

EDX HSV-2 Verification Panel Summary	
Catalog Number	HSV2P100
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	Single Use
Shelf Life	24 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

EDX HSV-2 Components	Concentration
EDX HSV-2 Panel Member 1	200 cp/mL
EDX HSV-2 Panel Member 2	2,000 cp/mL
EDX HSV-2 Panel Member 3	20,000 cp/mL
EDX HSV-2 Panel Member 4	200,000 cp/mL
EDX HSV-2 Panel Member 5	2,000,000 cp/mL

PROCEDURE:

The EDX HSV-2 Verification requires an extraction step. The panel must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The HSV-2 Verification Panel is formulated in Synthetic CSF Matrix but can be diluted 1:1 in NEG050, Exact Diagnostics Bulk Negative, which is True EDTA Plasma. Expected concentration values from the table above will be reduced by 50% for the diluted panel. EDX HSV-2 Verification Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX HSV-2 Verification Panel should be stored at -20°C or below.

Thaw EDX HSV-2 Verification Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX HSV-2 Verification Panel is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse.

Do not use EDX HSV-2 Verification Panel beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HSV-2 Verification Panel contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. 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.

INTENDED USE:

The EDX HSV-2 Verification Panel is a standard for various molecular assays. EDX HSV-2 Verification Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Herpes Simplex Virus-2 (HSV-2) DNA. EDX HSV-2 Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

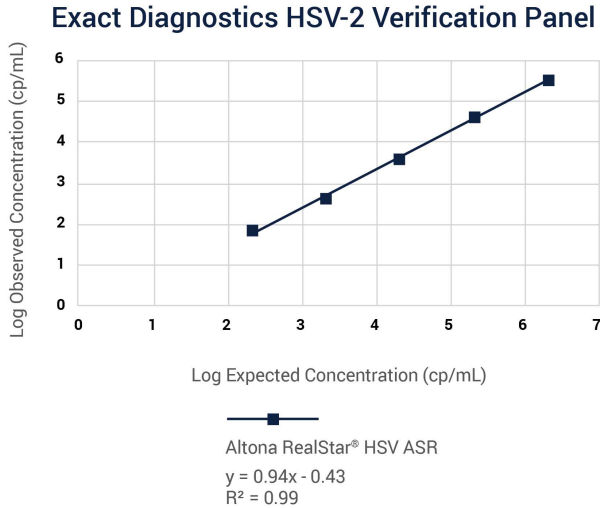
PRODUCT DESCRIPTION:

The EDX HSV-2 Verification Panel contains whole, intact virus that has been heat inactivated. EDX HSV-2 Verification Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HSV-2 Verification Panel is reported in copies per milliliter (cp/mL). EDX HSV-2 Verification Panel is value assigned by digital droplet PCR and manufactured according to ISO 17511:2003. EDX HSV-2 Verification Panel is formulated in Synthetic CSF Matrix, which contains preservatives.

PERFORMANCE CHARACTERISTICS:

Three unique lots of EDX HSV-2 Verification Panel were tested in triplicate across the assay identified in the graph below.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

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

SYMBOL REFERENCES:



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Do not re-use



Upper Limit of Temperature



Manufacturer



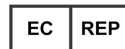
Caution



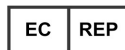
Consult Instructions for Use



European Mark of Conformity



Authorized Representative



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Exact Diagnostics LLC
3400 Camp Bowie Blvd CBH-214
Fort Worth Texas 76107
United States