

Rapid molecular detection of herpes simplex, varicella-zoster, and enteroviruses from a drop of cerebrospinal fluid

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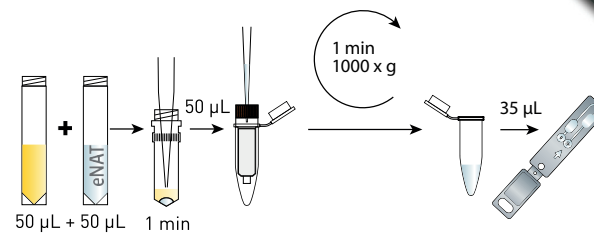
BACKGROUND AND MATERIALS

Background

- Reliable, robust, and easy-to-use molecular testing of viral meningitis/encephalitis is essential for optimal patient management
- Here, the detection of four most common meningitis/encephalitis causing viruses, herpes simplex virus type 1 (HSV-1) and 2 (HSV-2), varicella-zoster virus (VZV), and enteroviruses (EV) using the GenomEra[®] HSV-1/2, VZV + EV Assay Kit, is presented

Materials and methods

- The study was conducted at three institutions across Europe in 2022 and included a total of 193 retrospectively collected frozen cerebrospinal fluid (CSF) specimens
- The reference assays included:
 - FilmArray Meningitis/Encephalitis (ME) panel (bioMérieux)
 - Xpert[®] EV Assay (Cepheid)
 - artus VZV assay (Qiagen)
 - A well-characterized and validated non-commercial real-time RT-PCR assay for HSV-1/2, VZV, and EV detection



Sample preparation protocol of the GenomEra HSV-1/2, VZV + EV Assay Kit

RESULTS

- The GenomEra[®] HSV-1/2, VZV + EV Assay Kit demonstrated high overall specificity and high sensitivity
 - Clinical sensitivity: **92.2%** (95% CI: 82.7-97.4%)
 - Clinical specificity: **99.9%** (95% CI: 99.2-100%)
- The analyte-specific sensitivities and specificities are presented in Table 1.

Table 1. Clinical performance of the GenomEra HSV-1/2, VZV + EV Assay Kit (n = 193).

Analytes	Agreement with the reference methods					PPA % (CI 95)	NPA % (CI 95)
	n	TP	FP	TN	FN		
Herpes simplex 1 (HSV-1)	193	10	0	183	0	100% (69.2-100%)	100% (98.0-100%)
Herpes simplex 2 (HSV-2)	193	7	0	186	0	100% (59.0-100%)	100% (98.0-100%)
Varicella-zoster (VZV)	193	31	1	160	1*	96.9% (83.8-99.9%)	99.4% (96.6-100%)
Enterovirus (EV)	193	11	0	178	4*	73.3% (44.9-92.2%)	100% (98.0-100%)

* Threshold cycle (C_t) values were ≥35 with the reference assays.

CONCLUSION

- Requires only a tiny aliquot of specimen (50 µL) sparing the valuable specimens for additional analyses
- Short turnaround time
 - Time-to-result: 75 minutes for 1-4 samples
 - Hands-on-time: < 5 minutes
 - Assay run time: 70 minutes
- Straightforward sample preparation makes the GenomEra assay a competitive molecular test suitable for small and medium-sized laboratories not necessarily having a specialist in molecular biology

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