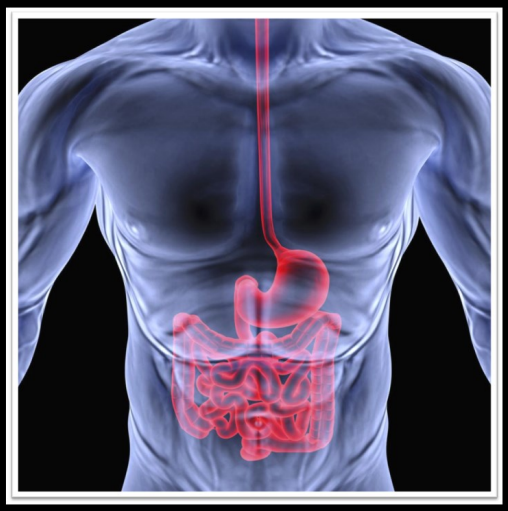


Luminex Multiplexing: Fast & Accurate

August 2016

The Value of xTAG Gastrointestinal Panel (GPP) to the Patient, Physician & Hospital

Numerous studies have evaluated the clinical utility of xTAG GPP for diagnosis of infectious diarrhea in a variety of different patient populations and environments, including pediatrics, immunocompromised and transplant patients, travellers, outpatients and during outbreaks.

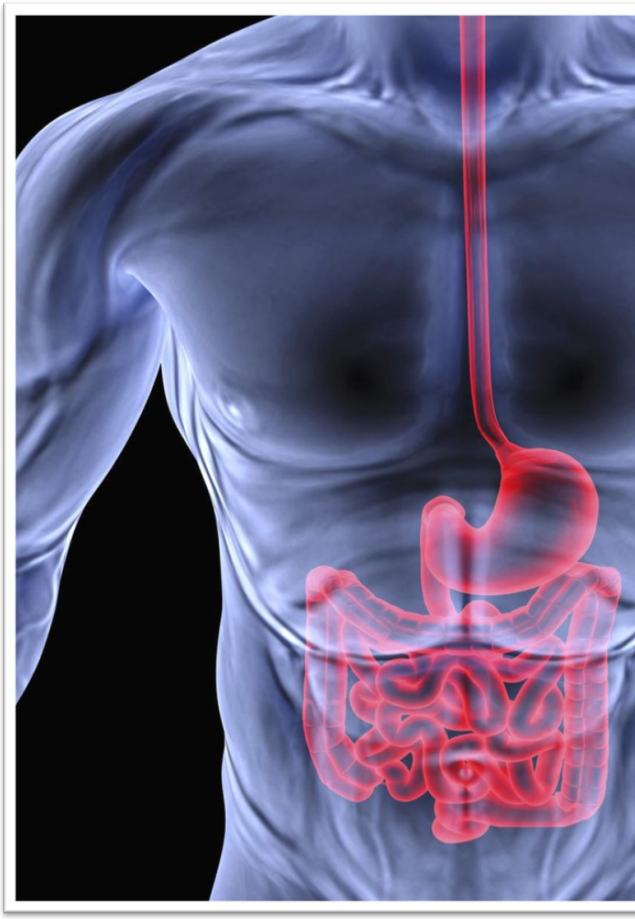
Beckmann and colleagues have examined xTAG GPP in 312 stool samples (296 patients) from 2 patient populations: 120 pediatric gastroenteritis patients presenting to the emergency room and 176 travellers (151 adults and 25 pediatrics) returned from the tropics with gastrointestinal symptoms or parasite infestation.[1] Overall, pathogens were identified in 28% of the stool samples. The detection rate in pediatric patients was 52%, which was significantly higher than the 11% found in travellers (mostly adult patients). The pathogen distribution found in the pediatric samples corresponds to that expected for diarrhoea in young children, with predominantly rotavirus (27%). This study demonstrated broad detection of relevant GI pathogens by xTAG GPP and the investigators perceive the major role of the assay to be for immunocompromised patients and patients with a broad differential diagnosis, since results could be provided rapidly and have an impact on clinical management, resulting in reduced hospital stay and costs. The authors recommended performing direct antigen detection for children with gastroenteritis first, and if found negative, or additional pathogens are clinically suspected, xTAG GPP is performed. For patients returning from the tropics, they recommended restricting xTAG GPP to patients with a clinical diagnosis of gastroenteritis. xTAG GPP testing can be selectively complemented with tests for additional suspect pathogens and for antimicrobial resistance testing as needed.

Zboromyrska and colleagues also evaluated xTAG GPP for etiological diagnosis of traveller's diarrhea.[2] 76 pathogens were identified from 185 stool samples. The detection rate was 31.9%, including 60 pathogens that were not detected by conventional methods or were not requested for testing. The main pathogens causing traveller's diarrhea were Shigella (24.2%), enterotoxigenic *Escherichia coli* (ETEC) (23.2%), enteroaggregative *E. coli* (EAEC) (14.7%), and Giardia (13.7%). Significant regional differences were noticed for ETEC with 19.4% of cases acquired in Africa, 11.3% in Asia, and none in South Central (SC) America. Giardia was found in 14.1% of those who had travelled to Asia, 3% of those who had travelled to SC America, and only 1.5% of those who had travelled to Africa. They concluded that xTAG GPP significantly improved the detection of enteropathogens and allowed better assessment of the etiology of traveller's diarrhea.

Mengelle and co-workers have analysed xTAG GPP for simultaneous detection of gastroin-

testinal (GI) pathogens in 440 samples from 329 patients, consisted of 102 immunosuppressed adults, 50 immunosuppressed children, 56 children in the neonatal unit and 121 children in the emergency unit.[3] Most of the samples collected from the children in the emergency unit tested positive for GI pathogens (92.6%) and most of these pathogens were rotavirus (98.6%) and norovirus (53.3%). Fewer positive samples were found in the other patient populations, with positivity rates of 17% from immunosuppressed adults, 25.3% from immunosuppressed children and 19% from children in the neonatal unit. The distribution of the pathogens differed from one patient population to another. Norovirus was also detected in the immunosuppressed children (26.7%) and the immunosuppressed adults (20%). *Salmonella* spp. was found most frequently in 61.9% from the children attending the emergency unit, while toxigenic *Clostridium difficile* was most common in immunocompromised adults (61.1%). The authors concluded that xTAG GPP is a very sensitive method for detecting multiple GI pathogens from a single stool sample and convenient for routine daily use due to its low turnaround time and technical hands-on time.

Diarrhea is a complication happens commonly in transplant patients. It is usually attributed to adverse effects of immunosuppressive therapy when microbiological examination is negative. A recent publication by Coste and co-workers shared the improvement of microbiological diagnosis and management of severe diarrhea in kidney transplant patients through implementation of molecular testing for infectious gastroenteritis.[4] For 54 severe diarrhea cases occurring in 49 adult kidney transplant recipients, molecular methods identified one or more enteric pathogens in 39 stool specimens. The primary diarrhea-causing pathogens in this patient population are Enteropathogenic *E. coli*, *Campylobacter* spp., and noroviruses. Statistical analysis of the data showed that the post-transplantation term of diarrhea onset due to norovirus was significantly prolonged compared to that of other causes of infectious and non-infectious diarrhea. In addition, immunosuppressive therapy combining cyclosporine and mycophenolate mofetil was associated with a significantly higher risk of developing viral gastroenteritis, particularly that caused by norovirus. The authors concluded that xTAG GPP is a powerful molecular assay for the microbiological diagnosis of enteric pathogens in kidney transplant patients due to its rapid and simultaneous detection of a wide range of bacterial, viral and parasitic pathogens and thus it becomes the key element of the management of severe acute diarrhea in these patients.



Malecki and co-workers reported on implementation xTAG GPP assay during the 2011 outbreak of enterohemorrhagic *E. coli* (EHEC) in Germany.[5] 20 patients suffering from hemorrhagic diarrhea or suspected to be infected with the new EHEC strain were tested by xTAG GPP. The results revealed 4 patients were found to be positive for the EHEC O104:H4 strain, 2 patients suffered from severe *Campylobacter* infections but were negative for EHEC, and 1 patient was positive for another EHEC strain that produced both Shiga toxins 1 and 2. In conclusion, xTAG GPP is a useful technique for pre-screening patients suffering from the new EHEC strain. Additional benefits are that only a preselected cohort of clinical

samples has to be analyzed for confirmation of suspected strains, and patients negative for EHEC but positive for other pathogens can be administered the correct antibiotic therapy. With the capability for high throughput testing, they experienced that xTAG GPP is able to manage the peaks in an outbreak situation.

With its multiplexing capability, faster turnaround time and higher sensitivity, use of the xTAG GPP assays have been proven to offer improved diagnostic capabilities, better patient care and better physician treatment satisfaction with additional pathogen information.

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