Cell Control Slides HPV (Human Papilloma Virus)

REF / Cat. No.: MB-CC HPV-S

Instructions for use

Intended use

The Cell Control Slides HPV are designed for the qualitative control of immunochemical staining and *in situ*-hybridisation of HPV infected tissue. They are intended for systems which detect the L1 capsid protein or the L1 capsid gene. It allows for discriminating between “high”- and “low-risk” HPV subtypes as “high-risk” and “low-risk” positive cell lines were attached to the slides.
It is intended for research use only.

Summary and Explanation

Three cores of different HPV infected cell lines, one core of a HPV negative cell line as well as a core of heart muscle for orientation are attached to the slides. Staining of the cores allows for a general control of the staining method for the respective HPV subtypes.

The cells infected with the different HPV subtypes within the cores express the respective L1 capsid protein. Therefore they show different reactions to immunochemical stainings. HPV 6/11 are considered “low risk” type, that cause benign genital warts or minor cytological atypia. HPV16/18 and HPV31/33/35 are considered as “high-risk” types which can lead to development of cancer of the cervix, vulva, vagina, penis, or anus. The 5 HPV subtypes 16/18/31/33/35 included in the array are responsible for about 80% of all high risk infections.

The cells were fixed in buffered formalin for 12-18 h and embedded in paraffin. The core of heart muscle serves for easy orientation. The sections were cut at 4 µm, attached to coated slides and dried over night at 37°C.
The small size of the control sections allows for simultaneous mounting of patient material sections and control sections on the same slide. Thus, you will have an on-slide control array staining (OSCAR) proving a regular stain even after years of storage.

Reagents provided

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5 slides **Cell Control Slides HPV (Human Papilloma Virus)**

Storage and handling

The sections should be stored refrigerated within the provided box. Please do not freeze the slides. When slides are taken from the box it is important to avoid condensation of air moisture on the remaining slides.

To avoid degradation, the control slides should be brought to room temperature directly before the staining. Use of the slides within 3 months after despatch is recommended. High air moisture and high temperature reduce the shelf life.

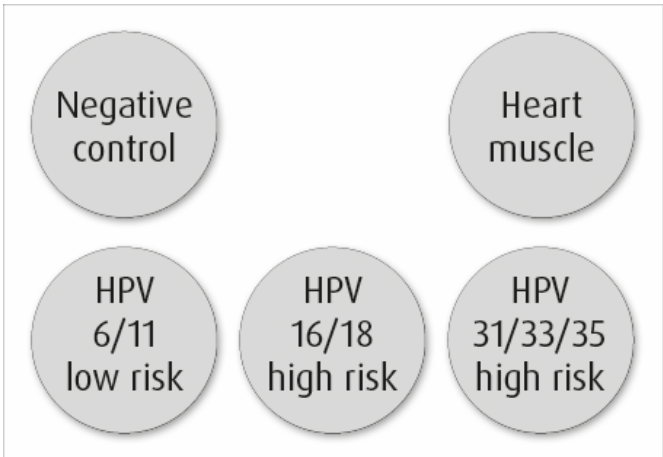
Precautions

Use by qualified personnel only.
Health hazards should not be expected. However, the slides should be handled as potential infectious formalin fixed paraffin embedded human tissue. Wear proper protection clothing.

A Material safety data sheet (MSDS) is available upon request.

Expected results

The localisation and evaluation pattern of the different HPV-subtypes is shown in the figure below.
In each control cell core not all cells replicated the different virus types to the same extent. Thus depending on sensitivity and specificity of the detection method variable percentages of cells can be positive at variable intensity, i.e. variable intense nuclear stain by immunochemistry.



Troubleshooting

If you observe unusual staining or other deviations from the expected results which could possibly be caused by the product, please read these instructions carefully, contact Zytomed Systems' technical support or your local distributor.

Limitations of the procedure

A large number of factors can considerably influence the staining results e.g. temperature during drying process, storage time of sections or staining reagents.
Any probe that has been proven effective in formalin-fixed *in situ* hybridisation should be applicable to the control slides.
However, with probes from some vendors cross reactivity between the various HPV subtypes (e.g. positivity of the 6/11 infected cells with probes directed against HPV 16/18) has been described.
Such cross reactivity can also be observed in the diagnostic tissue of interest and is depending on the specificity of the probe and significantly on the thoroughness of the washing steps. For further information please refer to the datasheet of the respective probe.
Any antibody that has been proven effective in formalin-fixed immunohistochemistry should be applicable to the control slides.
Cross-reactivity with IHC has not been described.

Performance characteristics

Zytomed Systems has conducted studies to evaluate the performance of the product. The product has been found to be suitable for the intended use.

Reference

Chan PKS *et al.,* Critical Rev Clin Lab Sci 49(4):117-136, (2012)
Doorbar J, Clinical Science 110:525-541, (2006)
Zheng Z, Baker P, Front Biosci. 11: 2286–2302, (2006)
Dabbs D Immunohistochemistry, Elsevier 2006 ISBN 0-443-06652-3

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1. Explanations of the symbols on the product label

Symbols are used in accordance with ISO 15223-1. Further symbols on the product label might be:

GSH02: Flammable

GSH05: Caustic

GSH07: Attention / Warning

GSH08: Systemic health hazards

RUO For Research Use Only