

Erfaringer med

STAT Dx DiagCORE Gastrointestinal Panel og Biofire Filmarray Gastrointestinal Panel

Indhold i de to paneler



BIOFIRE® FILMARRAY® GI Panel



TOP



14 bacteria

- Clostridium difficile toxin A/B
- Enteroinvasive E.coli (EIEC)/Shigella
- Enterotoxigenic E.coli (ETEC) lt/st
- Plesiomonas shigelloides
- Shiga-like toxin producing E.coli (STEC) stx1/stx2
- Vibrio cholerae
- Vibrio vulnificus
- Enteroaggregative E.coli (EAEC)
- Enteropathogenic E.coli (EPEC)
- Pathogenic Campylobacter spp. (C.jejuni, C.upsaliensis, C.coli)
- Salmonella
- Shiga-like toxin producing E.coli (STEC) O157:H7
- Vibrio parahaemolyticus
- Yersinia enterocolitica



4 parasites

- Cyclospora cayetanensis
- Entamoeba histolytica
- Cryptosporidium spp.
- Giardia lamblia



6 viruses

- Adenovirus F40/41
- Norovirus GI
- Rotavirus A
- Astrovirus
- Norovirus GII
- Sapovirus (I, II, IV, V)

22 target pathogens at once

BIOFIRE® FILMARRAY® GI Panel targets:

Bacteria	Diarrheagenic E. coli/Shigella
<ul style="list-style-type: none"> ▶ <i>Campylobacter (jejuni, coli & upsaliensis)</i> ▶ <i>Clostridium difficile (Toxin A/B)</i> ▶ <i>Plesiomonas shigelloides</i> ▶ <i>Salmonella</i> ▶ <i>Yersinia enterocolitica</i> ▶ <i>Vibrio (parahaemolyticus, vulnificus, & cholerae)</i> ▶ <i>Vibrio cholerae</i> 	<ul style="list-style-type: none"> ▶ <i>E. coli O157</i> ▶ Enteroaggregative <i>E. coli (EAEC)</i> ▶ Enteropathogenic <i>E. coli (EPEC)</i> ▶ Enterotoxigenic <i>E. coli (ETEC) lt/st</i> ▶ Shiga-like toxin-producing <i>E. coli (STEC) stx1/stx2 E. coli O157</i> ▶ <i>Shigella/Enteroinvasive E. coli (EIEC)</i>
Viruses	Parasites
<ul style="list-style-type: none"> ▶ Adenovirus F 40/41 ▶ Astrovirus ▶ Norovirus GI/GII ▶ Rotavirus A ▶ Sapovirus (I,II, IV, and V) 	<ul style="list-style-type: none"> ▶ <i>Cryptosporidium</i> ▶ <i>Cyclospora cayetanensis</i> ▶ <i>Entamoeba histolytica</i> ▶ <i>Giardia lamblia</i>

STAT Dx DiagCORE Gastrointestinal Panel



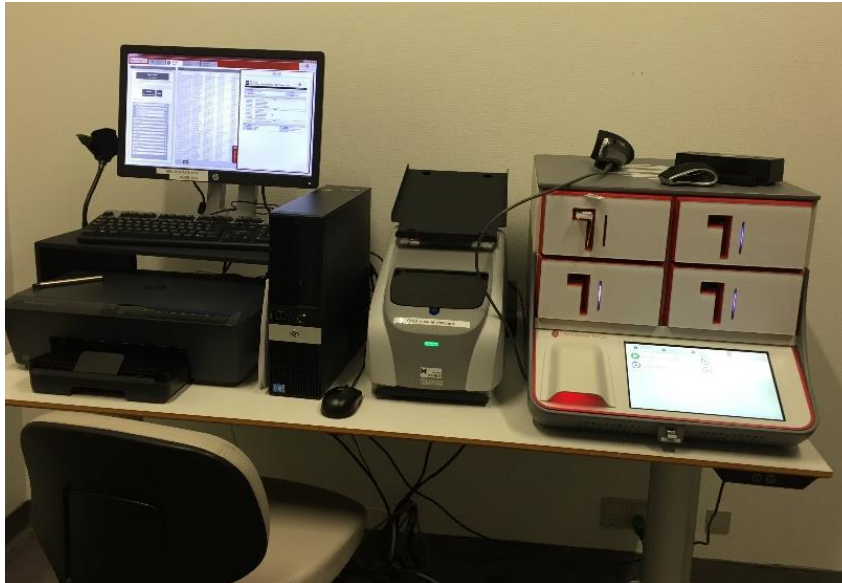
 **STAT Dx**
Closer to Care
Now a QIAGEN company



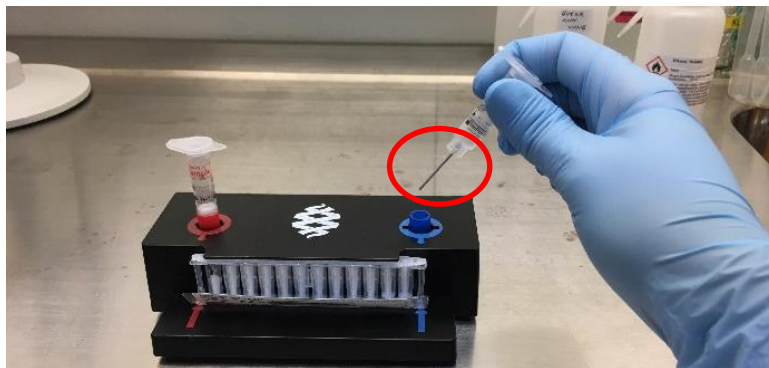
- Fordele
 - Nemt hands-on arbejde i lab
 - CT værdier
- Ulemper
 - Flere omkørsler



Biofire Filmarray Gastrointestinal Panel



- Fordele:
 - Ingen omkørsler
- Ulemper
 - Hands-on arbejdet mere besværligt, og indebærer omgang med spidse genstande
 - 10 min længere
 - Larm (står i separat lokale)

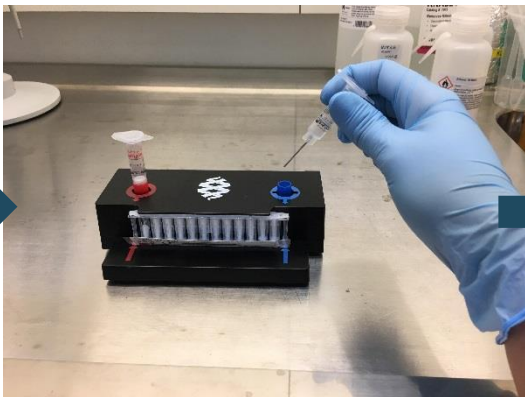
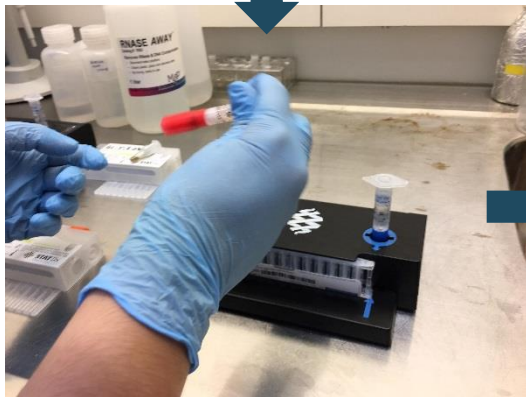
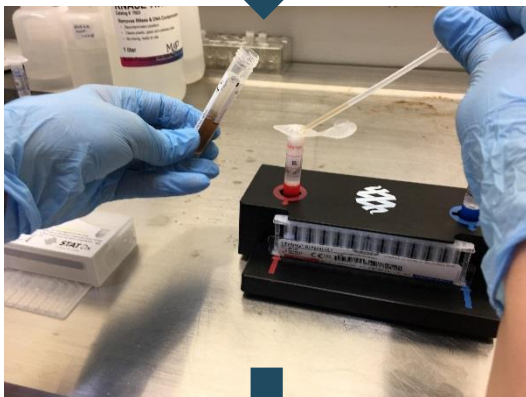
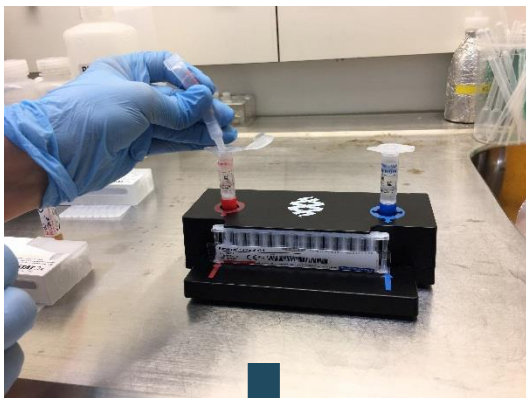




BIOFIRE® FILMARRAY®
GI Panel

Hands-on arbejde

STAT Dx
Click to Care
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DiagCORE - TEST REPORT (DETAILED)

2019 05 08 10:02

Sample ID: 1350_STAT GI-CPH
 Patient ID:
 Assay Name: GI_LUO
 Sample Type: Stool
 Controls: Passed
 Detected Pathogens: Enteropathogenic E. coli (EPEC), Enteroaggregative E. coli (EAEC), Salmonella, Vibrio cholerae

Result Details	Ct / End Point Fluorescence
Norovirus GI: Negative	- / -
Rotavirus A: Negative	- / -
Astrovirus: Negative	- / -
Norovirus GII: Negative	- / -
Cryptosporidium: Negative	- / -
Entamoeba histolytica: Negative	- / -
Giardia lamblia: Negative	- / -
Cyclospora cayetanensis: Negative	- / -
Vibrio parahaemolyticus: Negative	- / -
Clostridium difficile toxin A/B: Negative	- / -
Vibrio vulnificus: Negative	- / -
Enteropathogenic E. coli (EPEC): Positive	20.3 / 299,497
Campylobacter: Negative	- / -
Yersinia enterocolitica: Negative	- / -
Enterotoxigenic E. coli (ETEC) lt/st: Negative	- / -
Enteroinvasive E. coli (EIEC)/Shigella: Negative	- / -
Shiga-like toxin-producing E. coli (STEC)	- / -
Enteroaggregative E. coli (EAEC): Positive	32.2 / 32,407
Salmonella: Positive	31.6 / 46,513
Plesiomonas shigelloides: Negative	- / -
Sapovirus: Negative	- / -
Vibrio cholerae: Positive	26.9 / 245,000
E. coli O157: Failed	- / -
Adenovirus F40/F41: Negative	- / -

	FilmArray® GI Panel	 A BIOMERIEUX COMPANY www.BioFireDx.com	
Run Summary			
Sample ID:	1350_STAT GI-CPH	Run Date:	08 May 2019 11:41 AM
Detected:	Salmonella Vibrio Vibrio cholerae Enteroaggregative E. coli (EAEC) Enteropathogenic E. coli (EPEC)	Controls:	Passed
Result Summary			
Bacteria			
Not Detected	Campylobacter		
Not Detected	Clostridium difficile toxin A/B		
Not Detected	Plesiomonas shigelloides		
✓ Detected	Salmonella		
✓ Detected	Vibrio		
✓ Detected	Vibrio cholerae		
Not Detected	Yersinia enterocolitica		
Diarrheagenic E. coli/Shigella			
✓ Detected	Enteroaggregative E. coli (EAEC)		
✓ Detected	Enteropathogenic E. coli (EPEC)		
Not Detected	Enterotoxigenic E. coli (ETEC) lt/st		
Not Detected	Shiga-like toxin-producing E. coli (STEC) stx1/stx2		
⊗ N/A	E. coli O157		
Not Detected	Shigella/Enteroinvasive E. coli (EIEC)		
Parasites			
Not Detected	Cryptosporidium		
Not Detected	Cyclospora cayetanensis		
Not Detected	Entamoeba histolytica		
Not Detected	Giardia lamblia		
Viruses			
Not Detected	Adenovirus F 40/41		
Not Detected	Astrovirus		
Not Detected	Norovirus GI/GII		
Not Detected	Rotavirus A		
Not Detected	Sapovirus		
Run Details			
Pouch:	GI Panel v2.1	Protocol:	Stool FA v3.3
Run Status:	Completed	Operator:	Danah Knudsen (dknu)
Serial No.:	18424634	Instrument:	TM02442
Lot No.:	314118		

Metode

- Prospektive prøver sendt til tarmpatogene bakterier, virus, parasitter eller *C. difficile*
- Selekeret så de så vidt muligt dækkede alle patogener i STAT gastropanel (GP), samt prøver testet negative i KMA (ca. 60%).
- Prøvermateriale: Fecal-swab
- Alle prøver testet samtidig i STAT GP og Biofire Filmarray GP
- For at evaluere på egen diagnostik er prøver med påvist patogen, som vi ikke havde fundet, efterfølgende testet i relevant analyse.

Resultater

- I alt 412 prøver inkluderet
 - Fra 410 patienter (212 kvinder, mean alder 40,2 år)
 - 25% af prøverne fra børn (15% 0-2 år, 4% 3-5 år, 6% 6-17 år)
 - 75% fra voksne (25% fra 65år+)
- 220 hospitalsprøver, 192 praksisprøver

Resultater

412 prøver
testet

Antal positive prøver	KMA	STAT	BIOFIRE
Positiv	171	222	222
Negativ	241	190	190
Positiv rate	42%	54%	54%

Antal positive fund	KMA	STAT	BIOFIRE
Positiv	180	311	323

Antal fund per prøve

	STAT	Biofire	KMA (efter re-analyse)
0	190	190	212
1	165	163	171
2	32	31	24
3	19	15	5
4	5	12	0
5	1	1	0

Der blev fundet 143 patogener ved STAT/Biofire, som ikke var testet for på KMA

	Antal ekstra fundet	Positiv i både STAT og Biofire	Antal prøver re-testet på KMA, n	Ved retest på KMA findes, n
Virus				
Adenovirus	1	1	1	1
Astrovirus	7	7	-	
Norovirus	6	4	4 *	4
Sapovirus	3	3	3	3
Bakterier				
C. difficile	10	9	8	8
Campylobacter spp.	3	2	2	2
Plesiomonas shigelloides	2	2	-	
Vibrio cholera	1	1	-	
Vibrio parahaemolyticus	2	0	-	
VTEC	1	0	1	0
ETEC	15	11	14	6
EPEC (eae-positive E. coli)	44	40	41	8
Enterogastric E. coli	45	39	43	20
Parasitter				
Cryptosporidium spp.	2	1	2	1
Giardia intestinalis	1	1	1	0

* 2 var på forhånd negative i virus i KMA

29 ellers negative prøver testes positive

Overensstemmelse mellem de positive fund

	Detekteret i n antal prøver i mindst en platform	Fuld overensstemmelse alle 3 platforme	%	Agreement STAT-BIOFIRE (positive fund)	%
Adenovirus	7	7	100	7/7	100
Astrovirus	7	-		7/7	100
Norovirus	22	11	50	14/20	70
Rotavirus	30	26	87	26/29	90
Sapovirus	23	18	78	19/22	86
<i>Campylobacter</i> spp.	25	18	72	18/21	86
<i>Salmonella</i> spp.	19	18	95	18/19	95
<i>Shigella</i> spp./EIEC	24	21	88	22/24	92
<i>Yersinia</i> spp.	8	5	63	5/6	83
<i>Plesiomonas shigelloides</i>	2	-		2/2	
<i>Vibrio cholera</i>	1	-		1/1	
<i>C. difficile</i>	51	47	92	50/51	98
EAEC	52	22	42	44/51	86
EPEC	46	7	15	42/46	91
ETEC	16	5	31	11/16	69
STEC	2	1		1/2	
<i>Cryptosporidium</i> spp	6	4		4/6	67
<i>Giardia intestinalis</i>	4	3		3/4	75
<i>Entamoeba histolytica</i>	1	1		1/1	
				295 / 335	88

295/335

Campylobacter spp.

STAT	BIOFIRE	KMA	n
+	+	+	18 (75%)
+	-	-	2
-	+	-	1
-	-	+	3
+	-	?	1
21	19	21	25

Norovirus

STAT	BIOFIRE	KMA		
-	-	+	2	Ct 22
+	+	+	11 (50 %)	
+	+	-	3	
+ (GI)	-	+	1	
+ (GI)	-	-	2	
-	+	-	3	
17	17	14	22	

Ct 34-35

Omkørsler

	STAT	Biofire
Omkørsler	14 / 412 (3.4%)	0
- 1 omkørsel	12	
- 2 omkørsler	2	

Konklusion

- Der er stor overensstemmelse mellem STAT og Biofire Gastro-paneler
- STAT er nemmere at arbejde med og har en acceptabel omkørsels-rate
- Hvis man har en Biofire kan man sagtens anskaffe sig Gastro-panelet

I forhold til vores rutine-diagnostik

- de in-house PCR-analyser vi har er i god overensstemmelse med STAT/Biofire
- det at bruge et gastropanel øger antallet af detekterede patogener
 - det skyldes langt hen ad vejen at vi ikke har benyttet pakke-diagnostik
 - men også at vi anvender en mindre sensitiv metode til diagnostik af diarrefremkaldende *E. coli*



Multicenter evaluation of the new QIAstat Gastrointestinal Panel for the rapid syndromic testing of acute gastroenteritis

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Tak for opmærksomheden!