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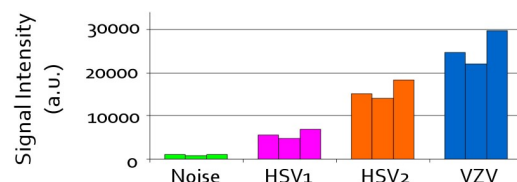
TruArray HE Test for Identifying Herpes Simplex Viruses in Cerebrospinal Fluid

OVERVIEW

Encephalitis, meningitis, and meningoencephalitis are potentially fatal diseases defined by acute swelling of the brain or protective membranes covering the brain and spinal cord. While most cases of viral encephalitis resolve without complications, herpes simplex encephalitis (HSE) is one of the most severe viral infections of the human central nervous system. Partial paralysis, seizures, hallucinations, and an altered state of consciousness are common indications, with young children and infants particularly at risk. The complications arising from cerebrospinal fluid (CSF) infection and appropriate treatment strategies depend on the type of viral infection, with many current home-brew or FDA approved tests being too slow, insensitive, or too narrowly focused to detect a range of viral CSF infections from a single sample. The TruArray HE test is the first array-based test for rapidly detecting and differentiating between three of the most important herpes simplex viral CSF infections.

TRUARRAY HE TEST CAPABILITIES

- **Integrated Workflow:** Akonni TruDiagnosis[®] Systems utilize the TruDx[™] 1000 Reader and TruCycler[™] Satellite Thermal Cycler for workflow integrated amplification, hybridization, detection, and analysis.
- **Multi-Target Coverage:** Simultaneously detects HSV1, HSV2, and VZV.
- **Sensitive and Specific:** Utilizes the polymerase chain reaction to offer reproducible detection to 10 genome copies per reaction.



Simultaneous detection of HSV1, HSV2, and VZV at 10 genome copies each in a single test.

TRUARRAY HE TEST BENEFITS

- **Rapid:** Starting from samples of 100 µl to 1.5 ml or more, the TruArray HE test delivers definitive results in a few hours with a total hands on time < 1 hr.
- **Accurate:** Simultaneous analysis from a single sample removes variability and delivers results you can trust.
- **Simple:** Affordably priced and easy to perform, one test detects three of the most important causes of viral encephalitis, with simple data output and reporting that requires minimal training to understand.
- **Extensible:** Future products will extend the multi-analyte detection capability to HHV6, CMV, and enterovirus for even more thorough coverage of life-threatening CSF infections.
- **Portable:** Very small bench-top footprint, suitable for low-resource settings.



MARKETS

INFECTIOUS DISEASES
GENETIC DISEASES
ONCOLOGY
PHARMACOGENETICS
ENVIRONMENTAL
BIOTHREAT
FORENSICS

TRUARRAY ADVANTAGE

In 2002, Akonni Biosystems acquired an exclusive license for medical applications of gel-element array technology developed by the Engelhardt Institute for Molecular Biology and Argonne National Laboratories. Since then, Akonni has significantly advanced the technology through improvements in manufacturing and providing an integrated, sample-to-answer capability for clinical laboratories or low-resource settings. The technology is now supported by over 100 scientific publications and 30 issued or pending patents. TruArray tests are well positioned to be the industry leader in molecular diagnostic tests.

Blinded Analysis of 10 CFS Samples			
CSF 10	TruArray Results	Average S/N Ratio	PCR C _t
1	HSV1	18	HSV1 (35.2)
2	HSV2	7	HSV2 (32.3)
3	VZV	40	VZV (31.4)
4	VZV	36	VZV (33.0)
5	VZV	35	VZV (31.0)
6	HSV1	9	HSV1 (33.1)
7	HSV2	29	HSV2 (30.2)
8	HSV2	17	HSV2 (38.3)
9	HSV2	10	HSV2 (36.7)
10	HSV1	27	HSV1 (28.0)

Blinded analysis and correct detection of 10 cerebrospinal fluid samples by TruArray HE. Average S/N ratio is based on four replicate probes per array. Single-target PCR results and threshold cycle values are shown for comparison.

YOUR TRUARRAY HE TEST KIT

Akonni TruArray HE tests are available as pre-packaged kits providing all materials and reagents needed to perform 10 tests. For best results, we recommend using Akonni TruArray HE tests as part of an integrated workflow that includes the TruCycler Satellite Thermal Cycler for amplification and hybridization and the TruDx 1000 Reader for image capture, data processing, data analysis, and reporting.

FDA STATUS

All of Akonni Biosystems tests are currently for Research Use Only, and are not for use in diagnostic procedures. Akonni is working to develop these products into Food & Drug Administration (FDA)-cleared diagnostic tests.

TO ORDER

- 200-10300** **TruArray HE test kit for detecting HSV1, HSV2, and VZV from cerebrospinal fluid.** Includes primers, buffers, and reagents required to perform 10 tests.
- 100-10000** **TruDiagnosis System for multiplexed molecular diagnosis.** Includes the Akonni TruDx 1000 Reader, Akonni TruCycler Satellite Thermal Cycler, and laptop computer with data collection and analysis software. Systems include one year warranty against defective parts. Accepts international AC; 90-264V, 50-60 Hz AC.

To order call +1 301.698.0101

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For Research Use Only. Not for use in diagnostic procedures. No claim or representation is intended for the diagnosis, prevention, or treatment of a disease.

Protected by 1 or more U.S. Pat: 6,460,094; 6,442,734; 6,795,949; 7,096,435. Other patents issued and pending.

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