

EDX HPV Genotype 16 Control Summary	
Catalog Number	HPV16C
Analyte	HPV Genotype 16
Matrix	PreservCyt®
Preservative	N/A
Storage	2-8°C
Fill Volume	5.0mL
Number of Vials Per Kit	10 Vials
Number of Uses	Multiple Use
Shelf Life	36 Months from Date of Manufacture
Precautions	Biological Risks Flammable
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX HPV Genotype 16 Control is an external quality control, intended to be used with HPV assays to monitor the performance of that given assay. The control is used to monitor the presence of Human Papillomavirus (HPV) Genotype 16. Routine use of EDX HPV Genotype 16 Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX HPV Genotype 16 Control is formulated with human cell lines containing an integrated HPV virus. EDX HPV Genotype 16 Control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HPV Genotype 16 Control is internally value assigned using Bio-Rad Digital Droplet PCR (ddPCR). The control is formulated in PreservCyt®.

PROCEDURE:

The EDX HPV Genotype 16 Control requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX HPV Genotype 16 Control is an unassayed control and does not have assigned values. The control is not a substitute for the manufacturer's kit controls provided with the assay. EDX HPV Genotype 16 Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX HPV Genotype 16 Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX HPV Genotype 16 Control should be stored at 2-8°C. Prior to use, vortex for five (5) seconds at maximum setting or mix by inverting gently.

The EDX HPV Genotype 16 Control is stable for 10 days when stored at room temperature. If stored at room temperature, any remaining materials must be disposed of after 10 days. Do not dilute.

Do not use EDX HPV Genotype 16 Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HPV Genotype 16 Control should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. The control is formulated in a flammable liquid. Keep away from all ignition sources. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.














Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

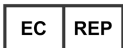
REFERENCES:

¹Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

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SYMBOL REFERENCES:

-  Catalog Number
-  Lot Number
-  For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Flammable
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use
-  Positive Control
-  European Mark of Conformity
-  Authorized Representative



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