompanying this product. No other rights are conveyed, including no right to use this product for *in vitro* diagnostic, therapeutic, or prophylactic purposes. Further information on purchasing licenses under the above patent may be obtained by contacting the Licensing Department, Life Technologies Corporation, 5791 Van Allen Way, Carlsbad, CA 92008. Email: outlicensing@lifetech.com.

5.3 Trademarks

foodproof® is a registered trademark of Hygiena Diagnostics GmbH. Other brand or product names are trademarks of their respective holders.

5.4 Contact and Support

If you have questions or experience problems with this or any other product of Hygiena Diagnostics GmbH, please contact our Technical Support staff (www.hygiena.com/support). Our scientists commit themselves to providing rapid and effective help. We also want you to contact us if you have suggestions for enhancing our product performance or using our products in new or specialized ways. Such customer information has repeatedly proven invaluable to us and the worldwide research community.

5.5 Reference Number

The reference number and original Hygiena Diagnostics GmbH article number: R 302 19



6. Change Index

Version 1, May 2013

First version of the package insert.

Version 2, March 2017

License Notice changed.

Revision A, January 2024:

Rebranding and new layout.

R 302 19 20 -> INS-KIT230046-RevA



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