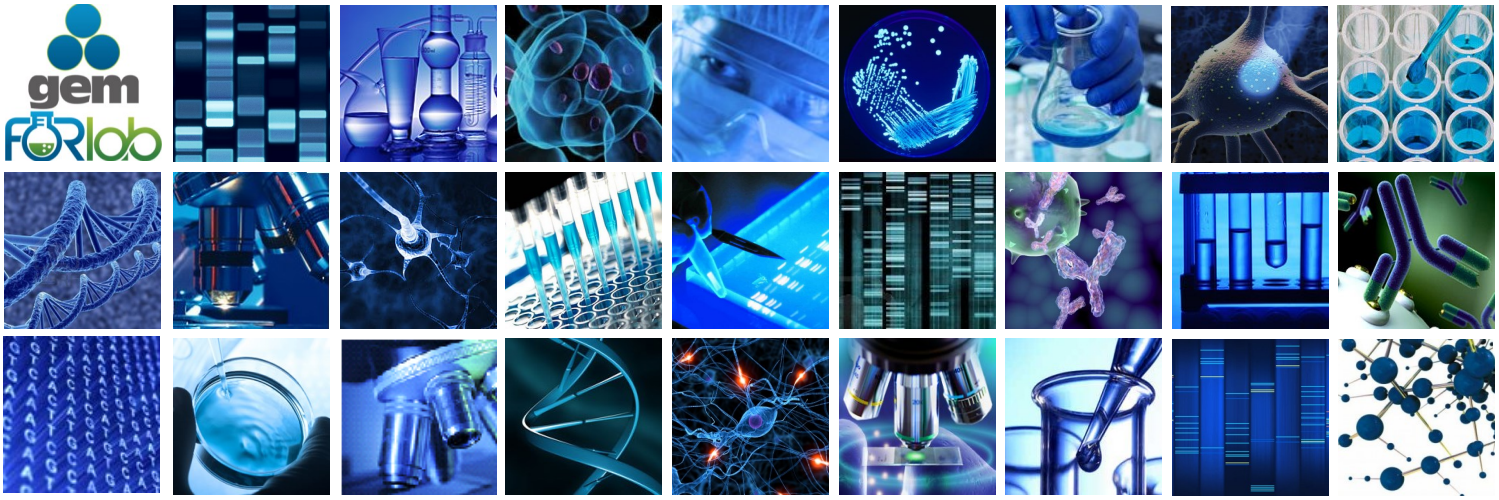

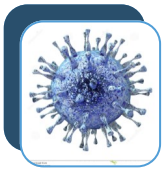

Analytical and diagnostic performance evaluation of IVD (in vitro diagnostic) reagents

Aim of the study

Analytical and clinical diagnostic evaluation of an IVD System for the extraction, detection and quantitation of viral and bacterial DNA/RNA by PCR.

Analyte

DNA from 15 different viruses/bacteria

Methodology

A sample-to-result solution dedicated to Molecular Diagnostics which automatically performs extraction, amplification and result interpretation.

Matrix Human whole blood, plasma, CSF, urine and nasal swab, stool and fecal swab

Therapeutic area In vitro diagnostic

Development stage Development

Customer A private enterprise manufacturing and commercializing IVD equipment and reagents.

Results

For each IVD kit a PCR analytical performance evaluatio was executed; the method efficiency, linearity, accuracy, precision, repeatability, reproducibility and sensitivity were analyzed. Several human samples from different donors (previously tested negative/positive for the target by reference method) were analyzed; this way their negativity/positivity was confirmed to assess the kit diagnostic specificity and sensitivity.

Advantage of the methodology

Is a bench-top solution integrating all the steps of molecular diagnostics in a single platform with best-in-class and proven technologies for acid nucleic ex-traction and RT-PCR amplification. Moreover, within one single session one to 12 samples can be processed in 12 parallel tracks.

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