




VisionArray PreCise Taq DNA Polymerase

REF VE-0001-100  100 tests

For the PCR-amplification of DNA sequences
subsequently used in VisionArray analyses



In vitro diagnostic medical device
according to EU directive 98/79/EC

1. Intended use

The VisionArray PreCise Taq DNA Polymerase is intended to be used for the amplification of DNA sequences in combination with a VisionArray Primer Kit by polymerase chain reaction (PCR).

For subsequent analysis the VisionArray Detection Kit, the respective VisionArray Chip, and the VisionArray Analysis Package are required.

This product is designed for *in vitro* diagnostic use (according to EU directive 98/79/EC). Interpretation of results must be made within the context of the patient's clinical history with respect to further clinical and pathologic data of the patient by a qualified pathologist.

2. Clinical relevance




Refer to the instruction for use of the respective VisionArray Chip.

3. Test principle

By polymerase chain reaction (PCR), DNA sequences can be amplified selectively. The basic principle of the PCR is based on a recurring circle of 3 steps: denaturation, annealing and elongation. Repetition of these steps leads to an exponential amplification of the target sequences.

4. Reagents provided

The following components are included:

Code	Components	Tests	Container
ES-0004-100	VisionArray PreCise Taq DNA Polymerase	 100	Screw-cap bottle (skirted)
WB-0013-100	PreCise Reaction Buffer, 10x	 100	Screw-cap bottle (skirted)
WB-0014-100	PreCise MgCl ₂ , 25 mM	 100	Screw-cap bottle (skirted)
	Instruction for use	1	

5. Materials required but not provided

Reagents:

- Corresponding VisionArray Primer Kit (see table 1)
- VisionArray Detection Kit (VK-0003)
- VisionArray Uracil-DNA Glycosylase (VE-0002)

Equipment:

- Corresponding VisionArray Chips (see table 1)
- VisionArray Analysis Package (E-4060)

Table 1: List of required products depending on examined disease

Disease	Product	Prod. Nr.
HPV	<u>VisionArray HPV Primer Kit 2.0</u>	VP-0001
	<u>VisionArray HPV Chip 1.0</u>	VA-0001
	<u>VisionArray HPV High Risk Chip 1.0</u>	VA-0002

6. Storage and handling

Store at -16...-22°C in an upright position. If these storage conditions are followed, the kit will function, without loss of performance, at least until the expiry date printed on the label.

The VisionArray PreCise Taq DNA Polymerase is shipped at 2...8°C but should be returned to storage conditions as soon as possible.

Return to storage conditions immediately after use. Do not use reagents beyond expiration date indicated on the label. The device is stable until expiration date indicated on the label when handled accordingly.

7. Warnings and precautions

- Read the instruction for use prior to use!
- Do not use the reagents after the expiry date has been reached!
- A material safety data sheet is available on request for the professional user.
- Do not reuse reagents.
- Avoid any cross-contamination and micro bacterial contamination of the reagents.
- Never pipet solutions with your mouth!
- A room separation of working steps with and without DNA as well as using clean benches for preparation of the PCR master mix is necessary to avoid contaminations.

8. Limitations

- For *in vitro* diagnostic use.
- For professional use only.
- Interpretation of results must be made within the context of the patient's clinical history with respect to further clinical and pathologic data by a qualified pathologist.
- The kit components are thoroughly adjusted to each other and the substitution of one or more components can lead to performance errors.
- It is important to use the indicated amounts of the components in order to avoid impairments of the reaction process.
- Repeated thawing and freezing of the DNA samples can lead to an impairment of the detection reaction.
- The performance was validated using the procedures described in this instruction for use. Modifications to these procedures might alter the performance and have to be validated by the user.

9. Interfering substances

- Low PCR efficiency due to PCR inhibition in DNA raw material (e.g. blood).
- High concentrations of EDTA in elution buffers may lead to an inhibition of the PCR.

10. Preparation of specimens

Refer to the instruction for use of the respective VisionArray Primer Kit for the preparation of sample DNA.

11. Preparatory treatment of the device

Refer to the instruction for use of the respective VisionArray Primer Kit.

12. Assay procedure

Refer to the instruction for use of the respective VisionArray Primer Kit.

13. Interpretation of results

Refer to the instruction for use of the respective VisionArray Chip.

14. Recommended quality control procedures

Refer to the instruction for use of the respective VisionArray Primer Kit.

15. Performance characteristics

Refer to the instruction for use of the respective VisionArray Chip.

16. Disposal

The disposal of reagents must be carried out in accordance with local regulations.

17. Troubleshooting

Any deviation from the operating instructions can lead to inferior results or to no results at all.

Refer to the instruction for use of the respective VisionArray Primer Kit.

Our experts are available to answer your questions.
Please contact helptech@zytovision.com



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