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Evaluation of the new RIDA GENE gastro panel for the direct detection of stool pathogens in comparison to routine diagnostic methods

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Background: According to WHO, gastrointestinal infections which can be caused by bacteria, viruses and parasites are among the most frequently reported diseases worldwide. The rapid identification of these diarrhea causing agents with specific and sensitive laboratory methods are important for prompt and precise patient therapy as well as the identification of the infection source. In recent years, syndrome-based PCR panels were introduced with promising sensitivity and specificity. In this study, we evaluated the syndrome-based RIDA®GENE Gastro Panel PCR assays(R-Biopharm AG) for the simultaneous, direct detection of the most important gastrointestinal pathogens in stool specimens.

Material/methods: 350 prospectively collected fecal samples were tested with the RIDA®GENE Gastro Panel on the LightCycler® 480II (Roche). Results were compared to the phenotypical and molecular laboratory methods which are used in the routine microbiology laboratory for the detection of bacterial, viral and parasite pathogens. These were as follows: selective bacterial culture media (bacterial pathogens), serology methods (*Shigella* spp., *Salmonella* spp., *Yersinia* spp., *Vibrio* spp.), EIA-assays (Viral pathogens, Campylobacter, parasites), MALDI-TOF MS, real-imePCR, PCR lineprobe assay (GenoType EHEC/EPEC, Hain Lifescience), the BD Max-System (toxigenic *C. difficile*, BD MAX Gastro Panel, both Becton Dickinson) and a PCR multiplex panel (Seegene Allplex™ Gastrointestinal Full Panel Assay). All assays were performed according to manufacturer's instructions

Results: In total the 350 stool specimens contained 101 bacterial stool pathogens (*Salmonella spp* (n=7), Yersinia enterocolicia (n=1), toxigenic *Clostridium difficile* strains (n=12), *Campylobacter spp.* (n=37), STEC (n=3), EHEC (n=1), EPEC (n=26), ETEC (n=5), EAEC (n=9), 29 viruses (norovirus (n=19), astrovirus (n=4), rotavirus (n=3), adenovirus (n=3) and 25 parasites (*Dientamoeba fragilis* (n=18), *Giardia lamblia* (n=3), *Cryptosporidium ssp.* (n=4). 24 patients showed multiple infections. The sensitivities and specificities of the RIDA®GENE Gastro Panel were 98.0% and 98.4%, respectively for

bacteria, 100% and 98.4% for viruses and 100% and 100% for parasites. For bacteria, one specimen culture-positive for *Salmonella* spp. and one enrichment-culture-positive for EHEC were negative with the RIDA®GENE PCR assays, but also negative with all other PCR assays used in the study (BD MAX, Seegene Allplex). It might be assumed that these stool specimens contained pathogen concentrations below the detection limit for the PCR tests. 5 specimens were adenovirus-positive with the RIDA®GENE panel and negative with the reference methods (EIA, multiplex-PCR). These results were considered as false-positive. Nevertheless, the RIDA®GENE panel includes adenovirus types which are not included in the comparator EIA methods and the Allplex multiplex panel. This might explain the five false-positive results with the RIDA®GENE panel.

Conclusions: The RIDA®GENE Gastro Panel multiplex-PCR assays showed sensitive and specific results for the detection of bacterial, viral and parasitic pathogens in stool specimens.