

EDX HSV-2 High Run Control	
Catalog Number	HSV2H102
Analyte	Inactivated HSV-2
Matrix	Synthetic CSF Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Multiple Use
Shelf Life	24 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

**INTENDED USE:**

The EDX HSV-2 High Run Control is an external quality control, intended to be used with HSV-2 assays to monitor the performance of that given assay. The control is used to monitor the presence of Herpes Simplex Virus-2 (HSV-2) DNA. Routine use of EDX HSV-2 High Run 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 HSV-2 High Run Control contains whole, intact virus that has been heat inactivated. The control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HSV-2 High Run Control is internally value assigned using Bio-Rad Droplet Digital PCR (ddPCR). EDX HSV-2 High Run Control is formulated in Synthetic CSF Matrix, which contains preservatives.

**PROCEDURE:**

The EDX HSV-2 High Run 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 HSV-2 High Run Control is formulated in Synthetic CSF Matrix but can be diluted 1:1 in NEG050, Exact Diagnostics Bulk Negative, which is True EDTA Plasma. EDX HSV-2 High Run 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 HSV-2 High Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX HSV-2 High Run Control must be established by the end user for their specific assay.

**STORAGE AND HANDLING:**

The EDX HSV-2 High Run Control should be stored at -20°C or below.

Thaw EDX HSV-2 High Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX HSV-2 High Run Control is stable for 24 hours when stored at 2-8°C. Product can be frozen and reused a maximum of four (4) times. After the fourth freeze thaw, any remaining materials must be disposed of.

Do not use EDX HSV-2 High Run Control beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX HSV-2 High Run Control contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced<sup>1</sup>. 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 contain pathogenic agents.

**REFERENCES:**

<sup>1</sup>Siegel 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:**

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use
-  CONTROL+ Positive Control
-  CE 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*  
**Diagnostics 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 39 • **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 91 430 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**