

RealStar® GPR PCR Master 1.0 – Product Information Sheet

Product number: 8001004

For Laboratory use

Product description

The RealStar® GPR PCR Master 1.0 is a general purpose reagent (GPR) for the *in vitro* amplification and detection of target DNA by real-time polymerase chain reaction (PCR). The RealStar® GPR PCR Master 1.0 is not intended for a specific diagnostic application, but must be combined with appropriate analyte specific reagents (ASR) or other general purpose reagents to generate a finished *in vitro* diagnostic test. The RealStar® GPR PCR Master 1.0 includes an amplification and detection system for an artificial nucleic acid sequence to facilitate the implementation of an Internal Control.

Material provided

Cap color	Component	Number of vials	Content
Yellow	Master Mix	16	204 µl
Green	Internal Control	2	1,000 µl

Master Mix: 1.8x Buffered salt solution containing Taq polymerase, dNTPs, Internal Control specific oligonucleotides (probe labelled with the fluorophore JOE™)

Internal Control: Buffered salt solution containing artificial DNA (Internal Control template)

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to support@altona-diagnostics.com for the Safety Data Sheet.

Storage and handling

- All components should be stored between -25 and -15 °C upon arrival.
- Before use all components should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly.
- Repeated thawing and freezing of Master Mix (more than twice) should be avoided, as this might affect the performance of the product. The Master Mix should be frozen in aliquots, if to be used intermittently.
- Storage between +2 and +8 °C should not exceed a period of two hours.
- Protect the Master Mix from light.

Note: The RealStar® GPR PCR Master 1.0 is shipped on dry ice. The components should arrive frozen. If one or more components are not frozen upon receipt, or if tubes have been compromised during shipment, contact altona Diagnostics USA, Inc. for assistance.

Warnings and precautions

Before first use check the product and its components for:

- Integrity
- Completeness with respect to number, type and filling
- Correct labelling
- Frozenness upon arrival
- Specimens should always be treated as infectious and/or biohazardous in accordance with safe laboratory procedures.
- Always handle samples and product components with caution to avoid contamination.
- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.













- Always wear protective disposable powder-free gloves when handling specimens or product components.
- Use separated and segregated working areas for (i) sample preparation, (ii) reaction setup and (iii) amplification/detection activities. The workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering a different area.
- Seal reaction tubes/plate thoroughly and do not open post amplification to avoid contamination.
- Do not autoclave reaction tubes/plate after the PCR, since this bears the risk to contaminate the laboratory area.
- Do not use product components that have passed their expiration date.
- Discard sample and product waste according to your local safety regulations.

Instructions for use

The Taq polymerase included in the Master Mix is inactivated. Polymerase activity is restored by an incubation step at 95 °C for at least 10 minutes.

Each laboratory should establish its own standard operating procedures and instructions for using the RealStar® GPR PCR Master 1.0 in a molecular assay.

Symbols

	Batch code
	Cap color
	Product number
	Content
	Number
	Component
	Global Trade Item Number
	General Purpose Reagent
	Consult Product Information Sheet
	Temperature limitation
	Use until
	Manufacturer

Limitations

The product is for professional use only.

Technical assistance

For technical advice, please contact our Technical Support:

e-mail: support@altona-diagnostics.com
phone USA: +1 614 706 1784
phone headquarters Hamburg: +49 40 548 0676 0