Abstract

Integrated Cycler. Cerebrospinal fluid (CSF) specimens are loaded directly onto a Direct Amplification Disc without any separate specimen preparation or extraction steps. Results are generated in approximately 60 minutes. Simplexa™ HSV 1 & 2 Direct detects and differentiates herpes simplex viruses (HSV) 1 and 2. The objective of this study was to evaluate and compare the performance of the Simplexa HSV 1 & 2 Direct assay with clinical and sequencing results that utilize conventional nucleic acid extraction procedures.

Methods

Limit of detection (LoD) studies were performed to determine the analytical sensitivity of the assay. A panel of bacteria and viruses was tested to evaluate cross-reactivity. A panel of potentially interfering substances was tested to determine whether any inhibition was observed. A reproducibility study panel was tested at 3 separate sites. Clinical performance was determined by testing blinded CSF clinical specimen panels with Simplexa HSV 1 & 2 Direct and comparing the results to the consensus of physician’s assessment based on clinical data which included neural imaging results when available, and results from two different sequencing assays.

Results

Limit of Detection: HSV-1 (McIntyre and HF strains) LoD was ≤20 TCID₅₀/mL. HSV-2 (G and MS strains) LoD was ≤50 TCID₅₀/mL in human CSF.

Cross Reactivity: The cross reactivity panel consisted of industry equivalent 10⁶ CFU/mL of bacteria or 10⁵ TCID₅₀/mL of virus in human CSF.

Inhibition/Interference: The interference panel was contrived with HSV-1 or HSV-2 at 4-fold above LoD concentration. Each substance was spiked into the HSV-1 or HSV-2 human CSF contrived samples and tested using Simplexa HSV 1 & 2 Direct kit.

Conclusions

Simplexa HSV 1 & 2 Direct is a simple and rapid molecular test. Simplexa HSV 1 & 2 Direct provides answers in ~60 minutes, without requiring a separate extraction step.

Simplexa HSV 1 & 2 Direct was capable of directly detecting and differentiating HSV-1 and HSV-2 from un-extracted CSF specimens, with performance comparable to sequencing and neural imaging.

Simplexa HSV 1 & 2 Direct is FDA cleared and CE marked and is currently available for sale.

For more information, visit: http://www.focusdx.com