

EDX HSV Verification Panel Summary	
Catalog Number	HSVP200
Analyte 1	Inactivated HSV-1
Analyte 2	Inactivated HSV-2
Matrix	Synthetic Matrix
Preservative	Sodium Azide
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	9 Vials
Number of Uses	Single Use
Shelf Life	18 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

EDX HSV Verification Panel Components
EDX HSV-1 3x LOD
EDX HSV-1 5x LOD
EDX HSV-1 10x LOD
EDX HSV-2 3x LOD
EDX HSV-2 5x LOD
EDX HSV-2 10x LOD
EDX HSV-1/HSV-2 3x LOD
EDX HSV-1/HSV-2 5x LOD
EDX HSV-1/HSV-2 10x LOD

INTENDED USE:

The EDX HSV Verification Panel is intended to be used with HSV-1 and HSV-2 assays to monitor the performance of that given assay. EDX HSV Verification Panel is used to monitor the presence of Herpes Simplex Virus-1 (HSV-1) and Herpes Simplex Virus-2 (HSV-2) DNA. EDX HSV Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

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

The EDX HSV Verification Panel is value assigned using digital droplet PCR. EDX HSV Verification Panel is formulated in Synthetic Matrix, which contains preservatives.

PROCEDURE:

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

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

STORAGE AND HANDLING:

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

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

Once thawed, EDX HSV 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 dilute.

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

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HSV 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 contained pathogenic agents.

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



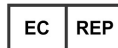
Consult Instructions for Use



Positive Control



European Mark of Conformity



Authorized Representative



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