

The Efficacy/Compatibility Of Liquid Transport Devices On The Filmarray® Platform

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Introduction

Many swab transport systems have been developed to stabilise clinical bacterial and viral material prior to downstream microbiological testing. Increasingly downstream testing is represented by a rapid syndromic multiplex molecular assay. The advent of liquid collection devices raises the question of compatibility with these molecular platforms. One such platform is the FilmArray® from Biomerieux. It is an FDA, CE-IVD, and TGA certified multiplex PCR system that integrates sample preparation, amplification, detection and analysis. The FILMARRAY® system enables simultaneous testing for bacteria, viruses, yeast, parasites and/or antimicrobial resistant genes. It is designed to be used with comprehensive panels that each offer testing for sets of pathogens. The validation of a wide spectrum of liquid swabs is clinically beneficial as during the medical examination process multiple swabs are frequently collected simultaneously and mix-ups are not uncommon. The general prescriptive approach of devices being validated for one collection device is also counter-intuitive. The broader the validation spectrum of collection devices, the simpler the process becomes for taking the specimen and builds in contingency if there are supplier issues with the collection devices.

The collection of Medical Wire and Equipment (MWE) liquid collection devices (Fig.2) are a convenient system for collecting samples and transporting specimens in small instrument-ready tubes, making it easier to transport the specimen to the laboratory.

This investigation looks at the potential use of various liquid transport systems for the detection of bacterial and viral pathogens and the effect of bacterial contamination on the detection of viral DNA/RNA utilising the Biomerieux FilmArray® platform (Fig.1). Of particular importance was the validation of the MWE faecal collection device as gastroenteritis is one of the leading causes of morbidity and mortality in young children where it is not always possible to get a bulk sample within a reasonable time-frame, particularly for outpatients and/or in resource limited settings. This inability to obtain a stool specimen at the time of the patient visit can delay the diagnostic process and contribute to inappropriate treatment (Schlenker and Surawicz, 2009).

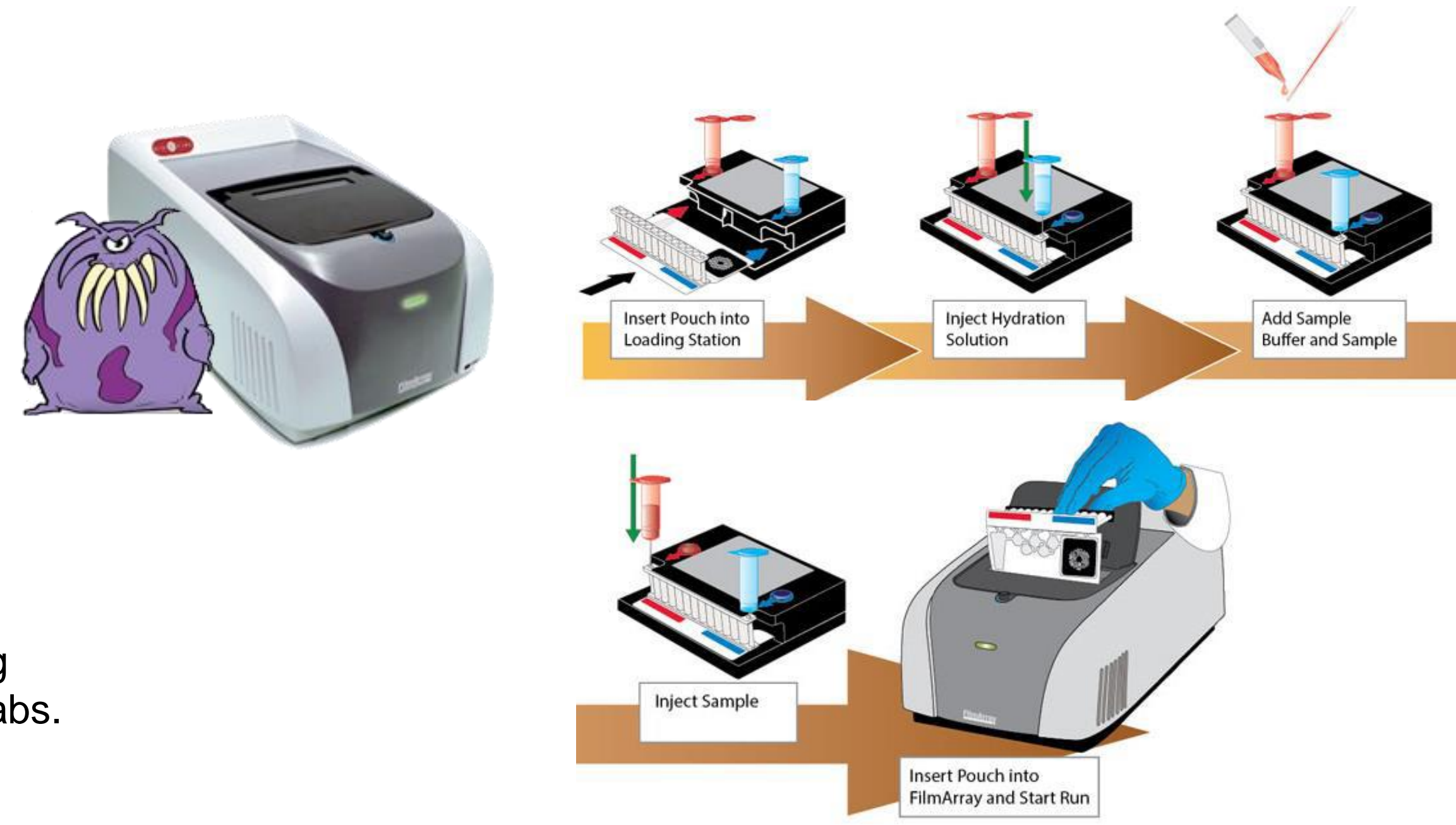
Methods

FilmArray® platform manufactured by BioFire Diagnostics and distributed by Biomerieux.

- FilmArray® Blood Culture Identification panel
- FilmArray® GI panel
- FilmArray® Respiratory panel

- Controls obtained from HHC were:
- NATrol GI Panel (BioFire) (product code NATGIP-BIO)
- NATrol RP Multimarker Control Pack (product code MDZ001)
- Streptococcus agalactiae ATCC® 12386™ (Culti-Loops™ from Thermo-Scientific)

The controls are purified intact organisms chemically modified to be non-infectious and mimicking clinical samples. Controls were vortexed for 10 seconds and utilised to seed a range of liquid swabs.



The targets of each panel are displayed below:

Blood culture identification panel targets
Listeria monocytogenes
Staphylococcus
Staphylococcus aureus
Streptococcus
Streptococcus agalactiae (Group B)
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Acinetobacter baumannii
Enterobacteriaceae
Enterobacter cloacae complex
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus
Serratia marcescens
Haemophilus influenzae
Neisseria meningitidis
Pseudomonas aeruginosa
Yeast
Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis

Gastrointestinal panel targets
Campylobacter
Clostridium difficile toxin A/B
Plesiomonas shigelloides
Salmonella
Vibrio
Vibrio cholerae
Yersinia enterocolitica
Enterococci
Enterotoxigenic E. coli (ETEC) It/st
Shiga-like toxin-producing E. coli (STEC) stx1/stx2
E. coli O157
Shigella/Enteroinvasive E. coli (EIEC)
Cryptosporidium
Cyclospora cayentanensis
Entamoeba histolytica
Giardia lamblia
Adenovirus F 40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus

Respiratory targets
Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A H1-2009
Influenza A H3
Influenza B
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Table 1: Repertoire of collection devices run on the FilmArray® panels.

FilmArray® Panels		
Respiratory (each swab type run in duplicate)	Gastrointestinal (GI) (each swab type run in triplicate)	Blood culture Identification (each swab type run in triplicate)
Sigma Virocult®	Faecal Transwab® (MW168S)	Sigma GBS™
Sigma Virocult® PF	Faecal Transwab®	Sigma GBS™
Sigma VCM™		
Sigma VCM™ PF		
Sigma Transwabs®		
Sigma Transwab® PF		



Liquid swabs were processed on the FilmArray® utilising 200ul of the seeded transport media. The process amounts to approximately 2 minutes hands on-time.

Filmarray panel	Swab product number	Swab description	Run	Results	Comment
Blood culture identification panel	MWGBS	Sigma GBS swab	1	1 Streptococcus agalactiae (Group B) detected	
Blood culture identification panel	MWGBS	Sigma GBS swab	2	2 Streptococcus agalactiae (Group B) detected	Holding period of 24 hrs
Blood culture identification panel	MWGBS	Sigma GBS swab	3	3	
Blood culture identification panel	MWGBSPF	Sigma GBS swab flocced	1	1 Streptococcus agalactiae (Group B) detected	
Blood culture identification panel	MWGBSPF	Sigma GBS swab flocced	2	2 Streptococcus agalactiae (Group B) detected	Holding period of 24 hrs
Blood culture identification panel	MWGBSPF	Sigma GBS swab flocced	3	3	

Filmarray panel	Swab product number	Swab description	Run	Results	Comment
Gastrointestinal panel	MW168S	Faecal transwab	1	1 Pass	run one negative control.
Gastrointestinal panel	MW168S	Faecal transwab	2	2 All targets detected except sapovirus	
Gastrointestinal panel	MW168S	Faecal transwab	3	3 All targets detected except sapovirus	Holding period of 24 hrs
Gastrointestinal panel	MW168PF	Faecal transwab flocced	1	1 All targets detected	
Gastrointestinal panel	MW168PF	Faecal transwab flocced	2	2 All targets detected	Holding period of 24 hrs
Gastrointestinal panel	MW168PF	Faecal transwab flocced	3	3 All targets detected	

Filmarray panel	Swab product number	Swab description	Run	Results	Comment
Respiratory panel	MW951S	Sigma Virocult	1	1 All targets detected	
Respiratory panel	MW951S	Sigma Virocult	2	2 All targets detected	Held at RT for 24 hrs
Respiratory panel	MW951PF	Sigma Virocult flocced	1	1 All targets detected	
Respiratory panel	MW951PF	Sigma Virocult flocced	2	2 All targets detected	Held at RT for 24 hrs
Respiratory panel	MW910S	Sigma VCM	1	1 All targets detected	
Respiratory panel	MW910S	Sigma VCM	2	2 All targets detected	Held at RT for 24 hrs
Respiratory panel	MW910PF	Sigma VCM flocced	1	1 All targets detected	
Respiratory panel	MW910PF	Sigma VCM flocced	2	2 All targets detected	Held at RT for 24 hrs
Respiratory panel	MW176S	Sigma Transwab	1	1 All targets detected	
Respiratory panel	MW176S	Sigma Transwab	2	2 All targets detected	Held at RT for 24 hrs
Respiratory panel	MW176PF	Sigma Transwab flocced	1	1 All targets detected	
Respiratory panel	MW176PF	Sigma Transwab flocced	2	2 All targets detected	Held at RT for 24 hrs

Conclusion

All MWE liquid swabs demonstrated compatibility with the FilmArray® system. This is of particular clinical use for the diagnosis of gastrointestinal disease as a simple rectal swab enables the rapid collection of a sample coupled with diagnostic power of the FilmArray®. The faecal swab system optimises the collection and transport of GI pathogens with the rapid diagnosis of gastrointestinal diseases. The liquid collection swab system from MWE, particularly Faecal Transwab®, is a great example of where two solutions meet in the middle, picking up where the other left off, to get to the right result fast. It provides a more convenient and compact workflow solution. Additional research on improved sensitivity and specificity of rectal swab sampling utilising the MWE faecal device would be of interest. Previous studies have shown to offer superior test accuracy for bacterial pathogens as compared to bulk stool testing on other multiplex PCR assays (Goldfarb *et al.*, 2014)

There was no indication of inhibitory substances being present in the swab types tested. Timely sampling is critical to take advantage of rapid diagnostic testing of the FilmArray®; especially should targeted antimicrobial therapy be indicated (if available). This study has shown that a wide range of liquid collection devices can be used for the FilmArray® giving more flexibility within the patient to diagnostic pathway.

References:

1. Biomerieux. FilmArrayInfo Sheet GI Panel. Nov 2014
2. Dunbar SA. (2013) Molecular revolution entering GI diagnostic testing. MLO Med Lab Obs 45:28
3. Goldfarb DM, et al. (2014) Evaluation of anatomically-designed flocced rectal swabs for the molecular detection of enteric pathogens in children admitted to hospital with severe gastroenteritis in Botswana. Journal of Clinical Microbiology; 52 (11):3922-7
4. Schlenker C, Surawicz CM (2009). Emerging infections of the gastrointestinal tract. Best Pract Res Clin Gastroenterol 23:89-99.

