

GenomEra[®] HSV-1/2, VZV + EV Assay Kit

Unique test for detecting viruses
causing viral meningitis





Why choose our test?

The GenomEra® HSV-1/2, VZV + EV Assay Kit is a rapid molecular test for the simultaneous detection of the four most common causes of viral meningitis and encephalitis—herpes simplex virus 1 (HSV-1) and 2 (HSV-2), varicella zoster virus (VZV), and enterovirus (EV)—from cerebrospinal fluid (CSF) specimens in just 70 minutes. In addition, the test is validated for the detection of HSV-1 and HSV-2 in lesion swab specimens.

Key benefits of the test

- Fast results: four results in 70 minutes
- Short hands on time: 5 min for 4 samples
- Easy to use system with pre-loaded and sealed GenomEra Test Chips
- Small sample volume: enables additional analysis
- High overall sensitivity and specificity

HSV-1, HSV-2 and VZV—all members of *Alphaherpesvirinae* subfamily—are double-stranded DNA viruses that establish latency in neuronal cells and can activate any time after the primary infection. EV's are small single-stranded RNA viruses which are the common cause of viral meningitis.

Key facts

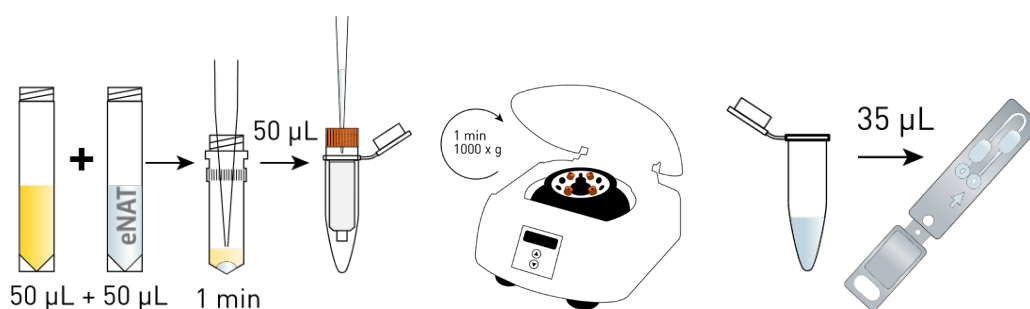
- Sensitive detection and differentiation of HSV-1, HSV-2, VZV, and EV from a single CSF specimen and HSV-1 and HSV-2 from a lesion swab specimen
- Small test volume (50 µl) enables additional analyses from a single specimen
- Automated, safe, and rapid real-time PCR testing—results for four samples in just 70 minutes
- Can be run at the same time with other tests using RT qPCR (70min) protocol.

Assay principle

The GenomEra HSV-1/2, VZV + EV Assay Kit is a rapid and easy-to-use multiplex real-time PCR test for the simultaneous qualitative detection and differentiation of HSV-1/2, VZV, and EV nucleic acids on the GenomEra® CDX System.

Sample preparation in the GenomEra HSV-1/2, VZV + EV Assay Kit is simple with minimal hands-on time—just three minutes for one sample and less than five minutes for four samples. Pre-loaded and sealed GenomEra Test Chips contain all the reagents needed, and the results are automatically reported by the GenomEra CDX Software in just 70 minutes.

Test procedure



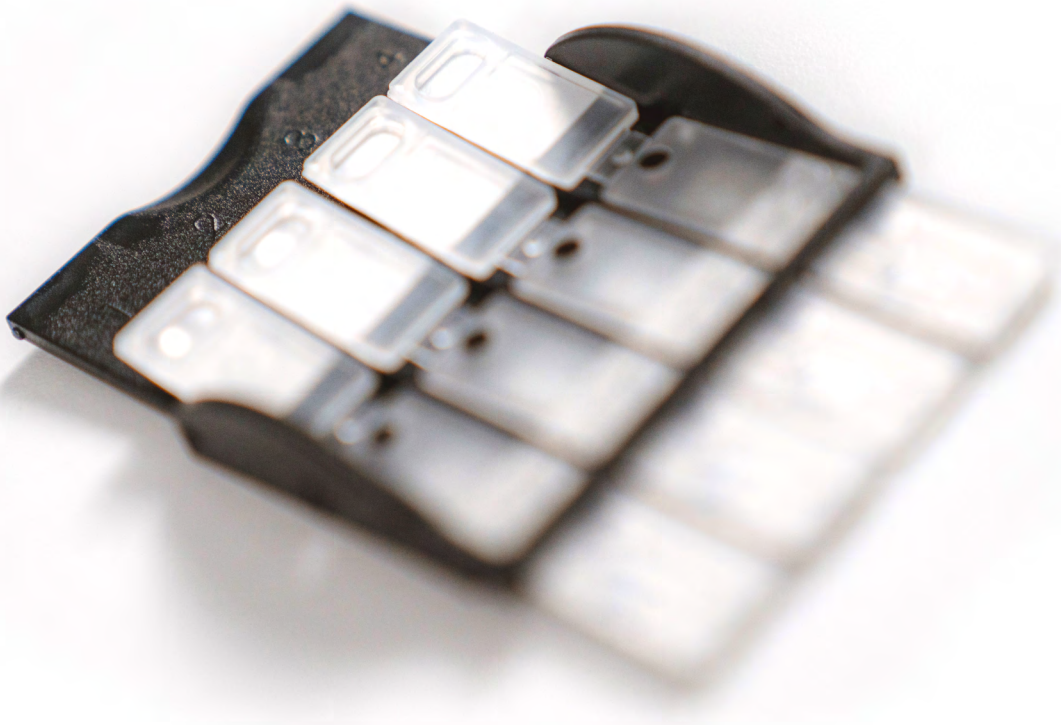
Clinical performance

The clinical performance of the GenomEra HSV-1/2, VZV + EV Assay Kit was evaluated retrospectively at three institutions across Europe during April–May 2022. Study specimens consisted of frozen CSF specimens from patients with signs and symptoms of a central nervous system infection and frozen lesion swab specimens collected in Copan eSwab from patients with cutaneous or mucocutaneous lesions. The reference assays used were in-house or commercial real-time PCR assays, including both singleplex and multiplex assays, developed for the detection of the target analytes.

Specimen type	Analyte	Sample size, n	PPA, %	NPA, %	Overall sensitivity, %	Overall specificity, %
CSF	HSV-1	193	100	100	92.2	99.9
	HSV-2	193	100	100		
	VZV	193	96.9	99.4		
	EV	193	73.3*	100		
Lesion swab	HSV-1	24	86.7	100		
	HSV-2	24	100	100		

Table 1. The GenomEra HSV-1/2, VZV + EV Assay Kit has an excellent overall sensitivity and specificity in frozen clinical specimens. PPA, positive percent agreement; NPA, negative percent agreement. CSF, cerebrospinal fluid; EV, enterovirus; HSV, herpes simplex virus; VZV, varicella zoster virus.

*Based on the clinical performance data obtained, the sensitivity for EV in frozen CSF specimens was 73.3% in comparison to over 95% for HSV-1, HSV-2 and VZV.



Ordering information

To place an order, please contact your local distributor at uniogen.com/distributors/

Product name	Product code
GenomEra HSV-1/2, VZV + EV Assay Kit, 20 pcs	CDX-170-01-20
GenomEra HSV-1/2, VZV + EV Assay Kit, 40 pcs	CDX-170-01-40
GenomEra CDX System	CDX-10-020

Manufacturer

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Distributor



GenomEra® products carry the Finnish Key Flag Symbol, a valued and trusted symbol of Finnish origin.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen Oy.

HSV-1/2, VZV + EV Assay Kit v. 2.0, February 2023

