

Instructions For Use

8257 Comprehensive Human Papillomavirus (HPV) Control Panel

Intended Use

The Comprehensive Human Papillomavirus (HPV) Control Panel is intended for use as non-viable, external, positive control material to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Table 1. This product has no qualitative or quantitative assigned values. It is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This product is not intended for any specific patient population or specimen.

Summary And Principles

The Comprehensive Human Papillomavirus (HPV) Control Panel can be used to monitor the extraction, amplification and detection process of molecular testing assays that detect HPV strains 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. Routine use of quality controls monitors test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

Composition

The Comprehensive Human Papillomavirus (HPV) Control Panel consists of 18 individually packaged lyophilized pellets: six pellets of positive control 1, six pellets of positive control 2, and six pellets of positive control 3.

HPV strains are represented by *E. coli* containing the corresponding gene inserted in a plasmid. Each pellet also contains human cells. All organisms have been thermally inactivated.

The Comprehensive Human Papillomavirus (HPV) Control Panel is lyophilized in a PCR compatible matrix. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use pellet.

Table 1. Contents of the Comprehensive Human Papillomavirus (HPV) Control Panel

Analytes*
Positive Control 1
HPV Type 31 Surrogate, gene target E6/E7
HPV Type 31 Surrogate, gene target L1
HPV Type 33 Surrogate, gene target E6/E7
HPV Type 66 Surrogate, gene target E6/E7
HPV Type 68 Surrogate, gene target E6/E7
HPV Type 68 Surrogate, gene target L1
Human Cells
Positive Control 2
HPV Type 16 Surrogate, gene target E6/E7
HPV Type 16 Surrogate, gene target L1
HPV Type 18 Surrogate, gene target E6/E7
HPV Type 18 Surrogate, gene target L1
HPV Type 35 Surrogate, gene target E6/E7
HPV Type 45 Surrogate, gene target E6/E7


HPV Type 45 Surrogate, gene target L1
HPV Type 59 Surrogate, gene target E6/E7
Human Cells
Positive Control 3
HPV Type 39 Surrogate, gene target E6/E7
HPV Type 51 Surrogate, gene target E6/E7
HPV Type 52 Surrogate, gene target E6/E7
HPV Type 56 Surrogate, gene target E6/E7
HPV Type 58 Surrogate, gene target E6/E7
Human Cells

*All analytes are added at a target concentration of $10^4 - 10^6$ gene copies/pellet. The input concentrations are not representative of recoverable concentrations or expected values.

Warnings And Precautions

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in use of the assay.
- The inactivated lyophilized pellets are single-use only. If hydrated, do not freeze for reuse. If reused, the inactivated lyophilized pellets may not perform as expected, including but not limited to, degradation or over-dilution of material resulting in false negatives, contamination resulting in false positive results or positive detection of organisms not in the pellet, and environmental contamination.
- Do not open foil pouch until ready to use.
- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. This product must be treated as a potential biohazard and be handled using universal laboratory precautions. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills and dispose of all materials in accordance with national and local regulations.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com or by contacting Customer Service at info@microbiologics.com.
- This product does not contain any hazardous substances listed in 1272/2008/EC.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

Storage And Expiration

 Store the Comprehensive Human Papillomavirus (HPV) Control Panel at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately.

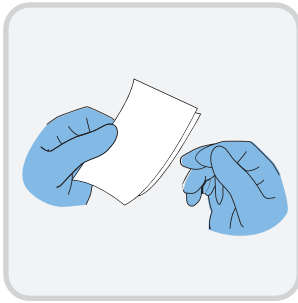
The Comprehensive Human Papillomavirus (HPV) Control Panel should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed
- Packaging is damaged

Materials Required But Not Provided

- Assay for detection including required instrumentation and consumables
- Rehydration buffer, such as SurePath Preservative Fluid or as specified by the assay requirements.
- Pipettors capable of delivering 0.5-1000 μ l volumes (if applicable)
- Nuclease-free aerosol barrier pipette tips (if applicable)

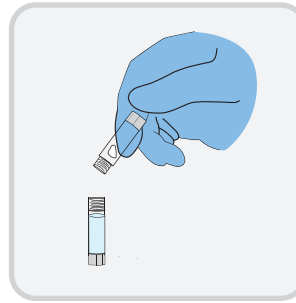
Instructions For Use



1. Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.



2. Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.



3. Hydrate the lyophilized pellet with 200 – 2000 μ l SurePath Preservative Fluid or as recommended by the assay provider. Resuspend each positive control pellet separately.



4. Recap the vial and vortex for 10 seconds at full speed to mix, or until pellet is completely dissolved.

5. If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial.
6. Process using the appropriate volume or transfer method, following assay instructions for use.
















Limitations

- There are no known extrinsic factors or interfering substances specific to this product. Please consult assay instructions for any extrinsic factors or interfering substances.
- This product is unassayed control material. It may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics' provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.
- Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These analytes are non-viable and may be used with any PCR-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified but does not guarantee specific analyte concentrations. Each laboratory should establish its own range of acceptable values on their assay system per their internal quality assurance procedure/program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.
- *E. coli* may be detectable in controls containing surrogate material.

Microbiological State

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

Key Of Symbols

	Authorized Representative in the European Community / European Union		Health hazard
	Batch code (Lot)		In vitro diagnostic medical device
	Biological risks		High positive control
	Calibrator A		Low positive control
	Calibrator B		Manufacturer
	Catalog number		Negative control
	Caution		Positive control
	CE mark		Quantity
	Consult instructions for use or consult electronic instructions for use		Telephone number
	Contains sufficient for <n> tests		Temperature limit
	Do not re-use		Use-by-date
	Do not use if package is damaged and consult instructions for use		

Please refer to product labels for applicable symbols.

Notice To Purchasers

The purchase of this product allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of this product.

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Website

Visit our website, www.microbiologics.com, for current technical information and product availability.

Bibliography

- Plotzker RE, Vaidya A, Pokharel U, Stier EA. Sexually Transmitted Human Papillomavirus: Update in Epidemiology, Prevention, and Management. *Infectious Disease Clinics of North America*. 2023;37(2):289-310. doi:<https://doi.org/10.1016/j.idc.2023.02.008>.
- Bedell SL, Goldstein LS, Goldstein AR, Goldstein AT. Cervical Cancer Screening: Past, Present, and Future. *Sexual Medicine Reviews*. 2020;8(1):28-37. doi:<https://doi.org/10.1016/j.sxmr.2019.09.005>.

Assistance



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Revision History

Publication History		
Revision	Date	Description of Change
A	2025-04	Initial Release
B	2025-09	Remove in-use stability information