

Supplementary Table 3. Major studies evaluating the performance of FDA approved/cleared multiplex gastrointestinal panels

| Study | Huang et al. (1) | | | | Buss et al. (2) | | Khare et al. (3) | | | | | | | | Wessels et al. (4) | | Spina et al. (5) | | Patel et al. (6) | |
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| | %Sensitivity/ %Specificity | | | | Sensitivity | Specificity | Prospective Study (samples tested n = 230) | | | | Retrospective Study (samples tested n = 230) | | | | Number of samples positive (samples tested n = 393) | | Number of pathogens detected | | 211 samples tested | |
| | Number of positives (samples tested, n = 152) | Verigene | Biofire GIP | Luminex GPP | | | Sensitivity | Specificity | Sensitivity | Specificity | Sensitivity | Specificity | Sensitivity | Specificity | Sensitivity | Specificity | Luminex xTAG-GPP | Routine diagnostics | BioFire GIP | Routine diagnostics |
| Biofire GIP | | | | | Luminex | | | | | | | | | | | | | | | |
| <i>Campylobacter species</i> | 12 | 83/99 | 100/100 | 92/100 | 34/35 (97.1%) | 1,497/1,521 (98.4%) | 100% | 100% | 100% | 100% | 96.6% | 99.6% | 79.3% | 100% | 15 | 12 | 53 | 83 | 1 | 1 |
| <i>Salmonella species</i> | 24 | 83/100 | 96/100 | 79/100 | 31/31 (100%) | 1,519/1,525 (99.6%) | 100% | 99.6% | 100% | 100% | 100% | 100% | 83.3% | 100% | 4 | 0 | 27 | 20 | 22 | 19 |
| <i>Shigella species/EIEC</i> | 43 | 95/99 | 100/100 | 100/100 | 47/49 (95.9%) | 1,505/1,507 (99.9%) | 100% | 100% | 100% | 99.6% | 90.6% | 99.6% | 81.8% | ND | 3 | 2 | 10 | 0 | 10 | 7 |
| <i>Vibrio species</i> | NA | | | | 0/0 | 1,554/1,556 (99.9%) | NA | NA | NA | NA | ND | ND | NA | NA | | | 0 | 1 | | |
| <i>Yersinia enterocolitica</i> | NA | | | | 1/1 | 1,555/1,555 (100%) | ND | 100% | ND | 100% | 100% | 99.6% | 48.1% | 100% | 13 | 13 | 19 | 0 | | |
| <i>Escherichia coli</i> 0157 | NA | | | | 3/3 (100%) | 34/35 (97.1%) | ND | 100% | ND | 100% | 100% | 100% | 90.9% | 99.6% | 1 | ND | | | | |
| Enterotoxigenic <i>E. coli</i> | NA | | | | 22/22 (100%) | 1,525/1,534 (99.4%) | 100% | 100% | 100% | 100% | ND | ND | ND | ND | | | 30 | 1 | | |
| Enteropathogenic <i>E. coli</i> | NA | | | | 314/317 (99.1%) | 1,167/1,201 (97.2%) | ND | ND | NA | NA | ND | ND | NA | NA | | | 107 | 3 | | |
| Enterogastric <i>E. coli</i> | NA | | | | 82/83 (98.8%) | 1,446/1,473 (98.2%) | ND | ND | NA | NA | ND | ND | NA | NA | | | 47 | 0 | | |
| <i>Plesiomonas shigelloides</i> | NA | | | | 3/3 (100%) | 1,538/1,553 (99%) | ND | 100% | NA | NA | 100% | 100% | NA | NA | | | 1 | 0 | | |
| <i>stx1/stx2</i> (Shiga toxin-producing <i>E. coli</i>) | 12 | 92/100 | 100/100 | 92/100 | 33/33 (100%) | 1,518/1,523 (99.7%) | ND | 99.6% | ND | 100% | 100% | 99.2% | 96.4% | 99.6% | 4 | 4 | 19 | 3 | 3 | 3 |
| <i>Clostridium difficile</i> (toxin A/B) | NA | | | | 163/165 (98.8%) | 1,350/1,391 (97.1%) | 100% | 96.6% | 95.8% | 97.2% | 91.7% | 97.9% | 91.7% | 98.3% | 1 | 1 | 65 | 17 | 23 | 23 |
| Norovirus GI/GII | 19 | 89/100 | 95/99 | 90/100 | 52/55 (94.5%) | 1,483/1,501 (98.8%) | 91.7% | 99.5% | 100% | 90.8% | 93.2% | 100% | 93.2% | 85.8% | 20 | 22 | 42 | 10 | 11 | 11 |
| Rotavirus A | 7 | 71/100 | 100/99 | 100/100 | 6/6 (100%) | 1,538/1,550 (99.2%) | ND | 99.6% | ND | 99.1% | 100% | 99.6% | 92.9% | 99.6% | 1 | 1 | 27 | 14 | 2 | 2 |
| Astrovirus | NA | | | | 7/7 (100%) | 1,548/1,549 (99.9%) | 100% | ND | NA | NA | 100% | 100% | NA | NA | | | 12 | 0 | | |
| Adenovirus 40/41 | NA | | | | 42/44 (95.5%) | 1,499/1,512 (99.1%) | 100% | 99.6% | 100% | 100% | 90.0% | 99.2% | 80% | 100% | 3 | 3 | 17 | 4 | | |
| Sapovirus | | | | | 46/46 (100%) | 1,497/1,510 (99.1%) | 100% | ND | NA | NA | 90.3% | 100% | NA | NA | | | 18 | 0 | | |
| <i>Cryptosporidium species</i> | NA | | | | 18/18 (100%) | 1,532/1,538 (99.6%) | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 3 | 3 | 13 | 4 | 11 | 14 |
| <i>Entamoeba histolytica</i> | NA | | | | 0/0 | 1,556/1,556 (100%) | ND | 100% | ND | 100% | 0% | 100% | 100% | 100% | 6 | 1 | | | | |
| <i>Giardia lamblia</i> | NA | | | | 20/20 (100%) | 1,529/1,536 (99.5%) | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 9 | 9 | 17 | 3 | 3 | 3 |
| <i>Cyclospora cayatanensis</i> | NA | | | | 19/19 (100%) | 1,537/1,537 (100%) | ND | 100% | NA | NA | ND | ND | NA | NA | | | 1 | 0 | | |
| Comparison methods | Culture: <i>Salmonella</i> , <i>Shigella</i> , and <i>Campylobacter</i> species; ImmunoCard STAT!EHEC: Shiga toxin; SURE-VUE Rota Test: rotavirus; Xpert norovirus: Norovirus | | | | Compared to conventional methods of culture, PCR, or PCR plus sequencing, not including additional positives detected by GIP or discrepant analysis | | Prospectively collected stool was stored in Cary-Blair at 4°C and tested within 5 days of collection. Retrospective specimens were previously characterized and stored at either 4°C or -20°C. The reference method for <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , <i>Yersinia</i> , <i>Aeromonas</i> , and <i>Vibrio</i> species and <i>Plesiomonas shigelloides</i> detection was culture. Real-time PCR was used for adenovirus, Shiga toxin (<i>stx1/stx2</i>), <i>Yersinia enterocolitica</i> , and <i>Salmonella</i> , <i>Campylobacter</i> , and <i>Shigella</i> species. <i>C. difficile</i> (toxin A/B) was detected with a laboratory-developed real-time PCR assay. Viral targets (aside from adenovirus) were detected using viral culture. Ova and parasite microscopic examination (concentrated wet preparations and permanent stains) was used to detect parasites. <i>Cyclospora</i> samples received a modified safranin stain. <i>Giardia</i> and <i>Cryptosporidium</i> species were also detected with the ProSpecT antigen enzyme. For some discordant results, samples were sent to the Minnesota Department of Health for real-time PCR analysis. | | | | | | | | Routine testing for bacteria and bacterial toxins was performed by culture and VIDAS (BioMérieux), while viruses and parasites were identified using multiplex real-time PCRs, with additional discrepant analysis performed. | | Samples were collected from 10 laboratories in 10 European countries and tested using their own routine testing. Each laboratory sent an aliquoted of stool in Cary-Blair medium to a central study lab to be tested using the BioFire GIP. | | This was a prospective study. The gold standard reference methods were: <i>Campylobacter</i> , <i>Salmonella</i> , and <i>Shigella</i> species - culture; Shiga toxin - Meridian premier EHEC EIA kit; <i>Clostridium difficile</i> - Cepheid Xpert C. <i>difficile</i> and MicroSEQ (16S rRNA gene sequencing); <i>E. coli</i> and <i>E. coli</i> O157:H7 - cultures and MicroSEQ; Norovirus GI/GII and Rotavirus A - CDC real-time PCR; <i>Cryptosporidium</i> and <i>Giardia</i> species - Meridian EIA Crypto/Giardia EIA. | |

NA = Not applicable, ND = Not done, LDT = Laboratory developed test

References:

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