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Poster Session V
Molecular and non-molecular diagnostics of viruses

STANDARDIZED KITS FOR RAPID SCREENING OF NOROVIRUS AND ENTERIC VIRUSES IN CLINICAL SAMPLES

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Noroviruses are the main agent responsible of viral gastroenteritis and constitute the principal origin of nosocomial infections. Other enteric viruses (rotavirus, adenovirus 40/41, astrovirus) are also frequently at the origin of viral diarrhea. Their diagnostic is important especially for young children and immune-compromised persons to determine the viral, bacterial or parasitic origin of the pathogens in stool samples and apply the right therapy. We have developed rapid, sensitive, specific and standardized methods for a quick screening of noroviruses and other enteric viruses.

Two screening kits have been developed: one for norovirus GI and GII and one for simultaneous detection of 5 enteric viruses (norovirus GI and GII, rotavirus, adenovirus 40/41 and astrovirus) in one reaction.

After design of primers and probes, the specificity and absence of dimer formations were validated by bioinformatics and experimentally. The sensitivity was determined by using serial dilution of nucleic acids extracted from positive stool samples. A robustness study (reproducibility, repeatability) was conducted. An internal positive control, negative and positive controls were included to ensure reliability of the diagnostic results. The two methods were also validated on different thermocyclers. All the performance criteria were compiled in validation reports and IVD labels were obtained. Two detection kits were then produced following ISO13485 certification and commercialized under ceeramTools trademark. The French National Reference Center (NRC) for enteric viruses validated them on 200 stool samples previously found positive for norovirus or other enteric viruses.

The specificity was validated for all viruses and no cross reactivity was observed. A limit of detection of 50 genome copies/reaction was reached with a confidence level of 95% for the norovirus screening kit. For the screening of the 5 enteric viruses a limit of 500 genome copies/reaction was obtained. The robustness study demonstrated standard deviations below 0,8 for inter and intra-assays and inter manipulator variations. On the 200 samples tested, no significant difference was observed between the results obtained using the NRC methods and norovirus@ceeramTools and gastrovirus1@ceeramTools kits.
With a results obtained in 2h after extraction, these two kits allow a rapid detection of norovirus and a fast screening of major enteric viruses in one reaction. With a quick determination of viral origin of gastroenteritis, antibacterial or anti-parasitic treatments can be avoided. To complete the screening of enteric viruses, a second screening kit is under development for the detection of Norovirus GIV, aïchi virus, sapovirus and enterovirus. If necessary, the exact viral origin or norovirus genogroup can be determined using ceeramTools simplex diagnostic kits.