

HPVAIP HPV Implementation Kit Instructions for Use

Product Overview	
Name	HPV Implementation Kit
Part Number	HPVAIP
Matrix	ThinPrep™ PreservCyt™ Solution
Analyte	HPV-16 Positive Cells HPV-18 Positive Cells HPV-68 Positive Cells (Other High-Risk HPV) HPV Negative Cells
Fill Volume	1.1 mL
Number of vials	80 vials
Storage Temperature	-20°C or below
Shelf Life	18 months from date of manufacture
Regulatory Status	For In Vitro Diagnostic Use

Product Description

The HPV Implementation Kit contains cultured human cell lines formulated in ThinPrep™ PreservCyt™ Solution. Control components include human papillomavirus (HPV) type 16-positive cells, HPV type 18-positive cells, and HPV type 68-positive cells, representing other high-risk HPV targets, as well as HPV-negative human cells that serve as an endogenous control for sample adequacy. Control components are provided at relative levels corresponding to 3x, 5x, and 10x the analytically determined limit of detection (LOD) for each HPV target. The materials are intended to be processed in the same manner as patient specimens to evaluate the entire molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection. The product is stable when stored under the recommended conditions. The product is unassayed and does not have assigned quantitative values. Each laboratory is responsible for establishing expected qualitative performance for its specific assay system.

Intended Use

The HPV Implementation Kit is an external, unassayed quality control panel intended for use with molecular diagnostic assays for the qualitative detection of high-risk human papillomavirus (HPV). The kit is designed for assay verification, validation, and workflow implementation activities in clinical, public health, and reference laboratories. This product is not a substitute for assay-specific controls provided by the assay manufacturer.

Kit Composition		
Kit Components	Expected Result†	Qty/Kit
HPV-16 3x LOD	HPV-16 Positive HPV-18 Negative Other HR HPV Negative	5 vials
HPV-16 5x LOD	HPV-16 Positive HPV-18 Negative Other HR HPV Negative	5 vials
HPV-16 10x LOD	HPV-16 Positive HPV-18 Negative Other HR HPV Negative	5 vials
HPV-18 3x LOD	HPV-16 Negative HPV-18 Positive Other HR HPV Negative	5 vials
HPV-18 5x LOD	HPV-16 Negative HPV-18 Positive Other HR HPV Negative	5 vials
HPV-18 10x LOD	HPV-16 Negative HPV-18 Positive Other HR HPV Negative	5 vials
Combined HPV 3x LOD	HPV-16 Positive HPV-18 Positive Other HR HPV Positive	15 vials
Combined HPV 5x LOD	HPV-16 Positive HPV-18 Positive Other HR HPV Positive	5 vials
Combined HPV 10x LOD	HPV-16 Positive HPV-18 Positive Other HR HPV Positive	5 vials
HPV Negative	HPV-16 Negative HPV-18 Negative Other HR HPV Negative	25 vials
†Expected qualitative results must be established by the laboratory for the specific assay system in use. For kit configuration, refer to the layout shown below.		

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Principles of the Procedure

The HPV Implementation Kit contains cultured human cell lines formulated in ThinPrep™ PreservCyt™ Solution. The control materials include HPV-positive cells representing high-risk human papillomavirus (HPV) targets and HPV-negative human cells that serve as an endogenous control for sample adequacy. Because the materials contain intact human cells, they are designed to be processed in the same manner as clinical specimens. When extracted and analyzed according to the assay manufacturer's instructions, the controls evaluate the full molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection.

The kit is intended to support assay verification, workflow implementation, and laboratory validation activities. The materials are not intended to replace assay-specific internal or external controls provided by the assay manufacturer.

Storage and Handling

The HPV Implementation Kit should be stored at -20 °C or below. Control components may not freeze at the recommended storage temperature due to the PreservCyt™ matrix; this is normal. Prior to use, allow vials to equilibrate to room temperature and mix each vial thoroughly before loading. Once brought to room temperature, control materials are stable for up to 24 hours when stored at 2-8 °C. Control components may be returned to -20 °C storage and may undergo a maximum of four (4) freeze-thaw cycles for reuse. Additional freeze-thaw cycles are not recommended.

Do not use HPV Implementation Kit beyond the expiration date. Do not dilute. Do not use the product if the kit carton or individual vials are damaged or show evidence of leakage. Discard affected materials in accordance with laboratory procedures.

Limitations

For in vitro diagnostic use. The HPV Implementation Kit is an unassayed external control. No quantitative values are assigned. Expected qualitative performance must be established by the laboratory for the specific assay system in use. The product is not intended to replace assay-specific internal or external controls provided by the assay manufacturer. Results obtained with these materials should be interpreted in conjunction with assay manufacturer instructions. Improper storage, handling, or use outside recommended conditions may affect performance.

Warnings and Precautions

The HPV Implementation Kit cultured human cell lines formulated in ThinPrep™ PreservCyt™ Solution. Handle the materials in accordance with universal precautions and standard laboratory biosafety practices. Use appropriate personal protective equipment (PPE), including gloves and laboratory coats, when handling this product.

ThinPrep™ PreservCyt™ Solution contains methanol and is flammable. Keep away from heat, sparks, open flames, and other sources of ignition. Use only in well-ventilated laboratory areas.

Do not pipette by mouth. Avoid eating, drinking, or smoking in areas where specimens or controls are handled.

In the event of a spill, absorb the bulk material with appropriate absorbent material (e.g., paper towels) prior to application of disinfectant. Clean the affected area with an appropriate laboratory disinfectant (e.g., freshly prepared 0.5% sodium hypochlorite solution) and dispose of contaminated materials in accordance with institutional biohazard procedures. Dispose of all materials and waste in accordance with local, regional, and national regulations. For professional laboratory use only.

Symbols



Catalog Number



Lot Number



Expiration Date



Upper Limit of Temperature



Caution



Flammable



For In Vitro Diagnostic Use



Positive Control



Instructions For Use



Manufacturer

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Box 1 of 2 - Kit Configuration										
	1	2	3	4	5	6	7	8	9	10
1	HPV-16 3x LOD	HPV-16 5x LOD	HPV-16 10x LOD	HPV-18 3x LOD	HPV-18 5x LOD	HPV-18 10x LOD	Combined HPV 3x LOD	Combined HPV 3x LOD	Combined HPV 5x LOD	Combined HPV 10x LOD
2	HPV Negative	HPV Negative	HPV Negative	HPV Negative						
3										
4	HPV-16 3x LOD	HPV-16 5x LOD	HPV-16 10x LOD	HPV-18 3x LOD	HPV-18 5x LOD	HPV-18 10x LOD	Combined HPV 3x LOD	Combined HPV 3x LOD	Combined HPV 5x LOD	Combined HPV 10x LOD
5	HPV Negative	HPV Negative	HPV Negative	HPV Negative						
6										
7	HPV-16 3x LOD	HPV-16 5x LOD	HPV-16 10x LOD	HPV-18 3x LOD	HPV-18 5x LOD	HPV-18 10x LOD	Combined HPV 3x LOD	Combined HPV 3x LOD	Combined HPV 5x LOD	Combined HPV 10x LOD
8	HPV Negative	HPV Negative	HPV Negative	HPV Negative						
9										
10										

Box 2 of 2 - Kit Configuration										
	1	2	3	4	5	6	7	8	9	10
1	HPV-16 3x LOD	HPV-16 5x LOD	HPV-16 10x LOD	HPV-18 3x LOD	HPV-18 5x LOD	HPV-18 10x LOD	Combined HPV 3x LOD	Combined HPV 3x LOD	Combined HPV 5x LOD	Combined HPV 10x LOD
2	HPV Negative	HPV Negative	HPV Negative	HPV Negative						
3										
4	HPV-16 3x LOD	HPV-16 5x LOD	HPV-16 10x LOD	HPV-18 3x LOD	HPV-18 5x LOD	HPV-18 10x LOD	Combined HPV 3x LOD	Combined HPV 3x LOD	Combined HPV 5x LOD	Combined HPV 10x LOD
5	HPV Negative	HPV Negative	HPV Negative	HPV Negative						
6	Combined HPV 3x LOD	HPV Negative								
7	Combined HPV 3x LOD	HPV Negative								
8	Combined HPV 3x LOD	HPV Negative								
9	Combined HPV 3x LOD	HPV Negative								
10	Combined HPV 3x LOD	HPV Negative								