foodproof® Yeast and Mold Quantification LyoKit

Revision C, April 2025

PCR kit for the quantitative detection of yeast and mold using real-time PCR instruments.

Product No. KIT230112 (LP)
Product No. KIT230113 (RP)
Product No. KIT230114 (DP)

Kit for 96 reactions (lyophilized) for a maximum of 94 samples

Store at 2 to 8 °C

For food 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 96 reactions with a final reaction volume of 25 µL each. Up to 94 samples (single sample preparation) plus quantification standard and negative control reactions can be analyzed per run.

1.2 Storage and Stability

- Store the kit at 2 to 8 °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.

1.3 Kit Contents

Vial No./Cap Color	Label	Contents, Function, Storage
foodproof® Yeast and Mold Quantification LyoKit Microplate, prefilled with 96 reactions (lyophilized)	Aluminum bag containing an 8-tube strip mat • KIT230112 with white low-profile tubes* • KIT230113 with clear regular-profile tubes* • KIT230114 with clear deep-profile (DP) tubes*	• 96 prefilled reactions (lyophilized). • Ready-to-use PCR mix containing primer and hydrolysis probes specific for DNA of Yeast and Mold and the Internal Control (IC) as well as Taq DNA Polymerase and Uracil-N-Glycosylase (UNG, heat-labile) for prevention of carryover contamination. • Store at 2 to 8 °C in the aluminum bag (tightly sealed). • **Protect from light and moisture!**
Quantification Standard	Vial 2 (purple cap)	• 1 x 400 µL • Contains a stabilized solution of DNA. • For use as a PCR run Quantification Standard. • Store at 2 to 8 °C.
Negative Control	Vial 3 (colorless cap)	• 3 x 1 mL • Nuclease-free, PCR-grade H_2O. • For use as a PCR negative control.
Cap strips	Plastic bag containing 8-cap strips	• 12 x 8-cap strip • For use in real-time PCR after addition of samples.

*Tube profile and instrument compatibility chart is available online: www.hygiena.com/documents

1.4 Additional Equipment and Reagents Required

- Real-time PCR cycler suitable for detection of FAM- and VIC-/HEX-labeled probes as well as for using low- or regular-profile strip tubes. If the strip tubes do not fit into the instrument, the samples must be transferred to appropriate PCR vessels after resuspension of the lyophilized PCR mix.
- Sample preparation kit (manual): foodproof StarPrep Two Kit (Product No. KIT230177)
- Sample preparation kit (high-throughput): foodproof StarPrep Six 8-Strip Kit (Product No. KIT230192)
- Pipettes and Nuclease-free, aerosol-resistant pipette tips
- Vortex centrifuge (choose one):
  - For PCR strips, Multispin MSC-6000 with the SR-32 Rotor
  - For PCR plates, CVP-2

1.5 Applicability Statement

The foodproof Yeast and Mold Quantification LyoKit is intended for the rapid detection of yeast and mold DNA isolated from all kinds of dairy samples that are potentially contaminated with yeast or mold.

The kit must not be used in diagnostic procedures.

The kit described in these Product Instructions has been developed for real-time PCR instruments with FAM and VIC/HEX detection channels.

- Versions KIT230112 and KIT230113 are performance tested with the following real-time PCR instruments: LightCycler® 480, LightCycler 96 (Roche Diagnostics), AriaMx® and Mx3005P® (Agilent Technologies), ABI™ 7500 Fast (Thermo Scientific), iQ™5 Real-Time PCR Detection System (Bio-Rad) and PikoReal® 24 (Thermo Scientific).
- Version KIT23014 is designed for instruments with FAM and VIC/HEX detection channels requiring clear plastic tubes (DP format). The kit's performance was tested with the Dualo 32® Beverage PCR instrument (Hygiena Diagnostics).

2. How to Use This Product

2.1 Before You Begin

2.1.1 Precautions

Detection of yeast and mold DNA using the foodproof Yeast and Mold Quantification LyoKit requires DNA amplification by PCR. The kit provides all the reagents required for the PCR. To achieve reliable results, the entire assay procedure must be performed under nuclease-free conditions. Follow the instructions below to avoid nuclease-, carryover- or cross-contamination:

- Keep the kit components 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 carryover contamination, transfer the required solutions for one experiment into a fresh tube rather than directly pipetting from stock solutions.
- Physically separate the workplaces for DNA preparation, PCR setup and PCR to minimize the risk of carryover contamination. Use a PCR hood for all pipetting steps.

Keep the foodproof Yeast and Mold Quantification lyophilized PCR Mix away from light and moisture.

2.1.2 Sample Material

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

2.1.3 Enrichment

Hygiena Diagnostics provides sample preparation kits suitable for all kinds of foods and PPS (see Additional Equipment and Reagents Required). For more product information, visit www.hygiena.com.

2.1.4 Positive Control

Always run a positive control with the samples. To prepare a positive control, replace the template DNA with the provided control DNA [foodproof Yeast and Mold Quantification Standard (vial 2, purple cap)] or with a positive sample preparation control.

2.1.5 Negative Control

Always run a negative control with the samples. To prepare a negative control, replace the template DNA with foodproof Yeast and Mold Negative Control (vial 3, 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.

2.2 Procedure

2.2.1 Program Setup for the Dualo® 32 Beverage Instrument (KIT230114)

The Dualo 32® Beverage (Product No. MCH230008) can be started from a pre-installed run template: Click on "New", select the appropriate template, and press "Select". After loading the samples, the instrument can be started by clicking on "Start Run".
For detailed instructions on how to program and start the PCR run on the Dualo 32® Beverage, please refer to the manual for this instrument.

2.2.2 Program Setup for other cyclers (KIT230112 / KIT230113)

The following procedure is optimized for a real-time PCR instrument with FAM (yeast and mold) and VIC/HEX (Internal Control) detection channels. 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):

Pre-incubation	**1** cycle
Step 1:	37 °C for 5 minutes
Step 2:	95 °C for 10 minutes
Amplification	**50** cycles
Step 1:	95 °C for 5 seconds
Step 2*:	63 °C for 60 seconds
Step 3:	72 °C for 60 seconds

* Fluorescence detection in step 2

Notes:

- For some real-time PCR instruments, the type of probe quencher as well as the use of a passive reference dye must be specified. The foodproof Yeast and Mold Quantification LyoKit contains probes with a non-fluorescent ("dark") quencher and no passive reference dye.
- For users of the Agilent Mx3005P instrument: Click 'Instrument → Filter Set Gain Settings' to open the Filter Set Gain Settings dialog box. For FAM and VIC/HEX, modify the Filter Set Gain Setting to 'x4'.

2.2.3 Preparation of the PCR Mix

Proceed as described below to prepare a 25 µL standard reaction. Use any sample material suitable for PCR in terms of purity, concentration, and absence of inhibitors.

Always wear gloves when handling tube strips or caps.

Note: The PCR strips must be stored in the provided aluminum bag with silica gel pads to avoid liquid absorption.

2.2.4 Procedure A: Quantitative Detection using a Standard Curve

1. Take the needed number of PCR tube strips out of the aluminum bag. Use scissors or a scalpel to cut the strips apart.

   Note: Tightly seal the bag afterward and store at the recommended conditions.

2. Place the PCR tube strips containing the lyophilized reagents in a suitable PCR tube rack. If the reagent pellets are not at the bottom of the tubes, briefly centrifuge or flick the pellets to the bottom before proceeding.

3. Carefully uncap the tube strips and discard the cap strips.

   Note: Do not leave strips open for extended periods of time. To avoid unwanted liquid absorption, only open strips shortly before filling.

4. Pipette sample into each PCR vessel:
   - For the samples of interest, add 25 µL of sample DNA (if using less volume, add Negative Control up to 25 µL).
   - For the negative control, add 25 µL of foodproof Yeast and Mold Negative Control (vial 3, colorless cap).
   - For the standard curve, add 25 µL of each dilution (in duplicate) of foodproof Yeast and Mold Quantification Standard (vial 2, purple cap) to generate the respective standard curve (see table below).

   Note: A typical experiment consists of 9 reactions needed for controls, plus n x reactions needed for the samples of interest, where (n) indicates the number of food samples of interest. Since 96 reactions can be made with the kit, up to 87 samples can be analyzed quantitatively during one PCR run.

   To reduce the risk of cross-contamination, it is recommended to prepare only one PCR tube strip at a time.

   Dilution of Quantification Standard

   Quantification of the yeast and mold content via the standard curve procedure requires the stepwise dilution of the foodproof Yeast and Mold Quantification Standard (vial 2, purple cap) with the foodproof Yeast and Mold Negative Control (vial 3, colorless cap) as shown below. Prepare each dilution step with a final volume of 100 µL by using 10 µL of the previous dilution step.

Dilution Step	Dilution	Concentration to Be Entered as Standard [GE/Reaction]
1	undiluted	10,000
2	1:10	1,000
3	1:100	100
4	1:1,000	10

5. Seal the PCR vessels tightly with the colorless cap strips.

   Note: Resuspend the pellet after sealing by mixing the tube strips thoroughly.

6. Spin the PCR vessels in a suitable centrifuge for only 5 seconds.

7. Cycle the samples as described above.

   Note: When using the LightCycler 480 instrument, a special adapter is necessary.

   For some PCR instruments, the PCR strips should be placed in a balanced order into the cycler block. For example, two strips can be placed in columns 1 and 12.

2.2.5 Procedure B: Qualitative Detection

1. Take the needed number of PCR tube strips out of the aluminum bag. Use scissors or a scalpel to cut the strips apart.

   Note: Tightly seal the bag afterward and store at the recommended conditions.

2. Place the PCR tube strips containing the lyophilized reagents in a suitable PCR tube rack. If the reagent pellets are not at the bottom of the tubes, briefly centrifuge or flick the pellets to the bottom before proceeding.

3. Carefully uncap the tube strips and discard the cap strips.

   Note: Do not leave strips open for extended periods of time. To avoid unwanted liquid absorption, only open strips shortly before filling.

4. Pipette sample into each PCR vessel:
   - For the samples of interest, add 25 µL of sample DNA (if using less volume, add Negative Control up to 25 µL).
   - For the negative control, add 25 µL of foodproof Yeast and Mold Negative Control (vial 3, colorless cap).
   - For the positive control, add 25 µL of foodproof Yeast and Mold Quantification Standard (vial 2, purple cap).

   Note: To reduce the risk of cross-contamination, it is recommended to prepare only one PCR tube strip at a time.

5. Seal the PCR vessels tightly with the colorless cap strips.

6. Mix thoroughly using a vortex centrifuge.

   Note: Hygiena Diagnostics recommends vortex centrifuges Multispin MSC-6000 for PCR strips or vortex centrifuge CVP-2 for PCR plates. Dedicated protocols are available for these centrifuges.

   Alternatively resuspend the pellet by manual mixing. This may be achieved by carefully pipetting the sample up and down multiple times during step 4 or flipping the tube strips after sealing while pressing down the cap strip.

7. Spin the PCR tube strips for 30 seconds at 150 – 200 x g in a suitable centrifuge.

   Note: If your centrifuge exceeds 200 x g, do not centrifuge for more than 5 seconds. Avoid centrifugation at forces exceeding 1000 x g!

8. Place the samples in your PCR cycler and run the program as described above.

   Note: When using the LightCycler 480 instrument, a special adapter is necessary.

   For some PCR instruments, the PCR strips should be placed in a balanced order into the cycler block. For example, two strips can be placed in columns 1 and 12.

2.3 Data Interpretation

The amplification of yeast and mold DNA is analyzed in the fluorescence channel suitable for FAM-labeled probe detection. The specific amplification of the Internal Control is analyzed in the fluorescence channel, which is suitable for VIC-/HEX-labeled probe detection.

Compare the results from the FAM (yeast and mold) and VIC/HEX (Internal Control) channels for each sample, and interpret the results as described in the table below.

Note: For LightCycler 480, analysis must be realized with the “Fit Points” setting.

2.3.1 Procedure A – Quantification using External Standards

Define the positions of the dilutions of the foodproof Yeast and Mold Quantification Standard as "Standard" with the respective concentrations given in the table above to generate a standard curve. Alternatively, a given standard curve from a previous PCR run can be imported if the real-time PCR instrument provides this opportunity.

The foodproof Yeast and Mold Quantification Standard is defined as GE/reaction, where GE is the genome equivalent. The use of the calibration curve results in one value for every sample analyzed. This value can be converted into CFU/g sample according to the following equation. It is recommended that the document "Yeast and Mold Quantification Template" from Hygiena Diagnostics be used for analysis.

$$\text{result}\left[\frac{\text{cfu}}{\text{g}}\right] = \text{result}\left[\frac{\text{GE}}{\text{reaction}}\right] * \text{correlation factor} * \text{sample dilution factor}$$

Example:

The following calculation is suitable for samples prepared with the foodproof StarPrep Two Kit:

The sample preparation factor depends on the sample preparation protocol.

With the foodproof® StarPrep Two Kit, the correlation factor is 10.

The sample dilution factor must be calculated.

- Sample dilution 1:10 (w/v) = 10 g sample homogenized with 90 mL solvent = total volume 100 mL
- Volume for sample preparation = 0.5 mL
- PCR template volume = 25 µL/ reaction

$$\text{sample dilution factor} = \frac{\mathbf{100\ mL}\ \text{(sample dilution total volume)}}{\mathbf{10\ g}\ \text{(sample)} * \mathbf{0.5\ mL}\ \text{(sample preparation volume)}} * \frac{\mathbf{25}}{\mathbf{25\ \mu L/reaction}\ \text{(PCR template volume)}} = \mathbf{20}$$

$$\mathbf{200}\left[\frac{\text{cfu}}{\text{g}}\right] = 1\left[\frac{\text{GE}}{\text{reaction}}\right] * \mathbf{20}\ \text{(sample dilution factor)} * \mathbf{10}\ \text{(correlation factor)}$$

2.3.2 Procedure B – Qualitative Detection

For qualitative detection, compare the results from FAM (yeast and mold) and VIC/HEX (Internal Control) channels for each sample and interpret the results as described in the table below:

FAM Channel	VIC/HEX Channel	Result Interpretation
Positive	Positive or Negative	Positive
Negative	Positive	Negative
Negative	Negative	Invalid

3. Troubleshooting

Observation	Possible Reason	Recommendation
No signal increase is observed, even with positive controls.	Incorrect detection channel has been chosen.	• Set Channel settings to FAM or VIC/HEX.
	Pipetting errors or omitted reagents.	• 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.	• Check the cycle programs.
No signal increase in the VIC/HEX channel is observed and the FAM channel is negative.	Inhibitory effects of the sample material (e.g., caused by insufficient purification).	• Use a recommended DNA sample preparation kit to purify template DNA. • Dilute samples or pipette a lower amount of sample DNA (e.g., 20 µL of PCR-grade H_2O and 5 µL of sample instead of 25 µL of sample).
Fluorescence intensity is too low.	Inappropriate storage of kit components.	• Store the foodproof Yeast and Mold Quantification lyophilized PCR Mix at 2 to 8 °C, protected from light and moisture.
	Low initial amount of target DNA.	• Increase the amount of sample DNA. Depending on the chosen DNA isolation method, inhibitory effects may occur.
Strong decrease of fluorescence baseline.	Resuspension of lyophilized PCR mix not complete.	• Always resuspend lyophilized PCR mix thoroughly.
Negative control samples are positive.	Carryover contamination is present.	• 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 carryover contamination. • Add positive controls after sample and negative control reaction vessels have been sealed.

Observation	Possible Reason	Recommendation
Fluorescence intensity varies.	Insufficient centrifugation of the PCR strips. Prepared PCR mix is still in the upper part of the vessel.	• Always centrifuge PCR strips.
	Outer surface of the vessel or seal is dirty (e.g., by direct skin contact).	• Always wear gloves when handling the vessel and seal.
Pellets are difficult to dissolve.	The lyophilized PCR mix started to rehydrate.	• Always store the lyophilized PCR mix in the aluminum bag with the silica gel pad. • Open the PCR strip shortly before filling.

4. Additional Information on this Product

4.1 How This Product Works

The foodproof Yeast and Mold Quantification LyoKit provides all necessary reagents and a control template for reliable interpretations of results. To ensure maximum reliability of the kit and to prevent misinterpretation of negative results due to inhibition of the amplification, an Internal Control (IC) is included. The hydrolysis probe was designed to bind specifically to the IC, allowing detection in the VIC/HEX channel, whereas the yeast and mold DNA is detected in the FAM channel.

In cases of a negative result due to inhibition of amplification by the sample DNA of interest, the amplification of the IC is suppressed as well, whereas a negative result for the sample DNA of interest and amplification of the IC clearly indicates the absence of yeast and mold DNA in the sample.

The foodproof Yeast and Mold Quantification LyoKit minimizes contamination risk and contains all reagents (except for template DNA) needed for the detection of yeast and mold DNA. Primers and probes provide specific detection of yeast and mold DNA in food samples. The described performance of the kit is guaranteed for use only on the real-time PCR instruments listed above.

4.2 Test Principle

1. Using the supplied sequence-specific primers in a polymerase chain reaction (PCR), the PCR instrument and its associated reagents amplify and simultaneously detect fragments of yeast and mold genomic DNA.
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.

4.3 Prevention of Carryover Contamination

The heat-labile Uracil-DNA Glycosylase (UNG) is suitable for preventing carryover 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 dUTP residue has been incorporated. The resulting abasic sites are hydrolyzed due to the high temperatures during 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 yeast or mold genomic DNA) 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 Yeast and Mold Quantification LyoKit, decontamination can be achieved with the provided reagents.

4.4 Background Information

Since yeast and molds are ubiquitous in the environment, foods can get contaminated easily through raw material, inadequately sanitized equipment or simply by airborne contaminants. When conditions for bacterial growth are less favorable [e.g., foods with low water activity (aw), low pH, high salt or high sugar content], yeasts and molds may become predominant spoilers in products. Therefore, the presence and the number of yeast and molds are regularly monitored in quality control. Conventional microbiological methods for the detection and quantification of yeasts and molds are very time-consuming, taking up to 14 days to perform. During this period, the product is not available for the market. The detection and enumeration of yeast and mold is the most time-consuming parameter; a rapid test would prolong the distribution time.

4.5 Product Characteristics

Specificity: The foodproof Yeast and Mold Quantification LyoKit inclusivity has been tested with 236 species. The selected strains represent a large variety of taxonomic groups within the phylogenetic tree of fungi (e.g., *Ascomycota: Dothideo-, Eurotio-, Hemiasco-, Leotio-, Saccharo-, Schizosaccharo-, Sordario-, Taphrinomycetes; Basidiomycota: Agarico-, Agaricostilbo-, Cystobasidio-, Microbotryo-, Tremello-, Wallemiomycetes; Zygomycota: Mortierellales, Mucorales).* All tested species could be detected by this kit (100% inclusivity).

Exclusivity was determined using 50 species of different prokaryotic and eukaryotic non-fungi species. The selection comprises different types of *Bacteria: Enterobacteriales, Pseudomonadales, Clostridia, Vibrionales, Lactobacilliales, Alteromonadales, Actinomycetales, Bacilliales; Chromista: Oomycota;* plants; animal species and human.

Sensitivity: The limit of detection (LOD) of the foodproof Yeast and Mold Quantification LyoKit is 1 genomic equivalent (GE) / PCR reaction.

4.6 References

1. DIN EN ISO 7218:2014-09. Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations (ISO 7218:2007 + Amd 1:2013).
2. DIN 10186:2005-10. Microbiological analysis of milk; enumeration of yeasts and moulds; reference method.
3. BVL L 01.00-37:1991-12. Determination of the number of yeasts and molds in milk and dairy products; reference method.
4. Boekhout T, Robert V, eds. (2003) Yeasts in food. Beneficial and detrimental aspects. B. Behr's Verlag GmbH, Hamburg.
5. Deak T. (1991) Foodborne Yeasts. *Adv Appl Microbiol* 36: 179 – 278.
6. Alexopoulos CJ. (1962). *Introductory Mycology*. Wiley and Sons, Inc.

4.7 Quality Control

The foodproof Yeast and Mold Quantification LyoKit is function-tested using the LightCycler 96 System.

5. Supplementary Information

5.1 Ordering Information

Hygiena Diagnostics offers a broad range of reagents and services. For a complete overview and for more information, visit us at www.hygiena.com and contact us via email or phone.

5.2 License Notice

The purchase price of this product includes limited, nontransferable rights under US 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 trademark of Hygiena Diagnostics GmbH. Hygiena® is a trademark of Hygiena.
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, contact our Technical Support staff (for details, see www.hygiena.com/support). Our scientists commit themselves to providing rapid and effective help. 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 602 42

6. Change Index

Version 1, October 2016
First version of the package insert.

Version 2, March 2017
License Notice changed.
Introduction of vortex centrifuges into the PCR Setup Procedure.

Revision A, December 2023
Rebranding and new layout.
R 602 42 20 -> INS-KIT230112-13-REVA.

Revision B, September 2024
Adding Dualo 32 Beverage and KIT230114 (DP).

Revision C, April 2025
Edits to program set-up for other cyclers in Section 2.2.2.
Addition of sample preparation kit in Section 1.4.

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