Exact Diagnostics HPV Verification Panel

REF HPVP200 IVD

Exact Diagnostics HPV Verification Panel Summary	
Catalog Number	HPVP200
Target Analyte 1	HPV Genotype 16
Target Analyte 2	HPV Genotype 18
Target Analyte 3	HPV Genotype 68
Source Material	Integrated Human Cell Line
Matrix	PreservCyt®
Storage	2-8°C
Shelf Life	36 Months from Date of Manufacture
Fill Volume	1.4 mL per Vial
Number of Uses	Single Use
Number of Vials Per Kit	16 Vials
Precautions	Flammable
Regulatory Status	In Vitro Diagnostic Use

Exact Diagnostics HPV Verification Panel Components	
EDX HPV 16 3x LOD	1 vial
EDX HPV 16 5x LOD	1 vial
EDX HPV 16 10x LOD	1 vial
EDX HPV 18 3x LOD	1 vial
EDX HPV 18 5x LOD	1 vial
EDX HPV 18 10x LOD	1 vial
EDX HPV 16/18/68 3x LOD	3 vials
EDX HPV 16/18/68 5x LOD	1 vial
EDX HPV 16/18/68 10x LOD	1 vial
EDX HPV Negative Control	5 vials

INTENDED USE:

The Exact Diagnostics HPV Verification Panel is intended to be used with HPV assays to monitor performance of that given assay. This product is to be used to monitor the presence of Human Papillomavirus (HPV) Genotype 16, Genotype 18, and Genotype 68 DNA. This product allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The Exact Diagnostics HPV Verification Panel is formulated with human cell lines containing an integrated HPV virus. The negative component is formulated with negative human cell lines. This product is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

This product is internally value assigned using Bio-Rad Digital Droplet PCR (ddPCR). This product is formulated in PreservCyt®.

PROCEDURE:

This product requires an extraction step. The product must be treated in a similar manner to other samples. This allows the operator to assess their extraction technique

This product is an unassayed control and does not have assigned values. The product is not a substitute for the manufacturer's kit controls provided with the assay. This product is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendation. Expected results utilizing this product must be established by the end user for their specific assay.

STORAGE AND STABILITY:

This product should be stored at 2-8°C.

Prior to use vortex briefly.

LIMITATIONS:

1. Do not use this product beyond the expiration date.
2. This product is for Laboratory/Professional use only.
3. All remaining materials must be disposed of after one use. Do not reuse.

SAFETY PRECAUTIONS:

1. **This product is formulated in a flammable liquid. Keep away from all ignition sources.**
2. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.
3. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
4. Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with water and then 0.5% sodium hypochlorite solution.
5. Dispose of any discarded materials in accordance with the requirements of the local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Service.


WARNINGS AND PRECAUTIONS:

Biological source material. Treat as potentially infectious.

Universal precautions and proper disposal should be practiced[1]. It is recommended that this product be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)[2], Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.[3,4]

A Safety Data Sheet (SDS) is available for professional users on www.bio-rad.com.

REFERENCES:

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission.
2. U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories- Sixth Edition HHS Publication (CDC) 300859: June 2020.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from Occupational Acquired infections; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4), Clinical and Laboratory Standards Institute Wayne, Pennsylvania 19087-1898, USA 2005.
4. Clinical and Laboratory Standards Institute (CLSI) Clinical Laboratory Waste Management; Approved Guideline – Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8), CLSI Wayne, Pennsylvania 19087, USA 2011.

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KIT CONFIGURATION:

	HPV 16 Genotype 3x LOD	HPV 16 Genotype 5x LOD	HPV 16 Genotype 10x LOD	
	HPV 18 Genotype 3x LOD	HPV 18 Genotype 5x LOD	HPV 18 Genotype 10x LOD	
HPV 16/18/68 Genotype 3x LOD	HPV 16/18/68 Genotype 3x LOD	HPV 16/18/68 Genotype 3x LOD	HPV 16/18/68 Genotype 5x LOD	HPV 16/18/68 Genotype 10x LOD
HPV Negative Control	HPV Negative Control	HPV Negative Control	HPV Negative Control	HPV Negative Control

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