ENTEROVIRUS ELITe MGB Kit passed all the performance acceptance criteria established for the analytical and clinical studies regardless the sample matrix and tested regardless the extraction and the amplification system used.

### Analytical Studies

100% of correct identification was obtained with the certified reference material panel used to assess the integrated system performance with ELITe STAR in combination with ABI instrument. All samples (12) of the 2012 Enterovirus QCMD panel included the main serotypes from the 4 Enterovirus groups A, B, C and D, were correctly detected. Eleven out of twelve samples were correctly detected with the ELITe GALAXY and the ELITe InGenius. The EVRNA 12-01 and EVRNA 12-10 samples which were not determined were defined by QCMD as “infrequently detected” because of the very high dilution. The results are described in the Table 1.

### Clinical Studies

The ENTEROVIRUS ELITe MGB Kit overall clinical sensitivity was 97% and the overall clinical specificity was 100% on the panel of samples tested. Clinical performance per matrix and per instrument are specified in the Table 4.

### Robustness Studies

The absence of cross-contamination, was verified by analyzing the results of several consecutive sessions in which samples positive for Enterovirus RNA were alternated with negative samples. All negative and positive samples were correctly detected confirming the absence of cross-contamination.

The overall failure rate of the system was verified by analyzing a panel of samples spiked for Enterovirus RNA of low titer (900 copies/mL, equivalent to approximately 3 x LoD). All samples were correctly detected by the system confirming the excellent reliability of the whole process for enterovirus testing.

### CONCLUSION

These studies demonstrated that the ENTEROVIRUS ELITe MGB Kit is a highly sensitive and robust assay for viral Molecular Diagnostics. The one-step format reduces the hands-on time, limits the risk of errors and improves the traceability while reducing the time-to-result which is crucial for encephalitis and meningitis diagnosis.

The ENTEROVIRUS ELITe MGB Kit was validated in parallel with several MDx workflow to meet diverse CE-IVD workflow for viral meningitis testing with ENTEROVIRUS ELITe MGB kit.

- Conventional PCR solutions adapted to low/medium throughput testing needs with ELITe STAR / ABI 7300 or adapted to high throughput testing needs with ELITe GALAXY and ABI 7500 Fast Dx.
- Sample-to-Result PCR solution with ELITe InGenius

The absence of cross-reactivity with potentially interfering pathogens, was evaluated by sequence comparison with nucleotide databases. The absence of cross-reactivity was also verified by testing reference materials from proficiency panel (Qnostics Ltd, U.K.) for phylogenetically near viruses and other frequent viruses: Rhabdovirus, Parechovirus, HSV1, HSV2, VZV, EBOV, and West Nile Virus. All tested samples were confirmed negative.

The Limit of Detection, calculated with the 2 matrices and the different instruments, are reported in the Table 2.

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