HPV Evaluation Panel 02

HPVEP02-D

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⚠ The following instructions must be read before using this product

IVD

Intended Use

Qnostics' Human Papilloma Virus (HPV) Evaluation Panels are and intended to help laboratories develop their molecular assay procedures for the identification of HPV.

The Panels can be used to support laboratory staff training and to assess assay performance in the molecular assays from extraction phase through amplification to detection.

Principles of the Panel

The Panel are manufactured to ISO standard 13485:2016 compliant systems. The samples were produced by making quantitative dilutions of characterised HPV cell lines positive for types 16, 18 or 45 in PreservCyt ™ transport medium (see Table 1). All Panel members have a background level of $1x10^4$ HPV negative cells.

All Panel members are provided at clinically representative levels with values obtained on a range of reference assays and traceability to the WHO International Standards for HPV16 and HPV18 where appropriate (data not shown). The HPV Evaluation Panel is suitable for use with the majority of commercial and in-house molecular methods. They can also be used to support the training and monitoring of new operators in line with laboratories quality management requirements.

Product Description and Performance Characteristics

The Panel consists of 6 x 4ml samples, 5 positive and 1 negative (see Table 1). The Panels are provided as a 'single–use' tube format. The target concentrations of the Panel have been designed to cover the dynamic range of most molecular assays and are consistent within each lot and across batches.

Table 1: Panel Components and Characteristics

Sample Code	Sample Description	Roche 4800 Range of Ct Values	Abbott M2000 Range of Ct Values	Number of vials
HPVEP02-S01	Type 16 High	30.50±0.42	24.25±0.18	1
HPVEP02-S02	Type 16 Low	34.00±0.0.5	26.05±0.16	1
HPVEP02-S03	Type 18 High	31.00±0.14	23.82±0.12	1
HPVEP02-S04	Type 18 Low	34.50±0.71	26.71±0.16	1
HPVEP02-S05	Type 45	31.25±0.21	26.48±0.61	1
HPVEP02-S06	Negative	Negative	Negative	1

IMPORTANT NOTE: The Panel members have **no assigned value.** The values provided in Table 1 are specific to the Qnostics' reference assay used for the qualification of the Panel. The actual Panel member quantification values may vary from those reported and are dependent on the evaluation procedure, the nucleic acid extraction and molecular assay used (see Limitations). It is the responsibility of the end user to establish their own target results for each of the Panel members using their laboratory's molecular procedures for their specific molecular diagnostic assay and appropriate statistical control.

Warnings and Precautions

The Panel contain whole HPV cell line material in a methanol based matrix (PreservCyt ™) and must only be handled by trained laboratory personnel and in accordance with Good Laboratory Practices, which must include the use of personal protective equipment (PPE). All residual materials must be treated as potentially hazardous and disposed of accordingly. This must be carried out according to the established procedures of the laboratory and in accordance with national and international regulations.

Do not pipette by mouth. Do not eat, drink or smoke when handling the samples or within laboratory spaces. Observe the expiration date for the Panels.

PreservCyt ™ is flammable, keep away heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hazard and Precautionary Statements: H226, H303, H333, P202, P210, P270, P280, P314

Additional Equipment Required but not Provided

The following equipment is not included:

- Personal Protective Equipment (PPE) - e.g. lab coat and gloves
- Biological safety cabinet
- Nucleic acid extraction kit used in accordance with the manufacturers' instructions
- Molecular Amplification assay specific for HPV and, where appropriate, used in accordance with the manufacturers' instructions
- Bench vortex
- Micro-centrifuge (12-14,000 RPM)
- Calibrated pipettes and sterile barrier filter tips

Procedure

- The Panel must be thawed at room temperature.
- Vortex briefly and spin down at 12,000 RPM for 30 seconds before opening the sample tube.
- The samples must then be treated in the same manner to that required by the laboratory for routine specimens, in the normal HPV molecular procedure being assessed.

IMPORTANT NOTICE: Each panel member is intended for 'single use' ONLY.

For technical queries please contact info@qnostics.com

Storage

The Panel must be stored within the recommended temperature range of 15 to 30°C.

Limitations

The Panel **must not** be used as a substitute for assay process controls and / or calibrators (Standards) provided by the manufacturer of the molecular assay.

This product is not an absolute reference material. The laboratory needs to establish its own target results using the Panel for their particular molecular assay system.

References

World Health Organisation (WHO). Laboratory Biosafety Manual, 3rd ed. 2004 ISBN 92 4 154650 6 (LC/NLM classification: QY 25).

Centers for Disease Control (CDC). Recommendations for the prevention of HIV transmission in healthcare settings. MMWR 1987; 36, Supplement no. 2S.

Centers for Disease Control (CDC). Update: Universal guidelines for the prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health-care settings. MMWR; 37:377-388

Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to healthcare and public-safety workers. MMWR 1989; 38(S6):1-36.

Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1:2016 Medical Devices – 'Symbols to be used with medical device labels, labelling and information to be supplied'.

REF	Product Code		Single use only
	Temperature limitations	Σ	Contains sufficient for "N" tests
LOT	Batch code		Attention, consult instructions for use
	Expiry date (last day of month)		Biohazard
IVD	In Vitro Diagnostic device		Manufacturer

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