

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 Droplet Digital 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

BIO-RAD and DROPLET DIGITAL PCR are trademarks of Bio-Rad Laboratories, Inc. in certain jurisdictions.

SYMBOL REFERENCES:

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



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
United States



Bio-Rad
Laboratories, Inc.

Clinical
Diagnosics Group

9500 Jeronimo Road
Irvine, California 92618
(800) 854-6737
FAX (949) 598-1550
bio-rad.com/qualitycontrol

Technical Service:
(800) 854-6737

United States Customer Service: 4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373
Also in: **South Granville, Australia,** Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888 **Vienna, Austria,** Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29 **Temse, Belgium,** Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01 **São Paulo, Brazil,** Phone +55 11 3065-7550 **Montréal, Canada,** Phone +1 514 334 4372 • Fax +1 514 334 0872 **Shanghai, China,** Phone +86 21 6169 8500 • Fax +86 21 6169 8599 **Prague, Czech Republic,** Phone +420 241 431 660 **Symbion Science Park, Denmark,** Phone +45 44 52 10 00 • Fax +45 44 52 10 01 **Helsinki, Finland,** Phone +358 9 804 22 00 **Marnes-la-Coquette, France,** Phone +33 (0)1 47 95 60 00 • Fax +33 (0)1 47 41 91 33 **Munich, Germany,** Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136 **Athens, Greece,** Phone +30 210 7774396 • Fax +30 210 7774376 **Quarry Bay, Hong Kong,** Phone +85 2 2789 3300 • Fax +85 2 2789 1257 **Budapest, Hungary,** Phone +36 1 459 6190 • Fax +36 1 459 6101 **Haryana, India,** Phone +91 124 4029300 • Fax +91 124 2398115 **Rishon Le Zion, Israel,** Phone +972 03 963 6025 • Fax +972 03 951 4129 **Milan, Italy,** Phone +39 024 94 86 600 • Fax +39 02 21609399 **Tokyo, Japan,** Phone +81 3 6361 7070 • Fax +81 3 5463 8481 **Seoul, Korea,** Phone +82 080 007 7373 • Fax +82 (2) 3472 7003 **Mexico D.F., Mexico,** Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246 **Veenendaal, The Netherlands,** Phone +31 (0) 318 540 666 • Fax +31 (0) 318 542 216 **Auckland, New Zealand,** Phone +64 (9) 415 2280 • Fax +64 (9) 415 2284 **Oslo, Norway,** Phone +47 23 38 41 30 • Fax +47 23 38 41 39 **Warsaw, Poland,** Phone +48 22 331 99 99 • Fax +48 22 331 99 88 **Amadora, Portugal,** Phone +351 21 47 27 700 • Fax +351 21 472 7777 **Moscow, Russia,** Phone +7 (495) 721-14-04 • Fax +7 (495) 721-14-12 **Singapore,** Phone +65 6415 3170 • Fax +65 6415 3189 **Johannesburg, South Africa,** Phone +27 11 442 8508 • Fax +27 11 442 8525 **Madrid, Spain,** Phone +34 91 490 6580 • Fax +34 91 590 5211 **Sundbyberg, Sweden,** Phone +46 844 98053 • Fax +46 8 55 51 27 80 **Cressier, Switzerland,** Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550 **Taipei, Taiwan,** Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-6890 **Bangkok, Thailand,** Phone (662) 651 8311 • Fax (662) 651 8312 **Hertfordshire, United Kingdom,** Phone +44 (0) 1923 471301 • Fax +44 (0) 1923 471340