



VisionArray Uracil-DNA Glycosylase

REF VE-0002-100 Σ 100 tests

For the prevention of carry-over contaminations from previous runs in polymerase chain reactions (PCR) carried out with a VisionArray Primer Kit



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

1. Intended use

The VisionArray Uracil-DNA Glycosylase is intended to be used for the prevention of carry-over contaminations from previous runs in polymerase chain reactions (PCR) carried out with a VisionArray Primer Kit. UDG hydrolyzes uracil from single-stranded and double-stranded DNA, but not from oligomers (<6 bases).

For subsequent analysis the VisionArray Detection Kit, the VisionArray PreCise Taq DNA Polymerase, 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

In PCRs even minuscule amounts of a contamination can be amplified and lead to a false positive result. Such contaminations are often from previous PCRs (carry-over contamination). One common strategy is substituting dUTP for dTTP during PCR amplification, to produce uracil-containing DNA. Treating subsequent PCR reaction mixtures with Uracil-DNA Glycosylase prior to PCR amplification and subsequent cleavage of apyriminic polynucleotides at elevated temperatures under alkaline conditions will remove contaminating uracil-containing DNA from the sample. This method, of course, requires that all PCR reactions in the lab have to be carried out with dUTP instead of dTTP.

4. Reagents provided

The following components are included:

Code	Components	Tests	Container
ES-0005-100	VisionArray Uracil-DNA Glycosylase (UDG)	Σ 100	Screw-cap bottle (skirted)
WB-0015-100	UDG Reaction Buffer, 10x*	Σ 100	Screw-cap bottle (skirted)
	Instruction for use	1	

*The UDG Reaction Buffer is not required for VisionArray applications

5. Materials required but not provided

Reagents:

- Corresponding VisionArray Primer Kit (see table 1)
- VisionArray Detection Kit (VK-0003)
- VisionArray PreCise Taq DNA Polymerase (VE-0001)

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 Uracil-DNA Glycosylase 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.
- Never pipet solutions with your mouth!

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.
- It is important to use the indicated amounts of the components in order to avoid impairments of the reaction process.

9. Interfering substances

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

10. Preparation of specimens

Refer to the instruction for use of the corresponding 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.

18. Literature

Longo M C, et al., (1990) Gene 93:125-128

Our experts are available to answer your questions.

Please contact help@zytovision.com



42 life sciences GmbH & Co. KG
Fischkai 1
27572 Bremerhaven/Germany
Phone: +49 471 4832-500
Fax: +49 471 4832-308
www.42ls.com
Email: info@42ls.com

Distributed by:

ZytoVision GmbH
Fischkai 1
27572 Bremerhaven/ Germany
Phone: +49 471 4832-300
Fax: +49 471 4832-509
www.zytovision.com
Email: info@zytovision.com

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