



DN*Allergen2* Peanut

REAL-TIME PCR KIT FOR PEANUT DNA DETECTION AND QUANTIFICATION.

Cat number HU0030224

for use on CFX96 Touch™ (Bio-Rad), CFX96 Opus
(Bio-Rad)

For 50 reactions



**GOLD
STANDARD
DIAGNOSTICS**

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1 INTRODUCTION

DNAllergen2 Peanut provides materials for the qualitative detection and/or for the quantitative analysis of DNA from food samples for Peanut, according to directive (EC) 1169/2011. DNAllergen2 Peanut enables the detection of Peanut (*Arachis hypogaea*).

DNAllergen2 Peanut is validated for use with the following real-time cyclers:

- Bio-Rad CFX96 Touch™, Bio-Rad CFX96 Opus

1.1 Test Principle

The procedure of the current kit follows the basic principles of the real-time PCR amplification method.

Each reaction contains an internal positive control (IPC). If the DNA contains PCR inhibiting substances, the signal of the amplification control will be affected, or the amplification will be suppressed. Examples for PCR inhibiting substances are alcohols (e.g. ethanol, isopropanol), surfactants (e.g. CTAB, SDS, Triton X100) and salts (e.g. sodium chloride). In addition, spices, herbs, algae, cocoa and further sample matrices may have PCR inhibiting effects.

For quantitative determination, a laboratory-grade, matrix-specific internal calibrant or a commercially available reference material (e.g. containing 40 mg Peanut / kg food sample), in combination with a standard dilution series, is required. For the standard curve five concentrations are measured with the calibration DNA included in the kit. Results from the amplification of the sample DNA and calibration curves are compared and the amount of allergen in the analyzed product (w/w) can be calculated. In general, this procedure is applicable for all homogenous food samples. The quantitative determination is inapplicable for swabs, sponges and inhomogeneous fluids/liquids.

To effectively prevent carry-over contamination between PCR assays, the DNAllergen2 Peanut PCR kit utilizes Uracil-DNA Glycosylase (UNG). Deoxyuridine triphosphate (dUTP) substitutes for deoxythymidine triphosphate (dTTP) in the PCR mix. Thus, newly synthesized amplicons contain deoxyuridine instead of deoxythymidine. The heat-labile UNG cleaves hydrolytically at the N-glycosylic bond of uracil and deoxyribose and is subsequently inactivated by the initial denaturation step in the PCR. A PCR preceded by this step exclusively amplifies from native thymine-containing DNA (e.g. Peanut DNA), reducing the risk of false positive signals due to carry over contamination of previous amplicons.

1.2 Limit of Detection and Limit of Quantification

The DNAllergen2 Peanut PCR has a limit of detection of ≤ 0.4 mg / kg using iMAGo extraction kit (Cat. no. 5524421001) or GeneSpin extraction kit (Cat. no. 5224400605). In accordance with DIN32645 the limit of quantification is 1 mg / kg using iMAGo extraction kit or GeneSpin extraction kit using blends of Peanut flour in corn flour containing these amounts of allergenic substance. The limit of detection and quantification of the complete method (DNA extraction and real-time PCR) depends on sample matrix, processing grade, DNA preparation and DNA content. Therefore, for the most accurate quantification possible, users must use a reference sample with a known amount of the allergen, whose composition and degree of processing corresponds as closely as possible to the sample to be tested and which is analyzed in parallel. The concentration of total DNA in the sample does not allow any conclusions to be drawn about the quantity and quality of the Peanut DNA.

WARNING: The DNAllergen2 Peanut PCR system is very sensitive and therefore even a small amount of target DNA can lead to a positive analysis result.

1.3 Components of the Kit

Table 1: Kit components, lid colors and volume of each component

Component	Lid color	No of tubes	Volume per tube
Oligo Mix	Yellow	1	390 µL
Basic Mix	Red	1	650 µL
Positive control	Black	1	50 µL
Calibration standard (details s. table below)	Blue	1	50 µL
Negative control	Green	1	100 µL
Diluent	Transparent	1	750 µL
ROX™ passive reference dye Note: only required when testing on the ThermoFisher Scientific ABI 7500 or ABI 7500 Fast*	Purple	1	23.9 µL

* **Note:** This kit is not validated on ABI 7500 instrument. Validation before using this instrument is the responsibility of the laboratory.

Store all reagents at $-20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, light protected and separated from PCR samples or post PCR areas.

Concentration of standard DNA is determined by digital droplet PCR (ddPCR). Use the undiluted calibration standard DNA and dilute the DNA in 1:10 steps with the provided Diluent to obtain a calibration series. Prepare a dilution series of 4 steps in 4 separate reaction tubes (labelled S2 to S5) and add 45 µL Diluent each:

Table 2: Preparation of standard DNA dilution series

Standard	Diluent	DNA	Final copy number per reaction*
Standard 1 (S1)	-	Standard DNA undiluted	500'000 copies
Standard 2 (S2)	45 µL Diluent	5 µL DNA of S1	50'000 copies
Standard 3 (S3)	45 µL Diluent	5 µL DNA of S2	5'000 copies
Standard 4 (S4)	45 µL Diluent	5 µL DNA of S3	500 copies
Standard 5 (S5)	45 µL Diluent	5 µL DNA of S4	50 copies

*5 µL of standard DNA are used for each calibration point.

1.4 Additional Equipment, Consumables and Reagents Required

Table 3: Appropriate real-time PCR cyclers and suggested consumables

Cycler	PCR plate	PCR clear heat seal
Bio-Rad CFX96 Touch™, Bio-Rad CFX Opus	<p>White PCR plates</p> <p>FrameStar® 96 Well Skirted PCR Plate, white wells, clear frame Cat no 4ti-0961/C from Azenta Life Science</p> <p>or</p> <p>Transparent PCR plates</p> <p>FrameStar® 96 Well Skirted PCR Plate, clear PP wells, clear PC frame, low profile, Cat. no. 4ti-0960/C from Azenta Life Science</p>	<p>Azenta Life Science Clear Heat Seal Cat no 4TI-0541</p> <p>for both plate types</p>

- 1.5 mL micro-tubes and tube rack
- Vortex mixer
- Centrifuge (1500 × g, preferably cooled)
- Centrifuge for micro titre plates (preferably cooled)
- Pipette sets and appropriate filter tips
- Powder-free disposable gloves

2 GENERALE RECOMMENDATIONS AND WORKING PRECAUTIONS

- For DNA extraction use only molecular-biology grade reagents and sterile-filtrated, deionised water (DNA-free) and 0.1 x TE buffer for DNA dilutions (Tris-HCl pH = 8.0 c = 1 mmol / L; EDTA pH = 8.0 c = 0.1 mmol / L).
- Use only powder-free gloves and change them frequently during the process.
- To obtain reliable results all pipettes must be calibrated regularly.

3 PREVENTION OF CROSS-CONTAMINATION

This section provides important information to prevent cross-contamination, which can lead to false-positive results and wrong decision-making. DNAllergen2 kits contains UNG, therefore the risk of false positive signals due to carry over contamination from previous amplicons is reduced, but as the DNAllergen2 kits are highly sensitive to genomic DNA, users are highly advised to follow these instructions strictly to ensure accurate and reliable test performance.

- Maintain strict physical separation between reagent preparation areas and all areas where samples are handled. For sample areas, keep sample preparation, sample extraction and amplification separated as well.
- Use unidirectional workflow and never bring amplified material into pre-amplification zones.
- Dedicated equipment (pipettes, racks, etc.) must be assigned to each area.

- Wear lab coat (separate lab coats for the different laboratory areas) and gloves and change gloves frequently, especially after handling samples or touching surfaces.
- Always use aerosol-resistant filter tips and avoid touching tube rims with pipette tips.
- Always include negative controls in the PCR runs and consider the risk of a potential contamination when one of those negative controls shows a target DNA amplification
- Open one tube at a time to avoid accidental mixing and minimize handling of tubes after addition of samples.
- Thaw and prepare reagents in the clean reagent preparation area only.
- Keep reagent tubes closed when not in use.
- Do not return unused reagents to the kit once they have been exposed to the sample handling area.
- Clean all work surfaces before and after use with DNA/RNA-degrading solutions (e.g., hypochlorite-based).
- Use UV decontamination where available (15–30 min exposure).
- Regularly monitor contamination risk using negative controls or environmental swabs.

4 PROCEDURAL NOTES

A thorough understanding of this document is necessary for correct use of the product. Reliable results will only be obtained by precise laboratory techniques and following the instructions accurately.

- Store the kit at $-20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ until opened for the first time.
- Thaw reagents just before use. Note: Frequent freezing and thawing might cause inactivation of the reagents. Do not freeze/thaw more than three times. If smaller volumes are needed: aliquot reagents at first use.
- Do not mix kit components of various kit lots.
- Do not use any component beyond the expiration date of the kit.
- After removing reagents from the freezer, allow them to thaw slowly and mix them by vortexing and briefly centrifuge before use.
- Thaw and prepare only as much Master Mix from the components as needed for PCR.
- Keep the Master Mix cooled during the working steps. The composed Master Mix can be stored up to 4 hours in the refrigerator but must not be used after this period.
- To avoid degradation/inactivation of components immediately start PCR reaction after adding sample DNA to the composed Master Mix. Do not store the mix with sample DNA.
- Unused reagents should be stored at $-20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.
- Master Mix and positive controls should be mixed by vortexing and briefly centrifuged before use.

Caution: The calibration standard contains high numbers of target copies and should be handled carefully and separately from test samples.

5 TEST PROCEDURE

Different approaches and assay formats are possible. Based on a long-term experience, we recommend the workflow outlined below.

5.1 Sample DNA for PCR analysis

The choice of the appropriate DNA extraction procedure is crucial and depends on the sample type. We recommend the use of automated iMAGo-Kit (Cat. no. 5524421001) iMAGo Food or for manual DNA-extraction GeneSpin extraction kit (Cat. no. 5224400605).

Absolute DNA amount and purity (absence of PCR inhibiting substances) affect the overall sensitivity, as well as the accuracy of the analysis. The use of an insufficient quantity of DNA results in poor LOD and LOQ with regards to the specific test sample. Insufficiently pure DNA displaying inhibitory effects increase inaccuracy or even lead to totally biased results.

The concentration of the DNA extraction used in the PCR should be measured and adjusted if necessary before setting up the PCR. The copy numbers of the sample DNA should be in the range of the calibration samples.

5.2 Calculation of the Number of Reactions and the Required Volume, Preparation of the PCR Master Mix

Calculate the total number of reactions needed (samples and control reactions) for the specific PCR assay. Recommended control reactions for the specific PCR assay: negative control (mandatory), extraction control (recommended), positive control (mandatory). The reaction mix contains an internal positive control (IPC) per reaction.

Reactions needed for the qualitative detection of Peanut:

- 1x positive control
- 1x negative control
- For each sample: at least 1 reaction for each sample DNA
- Additionally, 1x extraction control is recommended

Additional reactions needed for the quantitative detection of Peanut:

- Five reactions for the standard series
- Two reactions for reference material (internal matrix specific standard, calibration standard)

Depending on their own internal rules, laboratories can perform multiple technical replicates for the reactions mentioned above.

It is also recommended to prepare the Master Mix with 10 % additional volume to compensate reagent loss. Allow the reagents to thaw, mix and centrifuge before opening and use.

Table 4: Preparation of qPCR reactions

Components of the Master Mix	Lid color	Amount per reaction
Oligo Mix	Yellow	7.5 µL
Basic Mix	Red	12.5 µL
ROX™ passive reference dye ¹	Purple	0.45 µL
	Total volume	20 µL / 20.45 µL ²

¹ROX must be added at analyses on ABI 7500 instruments, ² In case ROX™ is needed, the respective volume is added to the Master Mix

Note: This kit is not validated on ABI 7500 instrument. Validation before using this instrument is the responsibility of the laboratory.

5.3 Setup of Reactions

1. Calculate the number of reactions and amount of equivalent Master Mix reagents before thawing the reagents.
2. In case you have aliquoted kit components prior to first use, only thaw just as much Oligo Mix and Basic Mix as needed.
3. Prepare the Master Mix by mixing the Basic Mix and the Oligo Mix as calculated: 12.5 µL of Basic Mix and 7.5 µL of Oligo Mix per reaction
4. Vortex and centrifuge the Master Mix.
5. The composed Master Mix without template DNA can be stored up to 4 hours in the refrigerator.
6. Add 20 µL of the Master Mix into appropriate wells.
7. Add each 5 µL of corresponding DNA solution (standards, controls, sample) or 5 µL of non-template control (NTC) to the reaction.

5.4 Cyclor Programming

Selection of detection channels, baseline and threshold settings

Set baseline and threshold values according to cyclor manufacturers' instructions and follow Good Laboratory Practice.

We recommend the following settings:

Table 5: Detection channels, threshold and baseline settings

Cycler	Peanut specific target	IPC	Ramping	Baseline Setting	Threshold Setting
Bio-Rad CFX96 Touch™ and Opus	FAM™	HEX™	Default maximum rate	Baseline subtracted curve fit- apply fluorescence drift correction.	Auto ¹

Refer to your cycler's manual for details. For all target probes: Non-fluorescent quenchers are used.

¹Check visually, if the threshold is set incorrectly in automatic mode, adjust it manually (see Troubleshooting section for details)

²The threshold should be placed at the beginning of the exponential amplification across all of the amplification plots. This region is depicted in the log view of the amplification plots as the linear portion of the plot. Please note: the threshold should not be placed in the region of background fluorescence or where splitting between replicates may be observed

Table 6: PCR Temperature Profile for Bio-Rad CFX96 Touch™ and Opus

	Temperature	Time	No of Cycles
UNG activity	50 °C	5 min	1
Initial enzyme activation	95 °C	10 min	1
Denaturation	95 °C	15 sec	41 repetitions
Annealing & extension	60 °C	45 sec	

Note: The lid heater must be set to 105°C.

6 EVALUATION

6.1 Cycling Parameters / Instrument Settings

After run completion, data should be evaluated using either the Gold Standard Diagnostics evaluation sheet or by using the appropriate software provided by the cycler manufacturer.

The Gold Standard Diagnostics DNAllergen2 evaluation sheet (Excel™) can be requested from your local sales support.

To achieve a standardised evaluation in the analyses and to normalise instrument-related differences between individual runs, we recommend setting the threshold based on the respective C+ on the PCR plate. For details see Troubleshooting section.

For raw data export, please follow the instruction in the corresponding cycler analysis software or refer to the Gold Standard Diagnostics evaluation sheet instructions.

Additional Information for Gold Standard Diagnostics Evaluation Sheet

If you wish to use the Gold Standard Diagnostics evaluation sheet with automated data import, please use the assay detector/ target identifier names given below and follow the instructions on the instruction page of the evaluation sheet:

Table 7: Gold Standard Diagnostics Evaluation Sheets

System	Detector	Identifier
Peanut specific	FAM™	14007a
IPC	HEX™	14007i

7 RESULTS

The quantification results reflect the copy number of allergen specific DNA targets in a sample detected by DNAllergen2 Peanut. A correlation to the amount of allergen (in mg / kg) in a sample can only be made by comparison with the detected copy numbers in a reference sample with known allergen content. In addition it must be taken in consideration that the amount of detectable DNA in a given sample can be influenced by processing (e.g. temperature, humidity, pH) and by storage of sample (e.g. temperature, time, light).

7.1 Interpretation of Results

The following chapters describe the interpretation of the results after following the workflow as described above.

Export Cq (= Ct) values to the Gold Standard Diagnostics evaluation sheet or create an own evaluation sheet following the parameters below. The evaluation sheet (Excel™) can be requested from your local sales support.

Table 8: Definitions of rules for interpretation of results

PCR System	Cycler	Cq Cut-Offs	Endpoint Fluorescence (EPF)- Limits
Peanut	Bio-Rad CFX96 Touch™ & Opus	Cq sample ≤ 36	Mean EPF (C+) x 0.1
IPC	Bio-Rad CFX96 Touch™ & Opus	Cut-off-1: mean Cq (NTC) -3 Cut-off-2: mean Cq (NTC) +3	Cut-off-1: mean EPF (NTC*) x 0.2 Cut-off-2: mean EPF (NTC*) x 0.1

Table 9: Scoring of Inhibition Control (IPC) as also defined in Gold Standard Diagnostics evaluation sheet

Cq	EPF	Result
Cq Cut-off 1 $\leq$ Cq sample $\leq$ Cq Cut-off 2	EPF sample $\geq$ EPF Cut-off 1	IPC valid
Cq sample $>$ Cq Cut-off 2	-	IPC invalid
-	EPF sample $<$ EPF Cut-off 2	IPC invalid
Cq sample $<$ Cq Cut-off 1	EPF sample $<$ EPF Cut-off-1	IPC invalid
Cq sample $<$ Cq Cut-off 1	EPF sample $\geq$ EPF Cut-off-1	Check amplification!
Cq Cut-off 1 $\leq$ Cq sample $\leq$ Cq Cut-off 2	EPF Cut-off-2 $\leq$ EPF sample $<$ EPF Cut-off-1	Check amplification!
No Cq	-	IPC invalid

Note: In case of “Check amplification!”, the linear scale amplification plots must be carefully checked for presence or absence of a sigmoid PCR amplification signal. If the curve is sigmoid, the result is positive; if not, the result is negative.

Table 10: Scoring of Detection Systems as also defined in Gold Standard Diagnostics evaluation sheet

Cq (target)	EPF (target)	Preliminary Result
Cq sample $\leq$ Cq Cut-Off	EPF sample $\geq$ EPF Limit	Positive
Cq sample $\leq$ Cq Cut-Off	EPF sample $<$ EPF Limit	Check amplification!
Cq sample $>$ Cq Cut-Off	EPF sample $<$ EPF Limit	Negative
Cq sample $>$ Cq Cut-Off	EPF sample $\geq$ EPF Limit	Check amplification!
No Cq	-	Negative

Note: In case of “Check amplification!”, the linear scale amplification plots must be carefully checked for presence or absence of a sigmoid PCR amplification signal. If the curve is sigmoid, the result is positive; if not, the result is negative.

Table 11: Final Result derived from combination of Inhibition Control and Test Reaction

IPC Result	Preliminary Result	Final Result
Valid	Reaction positive	Positive
Valid	Reaction negative	Negative
Valid	Check Amplification	Check Amplification of the target PCR to decide if the final result is positive or negative
Invalid	Reaction positive	Positive
Invalid	Reaction negative	Inhibited
Invalid	Check Amplification	Check Amplification of the target PCR to decide if the final result is positive or inhibited

IPC Result	Preliminary Result	Final Result
Check Amplification	Reaction positive	Positive
Check Amplification	Reaction negative	Check Amplification of IPC to decide if the final result is negative or inhibited.
Check Amplification	Check Amplification	Check Amplification of IPC and the target PCR to decide if the final result is positive, negative or inhibited.

7.2 Calculation of Quantification Results

For the evaluation of the quantification, please follow the analysis software recommendation of the real-time PCR instrument manufacturer or use the Gold Standard Diagnostics DNA_llergen2 evaluation sheet (Excel™).

The resulting copy numbers can be used to calculate the relative amount of Peanut in each sample by comparison with spiked matrices or standard material.

The concentration of allergen in an analyzed sample can be determined by a relative comparison of the DNA copies measured in this sample with the DNA copies measured in a parallel analyzed reference sample with a known allergen content. It is to be expected that the more similar the composition and processing of the analyzed sample and the reference sample are, the more precise the determination of the allergen quantity in the analyzed sample will be.

Even if the composition and processing of the analyzed sample and the reference sample are similar, other factors such as the starting material, its storage and age as well as the part of an animal or plant that has been processed can influence the determination of the amount of allergen in a sample.

The quantitative detection of allergens is based solely on the measurement and comparison of the amount of DNA in the analyzed sample and the reference sample, not the amount of allergen by weight.

In short, quantification of Peanut DNA content in a given sample is based on a five-step calibration curve prepared of synthetic target DNA (ranging from 50 to 500'000 copies per reaction). In addition, spiked matrices or standard material with known concentration of Peanut must be analyzed. The relative quantity of Peanut in the unknown samples could be calculated using the specified formula given in the evaluation sheet, taking into account the C_q-values of the unknown samples and the reference material and the slope of the calibration curve.

7.3 Limitations of the method

- The presence of PCR inhibitors may cause invalid results.
- Extremely low levels of target DNA below the limit of detection (LOD) may be detected, but results may not be reproducible.
- Samples tested negative could still contain an allergen contamination below the limit of detection of the assay, or they might contain other allergen components like proteins or lipids for example.

8 TROUBLESHOOTING

Table 12: Troubleshooting

Result	Possible reasons	Possible verification and measures
No target and IPC amplification	Inhibition of PCR by inhibitory substances or too much DNA.	<p>If PCR remains inhibited, dilute the lysate with DNA-/Nuclease free water (one-part sample plus nine parts water).</p> <p>If PCR remains inhibited, repeat lysis of enrichment, and repeat PCR.</p> <p>Check if the matrix type has been validated for use with the used DNA extraction method and the DNAllergen2 Peanut. The method should only be applied to validated matrices.</p>
No target amplification in the PCR positive control	<p>Incorrect PCR program</p> <p>Incorrect or no positive DNA was used</p>	<p>Check and correct PCR program</p> <p>Repeat with a new aliquot of positive control DNA</p>
PCR positive control later as defined criteria	Amount of PCR positive control not sufficient	Check volume of PCR positive control needed and repeat PCR with correct amount
Target amplification in the PCR negative control	Contamination of PCR components or Mastermix with allergen target DNA or control DNA	Clean working space and repeat analysis with new PCR components
Standard curve is invalid: the value for the slope of the standard curve is not between -3.1 and -3.6 and the correlation coefficient R^2 is below 0.98.	Dilution of standard DNA was not performed according to description in table 2 "Preparation of standard DNA dilution series"	Repeat dilution of standard DNA according to description in table 2 "Preparation of standard DNA dilution series" and repeat PCR
PCR amplification signals are not evaluated correctly due to wrong automatic threshold setting in the respective real-time PCR software.	Due to e. g. matrix effects, baseline and therefore threshold settings did not work properly. The automatic set threshold can be either far too high leading to false negative results or too low (sometimes even in the negative range), leading to false positive results.	<p>We recommend setting the threshold manually, based on the C+ (tube with black lid) on the same plate. The Cq-value of the C+ should be close to 30 after adjusting the threshold.</p> <p>Examples of incorrectly set automatic thresholds by the respective real-time cycler software and how to correct manually are shown in in Fig 1.</p>

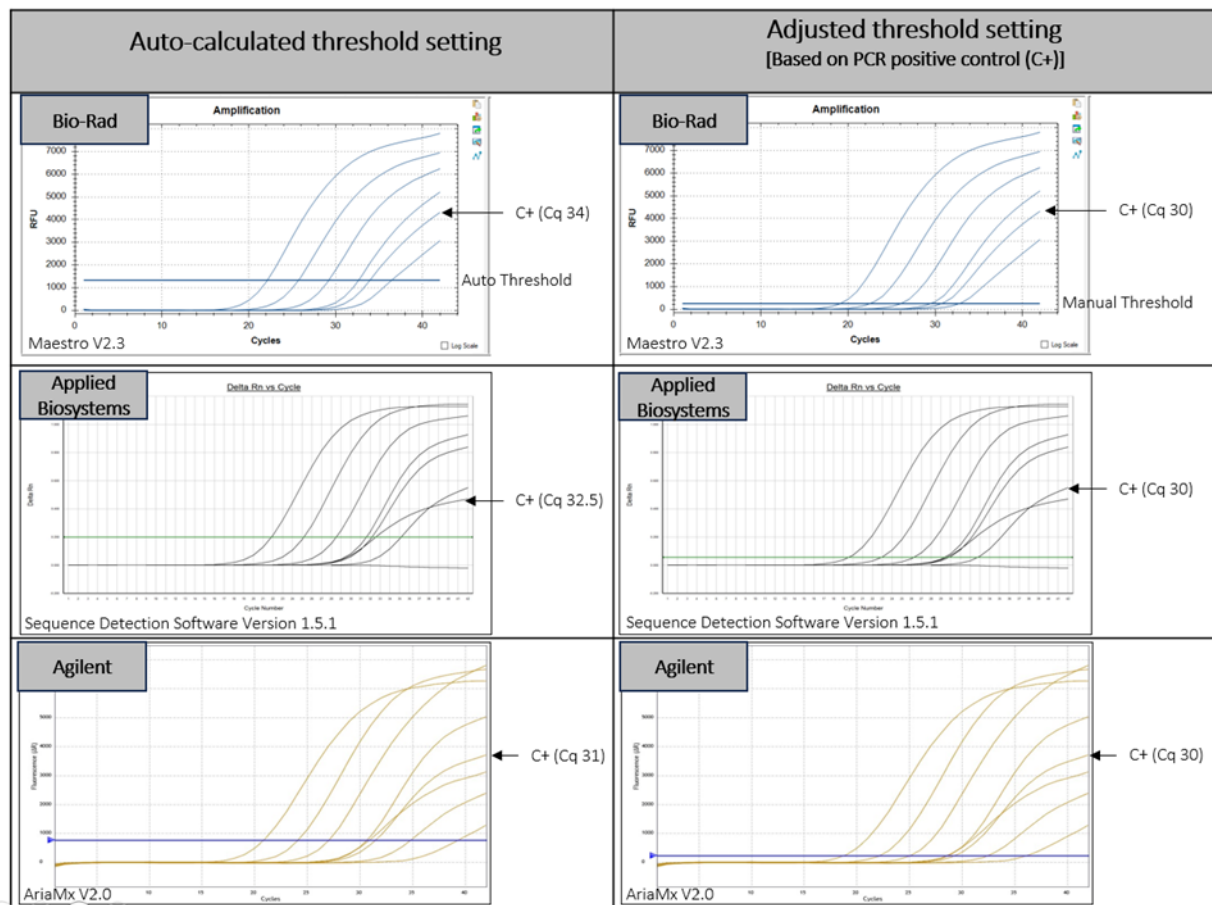


Fig 1: Left: Automatically set thresholds by the three real-time cycler software. Right: How to correct manually depending on the C+ on the same plate. Cq-value of the C+ should be close to 30.

Note: This kit is not validated on Applied Biosystems or Agilent instruments. Validation before using this instrument is the responsibility of the laboratory.

9 REFERENCES

- [1] Validation Report DNAllergen2 Peanut
- [2] Gold Standard Diagnostics DNAllergen2 evaluation sheet (Excel) Sheet for allergen testing assays (contact your local sales support)

10 PRODUCT WARRANTIES, SATISFACTION GUARANTEE

Gold Standard Diagnostics Budapest ("GSDB") warrants the products manufactured by it will be free of defects in materials and workmanship when used in accordance with the applicable instructions before the expiration date marked on the product packaging and when stored under the storage conditions recommended in the instructions and/or on the package. GSDB makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.

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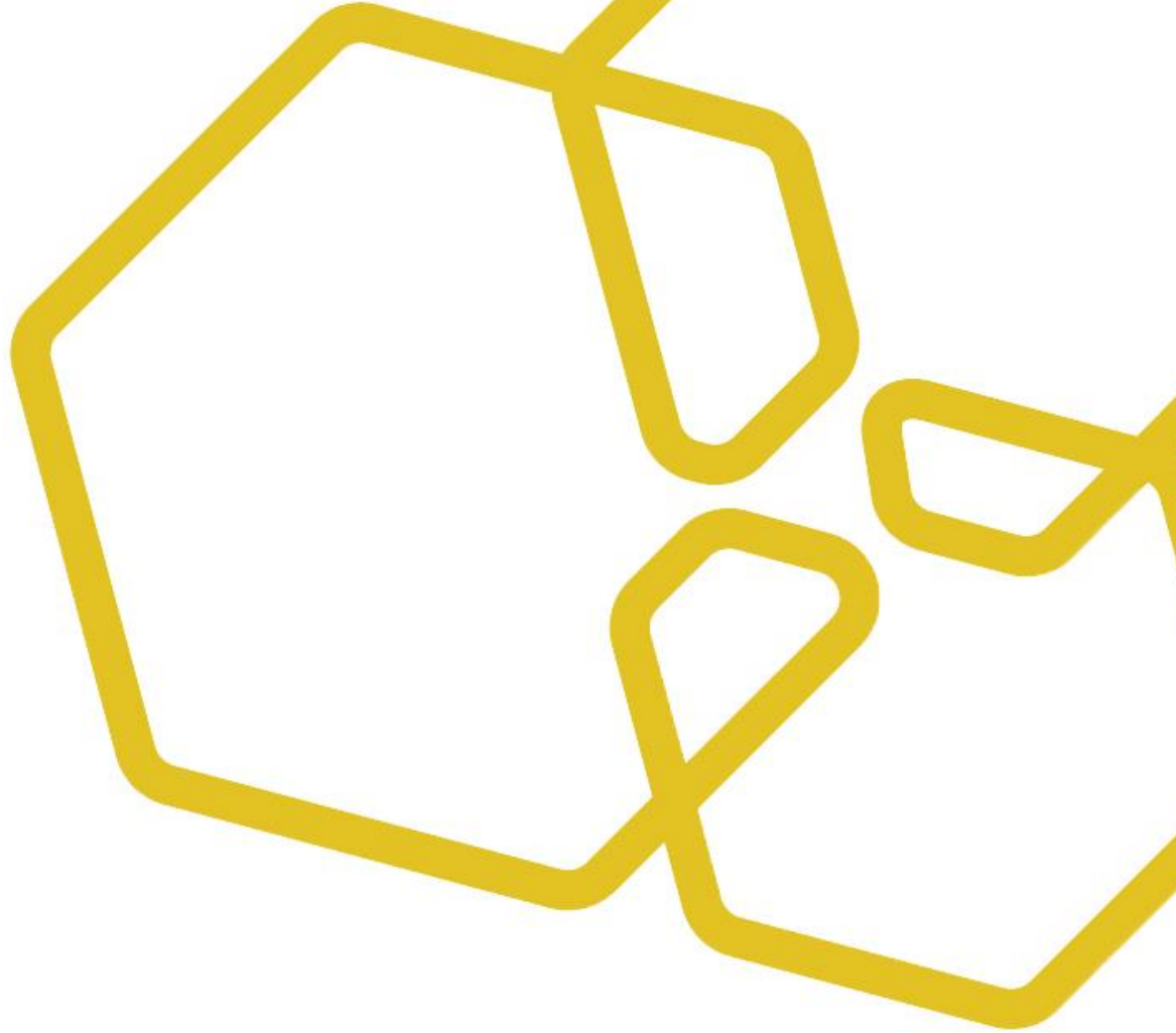
11 IMPORTANT NOTES

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12 VERSION CONTROL

Version	Date	Changes
1	14.07.2025	First version.
2	20.07.2026	Adjustment of Evaluation criteria.



TECHNICAL SUPPORT SERVICE

For technical assistance and more information, please contact Gold Standard Diagnostics Budapest's customer service or your local distributor.

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