

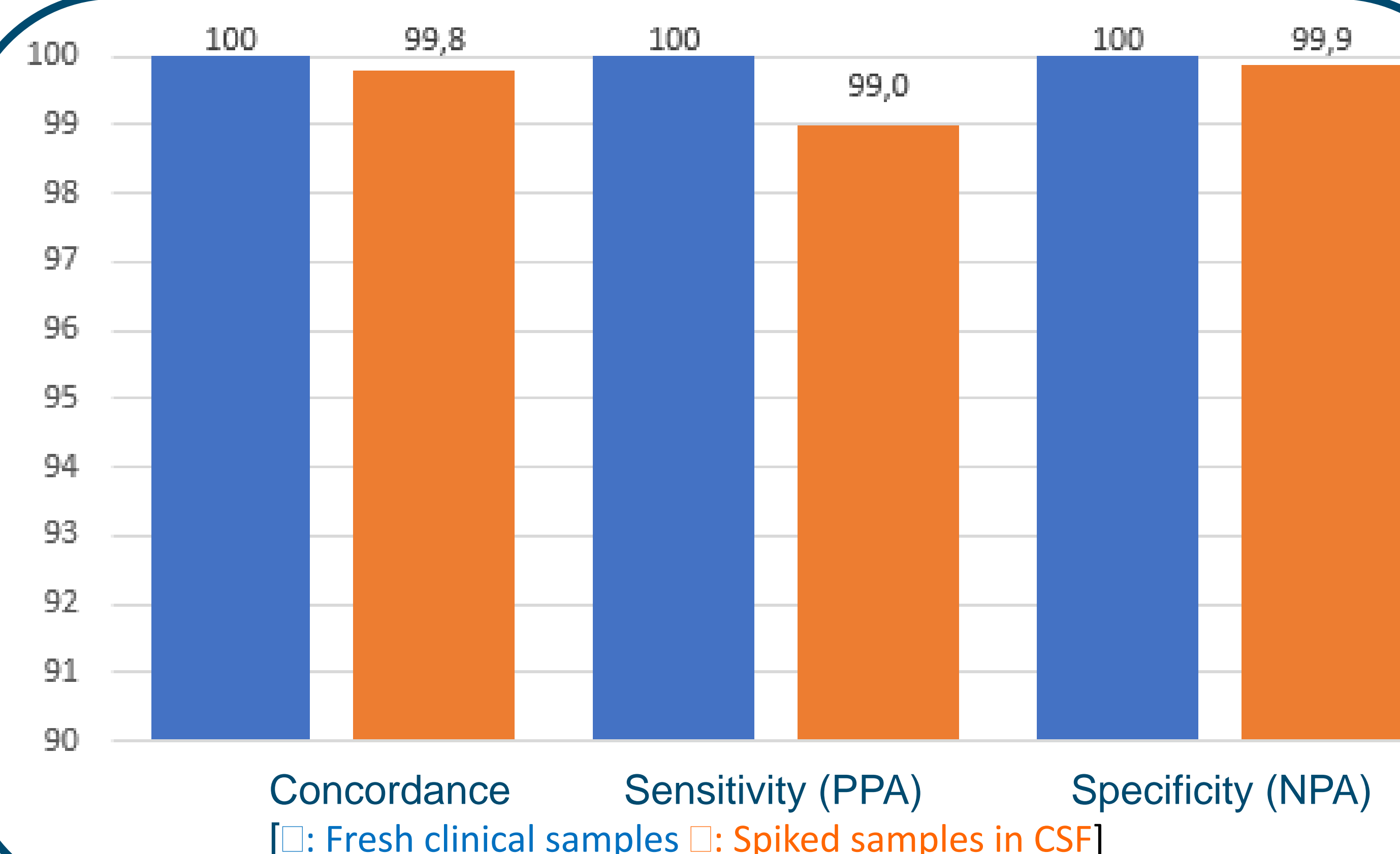
Very Rapid and Accurate Detection of Acute Bacterial Meningitis in Clinical Samples

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Background

Acute bacterial meningitis is a severe and rapidly progressing infection and is on a rise globally. The CDC reported a significant increase of the disease in the US in 2023/24 (e.g. *Neisseria meningitidis* Sg. Y)¹ and WHO adopted a road map "Defeating meningitis by 2030"². The recent meningitis report of the Institut Pasteur (3rd May 2024) stated that "rapid diagnosis is crucial"³. Therefore, we evaluated a new molecular test for rapid diagnosis. The Vivalytic analyser is a new PCR platform for detection of nucleic acids from microbes: either real-time PCR, isothermal amplification or microarray technology. The easy-to use and scalable cartridge system can be applied in the laboratory or as point-of-care test (POCT). Rapid diagnostics are crucial for clinicians to start effective antibiotic treatment. Therefore, it is key for complete restitution of affected patients.



Methods

In total, 374 cerebrospinal fluid (CSF) samples were tested. 74 of the samples were fresh clinical samples and 300 samples were spiked with respective reference material (all in CSF samples, not artificial matrix!) to validate the assay accurately and retrieve statistically significant data. Titered frozen reference materials for all 6 respective pathogens (*Streptococcus pneumoniae*/srpn, *Haemophilus influenzae*/hain, *Neisseria meningitidis*/neme, *Listeria monocytogenes*/limo, *Escherichia coli*/esco and *Streptococcus agalactiae*/srag) were purchased from ZeptoMetrix (Buffalo/NY, USA). All CSF samples were analysed on a Vivalytic analyser (Bosch Healthcare Solutions, Waiblingen, Germany) using the Vivalytic Bacterial Meningitis test cartridges. The Allplex Meningitis B assay (Seegene, Seoul, South Korea) was used as comparator test. To achieve comparable results both tests were performed within 48 hours.

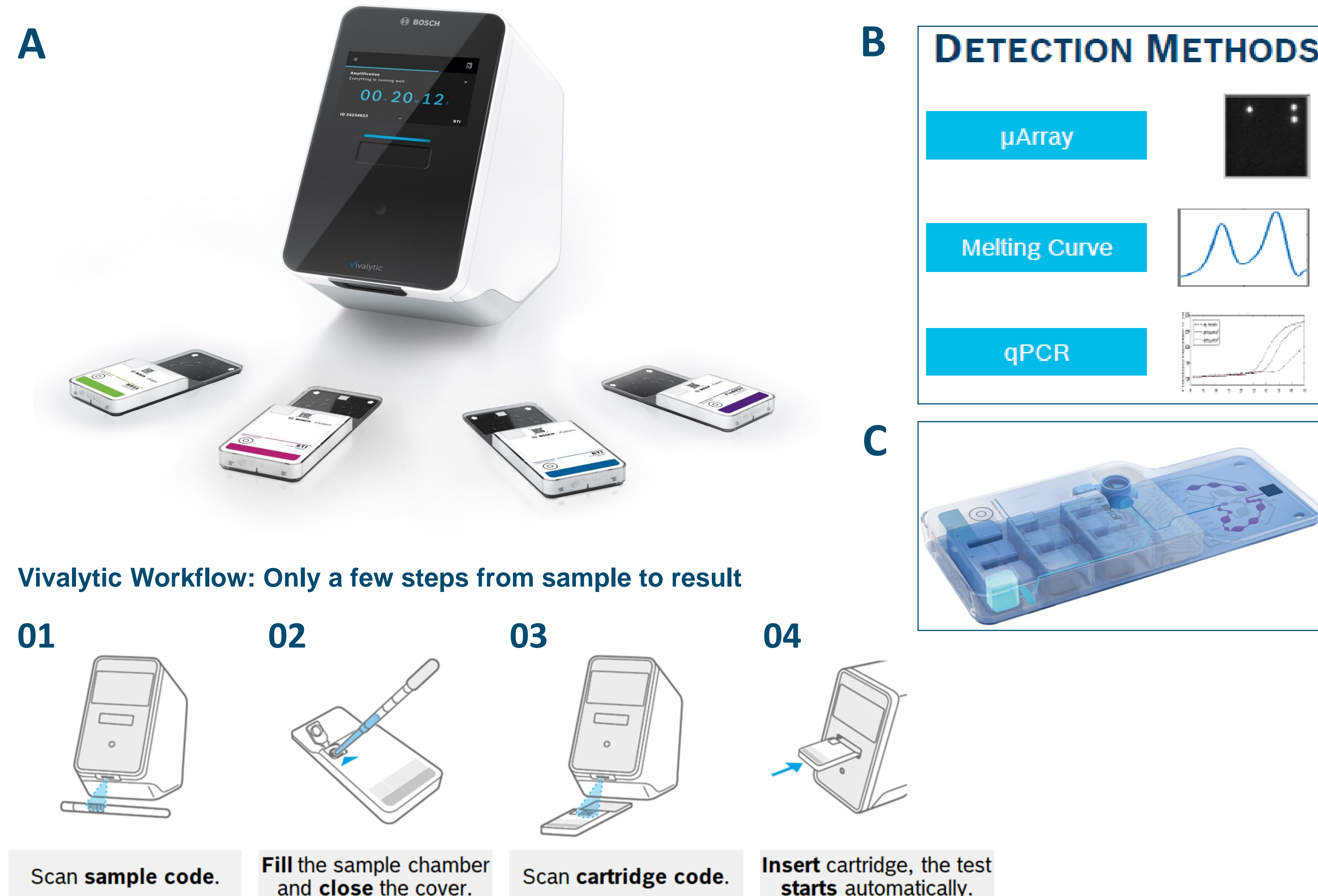
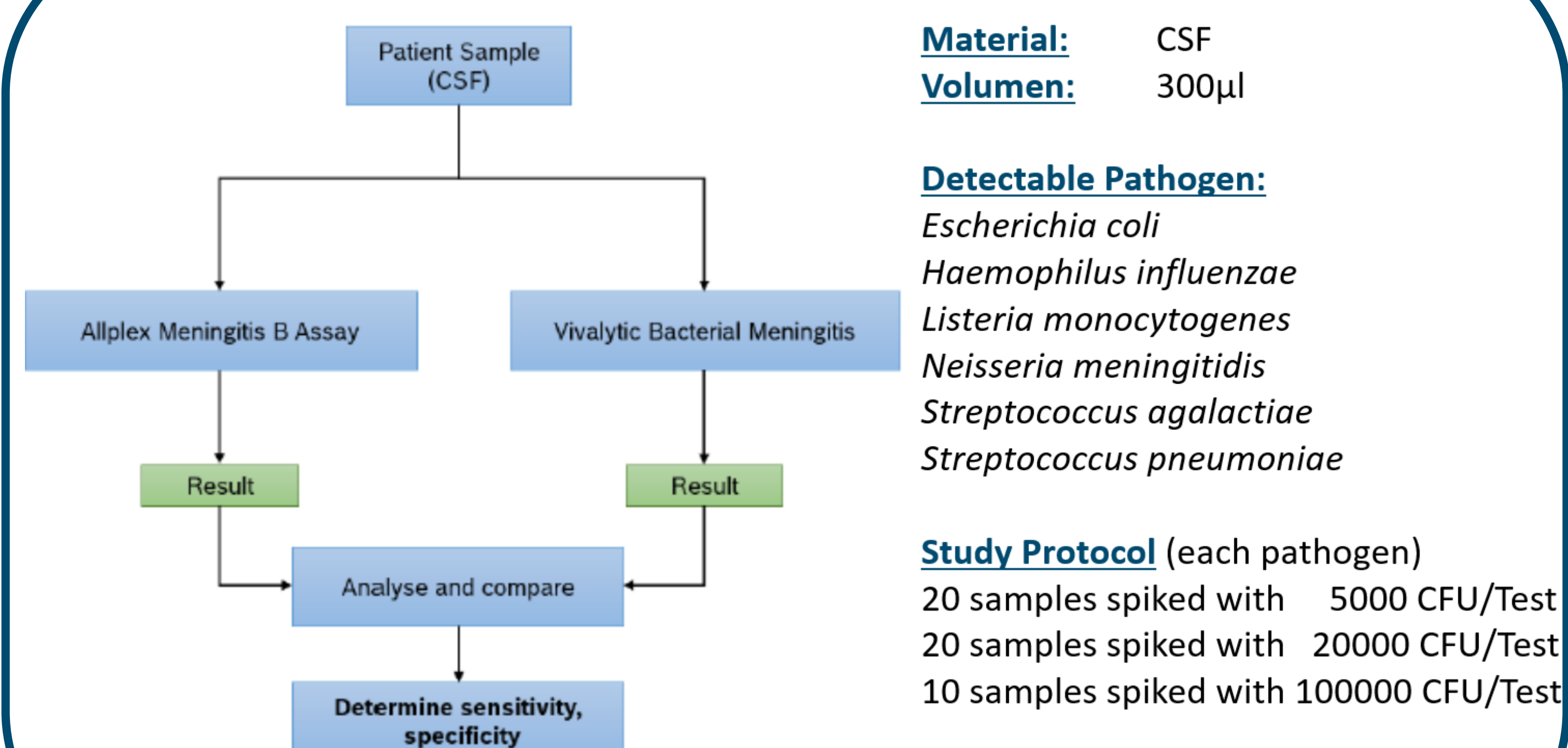


Fig. 1:
Vivalytic analyser (A)
Detection methods: µ Array, Melting curve analysis and real-time PCR (B)
Cartridge with reservoirs and microfluidic system (C)
[The study was supported by BHCS by providing Vivalytic cartridges]

Results and Conclusion

The Vivalytic assay showed an excellent performance: overall sensitivity was 99% (296/299). For srpn/hain/esco the sensitivity was 100% (50/50 each) and for neme/limo/srag it was 98% (49/50 each). The specificity of the new test and the robustness was investigated at five different labs and the overall specificity was 99,95%. The objectives of the study protocol for positive percent agreement (PPA >94%) and negative percent agreement (NPA >98%) were met for every single pathogen. The maximal time-to result was 56 min for the Vivalytic test (first results: 22 min; "result-on display") compared to 150 min for the comparator assay. The Vivalytic Bacterial Meningitis cartridge demonstrated excellent concordance with a sensitive reference test and delivered accurate and rapid results. The assay is suitable for hospital labs (scalable; range 1-48 analysers) and for outpatients' settings (POCT) due to its ease of use and short time-to-result. Therefore, it meets the WHO criterion, that "rapid diagnosis is needed to treat immediately".

References:

- 1) CDC report on meningitis 13/11/2024
- 2) WHO "Defeating meningitis by 2030 road map": [Defeating Meningitis by 2030 \(who.int\)](https://www.who.int/publications/m/item/defeating-meningitis-by-2030-road-map)
- 3) Institut Pasteur "Meningitis report" 03/05/2024: [The lowdown on meningitis, a public health challenge | Institut Pasteur](https://www.pasteur.fr/fr/actualites/le-baissement-de-la-meningite-un-defi-de-santepublique)

Amendment: BHCS Meningitis Assay was CE certified in February 2025.