Analytical Performance of the FilmArray® Global Fever Panel

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ABSTRACT

Acute Febrile Illness (AFI) can be caused by a large number of pathogens that include bacteria, viruses and parasites. BioFire Defense is developing the Global Fever (GF) Panel to be used on the FilmArray System in collaboration with the Department of Defense[a] and NIAID[b]. The FilmArray is an in vitro diagnostic test platform that combines nucleic acid purification and nested multiplex PCR for the simultaneous identification of many infectious agents in under an hour using a closed, sample-to-answer system. The FilmArray GF Panel detects and identifies nucleic acid from Chikungunya virus, CCHF virus, dengue virus (serotypes 1-4), Ebolavirus, Lassa virus, Marburgvirus, West Nile virus, Yellow fever virus, Zika virus, *Bacillus anthracis*, *Francisella tularensis*, *Leptospira* spp., *Salmonella enterica* serovar Typhi and Paratyphi A, *Yersinia pestis*, *Leishmania donovani* complex, and *Plasmodium* spp. in venous blood specimens from individuals with signs and/or symptoms of AFI or recent AFI and with known or suspected exposure to target pathogens. Estimated LoD studies demonstrate clinically relevant detection levels and exclusivity testing shows high specificity. For example, estimated LoD levels for the following organisms: dengue virus New Guinea C at 360 copies/mL, Marburgvirus Musoke at 50 copies/mL, Zika virus at 130 copies/mL, *Leishmania donovani* at 10 copies/mL, *Plasmodium* at 10 copies/mL, *Bacillus anthracis* at 64 copies/mL, and *Yersinia pestis* at 15 copies/mL.[c] Preliminary off-panel exclusivity studies assessing specificity with closely related organisms or organisms that may be found in whole blood show no significant cross-reactivity. A multiplex FilmArray panel could aid in rapid and actionable AFI diagnosis.

a. MCS-JPEO and USAMMDA Contract No. W911QY-13-D-0080, under the NGDS program.

b. NIAID Contract No. HHSN272201600002C, "Advanced Development of Multiplex Diagnostic Platforms for Infectious Diseases (Global Fever Panel)".

c. Estimated LoD levels updated to reflect the most recent data.

INTRODUCTION

The FilmArray Global Fever (GF) Panel is currently under development as a qualitative, multiplexed, nucleic acid-based test intended for use with the FilmArray 2.0 system. The FilmArray GF Panel detects and identifies bacterial, viral, and protozoan nucleic acids directly from human whole blood (EDTA) collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and with known or suspected exposure to target pathogens. The following organisms are identified using the FilmArray GF Panel: *Bacillus anthracis*, *Francisella tularensis*, *Leptospira* spp., *Salmonella enterica* serovar Paratyphi, *Salmonella enterica* serovar Typhi, *Yersinia pestis*, Chikungunya virus, Crimean-Congo hemorrhagic fever virus, Dengue virus, Ebola virus, Lassa virus, Marburg virus, West Nile virus, Yellow fever virus, Zika virus, *Leishmania* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum*, *Plasmodium vivax*, and *Plasmodium ovale*).

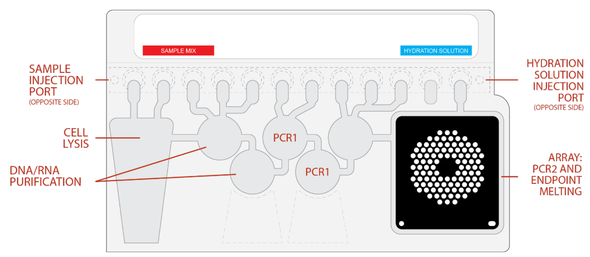

Figure 1. FilmArray Global Fever Pouch

The FilmArray GF pouch is a closed system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple pathogens within a single clinical whole blood specimen. After sample collection, the user injects hydration solution on one side of the pouch and sample combined with sample buffer into the other side of the pouch, places the pouch into a FilmArray instrument, and starts a run. Loading the pouch takes about 2 minutes, and the entire run process takes about an hour.

During a run, the FilmArray system:

- Lyses the sample by agitation (bead beating).
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
  - First performing a single, large volume, highly multiplexed first-stage PCR reaction (PCR1).
  - Then performing multiple, singleplex second-stage PCR reactions (PCR2) to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect and generate a result for each target on the FilmArray GF array.

ESTIMATED LIMIT OF DETECTION

The purpose of this study is to determine the estimated Limit of Detection (LoD) for the FilmArray GF Panel using a collection of representative organisms covering each test result. LoD_{95} is defined as the lowest concentration of organism that can be consistently detected by the panel; analyte is detected in at least 19/20 samples (≥ 95% detected). An initial Estimated LoD (Table 1) is established using serial 10-fold dilutions. The estimated LoD is the lowest concentration at which 3/3 replicates returned a detected result. Samples are prepared in whole blood obtained from a repository, Bioreclamation IVT.

The estimated LoD is determined for the FilmArray GF Panel test results using 'primary' analytes.

TABLE 1. ESTIMATED LIMIT OF DETECTION VALUES

Organism		Strain / Source ID	Estimated LoD (Copies/mL)
BACTERIA			
Bacillus anthracis		Ames 35	6.4E+01
Francisella tularensis		Schu4	1.2E+02
Leptospira spp.		*interrogans icterohaemorrhagiae*	3.9E+02
Salmonella enterica		Typhi	1.2E+01
		Paratyphi	1.2E+01
Yersinia pestis		A1122	1.5E+01
VIRUSES			
Chikungunya virus		R80422	5.5E+01
CCHF Virus		IbAr10200	6.4E-01
Dengue virus	DENV-1	Hawaii	2.7E+02
	DENV-2	New Guinea C	3.6E+01
	DENV-3	H87	1.6E+01
	DENV-4	H241	7.6E+01
Ebolavirus	Bundibugyo	BEI NR-31813	1.4E+03
	Tai Forest	BEI NR-44241	8.3E+01
	Reston	BEI NR-44238	2.8E+03
	Sudan	BEI NR-31810	1.1E+04
	Zaire-Gueckedou	BEI NR-49462	1.1E+02
Lassa Virus		Josiah BEI NR-31822	5.6E+03
Marburgvirus	Musoke	BEI NR-48951	5.0E+01
	Ravn	BEI NR-31819	2.6E+02
West Nile Virus		NY 2001-6263	3.2E+02
		B-956 Uganda	3.2E+03
Yellow Fever virus		17D	1.2E+02
Zika virus		PRVABC59	1.3E+01
PROTOZOA			
Leishmania donovani		*donovani* BEI NR-48822	1.0E+01
Plasmodium spp.[1]	*falciparum*	MRA-1238	1.0E+01
	vivax	MRA-383	7.7E+01
	ovale (clinical sample)	N8K9QK19	2.4E+01
Plasmodium[1]	*falciparum*	MRA-1238	1.0E+02
	vivax	MRA-383	7.7E+01
	ovale (clinical sample)	N8K9QK19	2.4E+02

[1] *Plasmodium* spp. refers to the pan assay whereas *Plasmodium* refers to the specific organism assays.

INCLUSIVITY

To ensure the FilmArray GF Panel is inclusive for the genetic variation expected for each analyte, the analytical reactivity of the assays was evaluated by testing multiple isolates per analyte. Isolates are selected based on the availability of live and inactivated stocks, genetic, temporal and geographic diversity, and clinical relevance of the various species, strains, subspecies, serotypes, genotypes and genetic variants available for testing. In addition, *in silico* data (sequence searches and alignments to assay primers) are also used to support the inclusivity of the FilmArray GF Panel assays. Here we present a subset of inclusive organisms tested.

Samples are prepared by spiking analytes into whole blood from healthy donors (obtained from Bioreclamation IVT repository) at a concentration near 3× estimated LoD. Figure 2 depicts the protocol followed to establish inclusivity of the isolates tested. An initial subset of analytes tested on the GF Panel are shown in Table 4.

Figure 2. Inclusivity testing workflow for contrived specimens

TABLE 4. INCLUSIVITY

FilmArray Global Fever Panel Analyte	# Isolates Detected/Tested	Tested Isolate	Concentration Detected (copies/mL)	Fold Est. LoD	Test Results (Detected/ Tested)
BACTERIA					
Bacillus anthracis	4/4	Ames	6.4E+01	1	3/3
		Ames35 (genomic)	9.0E+01	3	3/3
		Sterne (-pXO2)		3	3/3
		UM23-1 (genomic)		3	3/3
Francisella tularensis	1/1	Schu4	1.2E+02	1	3/3
Leptospira spp.	8/8	interrogans (icterohaemorrhagiae)	3.9E+02	1	3/3
		kirschneri (bogvere)	1.2E+03	3	3/3
		noguchi (LPT1E)			
		borgpetersenii (LPT1D)			
		kmetyi Bejo-Iso9T			
		weilii 6712			
		weilii A102			
		weilii Topaz			
Salmonella enterica serovar Paratyphi A	2/2	serovar Paratyphi-A	1.2E+01	1	3/3
		Paratyphi A (ATCC-12176)	3.6E+01	3	3/3
Salmonella enterica serovar Typhi	4/4	Subsp. Enterica Ty2	1.2E+01	1	3/3
		ATCC 19430	3.6E+01	3	5/5
		ATCC 19937			3/3
		ATCC 33458			3/3
Yersinia pestis	1/1	A1122	1.5E+01	1	3/3
VIRUSES					
Chikungunya virus	1/1	R80422	5.5E+02	1	3/3
CCHF	1/1	IbAr10200	6.4E+00	1	3/3
Dengue virus	6/6	Hawaii (DENV-1)	2.7E+01	1	3/3
		VN/BID-V1792/2007	8.1E+01	3	3/3
		276RK1	2.7E+03	100	3/3
		strain 12150			3/3
		strain BC89/94			3/3
		228690			3/3
	5/5	New guinea C (DENV-2)	3.6E+01	1	3/3
		VN/BID-V1002/2006 (2-1)	1.1E+02	3	3/3
		DakArA1247 (2-1)		3	3/3
		BC102/94 (2-1)		3	3/3
		strain 429557 (2-2)		3	3/3
	3/3	H87 (DENV-3)	1.6E+03	1	3/3
		VN/BID-V1329/2006	4.8E+03	3	3/3
		strain C0360/94			3/3
	5/5	H241 (DENV-4)	7.6E-01	1	3/3
		BC258/97	2.3E+00	3	4/5
		strain 703	7.6E+00	10	3/3
		BC13/97	7.6E+01	100	3/3
		BC287/97			3/3
Ebolavirus	1/1 each species	Bundibugyo	1.4E+04	1	3/3
		Tai Forest	8.3E+01	1	3/3
		Reston	2.8E+03	1	3/3
		Sudan	1.1E+04	1	3/3
	2/2	Zaire, Mayinga	1.1E+03	1	3/3
		Zaire, Makona-Guéckédou	3.3E+03	3	3/3
Lassa virus	1/1	Josiah	5.6E+03	1	3/3
Marburgvirus	3/3	RAVN	2.6E+01	1	3/3
		Ci67	5.0E+01	1	3/3
		Musoke	1.5E+02	3	3/3
West Nile virus	1/1	B-956 Uganda (WNV2)	3.2E+03	1	3/3
	2/2	NY2001 (WNV 1)	9.6E+02	0.1	3/3
		1986 (WNV1)			3/3
Yellow fever virus	1/1	strain 17D	1.2E+02	1	3/3
Zika virus	7/7	PRVABC59	1.3E+01	1	3/3
		Ibh 30656	3.9E+01	3	3/3
		MR 766			
		H/PAN/2016/BEI-259634			
		FLR			
		PLCal			
		R103451			
PROTOZOA					
Leishmania spp.	4/4	*donovani*	1.1E+01	1	3/3
		donovani, 1S	3.3E+01	3	3/3
		braziliensis Vianna	1:2.6*10[10]	N/A	3/3
		infantum Nicolle	1.1E+02	10	3/3
Plasmodium spp.	18/18	*falciparum*, Pursat	1.0E+01 (spp.) 1.0E+02 (falc.)	1×	3/3[d]
		vivax, 11 Strain Chesson	7.7E+01	1×	3/3[c]
		ovale, (CDC N8K9QKI9)	2.4E+01 (spp.) 2.4E+02 (ovale)	1×	3/3[c]
		brasilianum	3.0E+01	3×	3/3[b]
		cynomolgi			3/3[b]
		fieldi			2/3[c]
		Inui			3/3[b]
		berghei	0.00001×[e]	3×	3/3[b]
		fragile			3/3[c]
		knowlesi			3/3[b]
		malariae			2/3[b]
		simiovale			3/3[c]
		vivax Panama			3/3[c]
		falciparum SenTh021.09	3.0E+01	3×	3/3[d]
		falciparum St. Lucia	3.0E+02	30×	3/3[d]
		falciparum Tanzania	3.0E+02	30×	3/3[d]
		ovale, (CDC N8K94F8H)	2.4E+02	10×	3/3[c]
		ovale, (CDC N8K9QL0S	2.4E+01	1×	3/3[c]

[a] Dilution factor used for stock with unknown concentration
[b] *Plasmodium* spp. Detected
[c] *Plasmodium* spp. and *Plasmodium vivax/ovale* Detected
[d] *Plasmodium* spp. and *Plasmodium falciparum* Detected

EXCLUSIVITY

To determine whether the FilmArray GF Panel assays cross-react with sequences from various microorganisms/viruses that may be present in clinical specimens, the analytical specificity of the panel was assessed by *in silico* analysis and by testing a broad spectrum of organisms/viruses at high concentrations. Typical stock concentrations for on-panel analytes tested are: 10^7-10^{10} copies/mL for bacteria, 10^7-10^9 copies/mL for virus, and 10^6-10^8 copies/mL for protists. Both on-panel and off-panel organisms were evaluated to test inter-assay specificity and overall assay/panel specificity, respectively. Here we report a subset of off-panel testing.

- On-panel testing consists of contrived samples spiked into sterile saline with the highest concentration of on-panel analytes that is possible based on the concentration of the organism stock (up to 10% of the total sample volume). On-panel isolates are the same as those evaluated for the Estimated LoD study.
- Off-panel organisms are selected based on 1) phylogenetic and/or genetic similarity to the panel analytes and assays, and 2) the possibility that the organism(s) could be present as normal flora, contaminants associated with sample collection, or pathogens in whole blood.

TABLE 2: ON-PANEL EXCLUSIVITY

Organism		Species/Serotype/ Strain	Concentration Tested (Copies/mL)	Panel Assay (D=Detected, ND=Not Detected)																			
				Bacillus anthracis	F. tul	Lepto	Paratyphi	Typhi	Y.Pestis	CCHF	ChikV	Dengue	Ebola virus	Lassa Virus	Marburg Virus	West Nile	Yellow Fever	Zika virus	Leish	Plas. Sp	Plas falciparum	plas vivax/ ovale
BACTERIA																							
Bacillus anthracis		Ames vegetative	4.90E+07	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Francisella tularensis		Schu S4	8.70E+06	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Leptospira		*interrogans*	1.10E+06	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Salmonella enterica subsp. enterica		*Paratyphi A*	1.40E+08	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Typhi - Ty2	1.20E+08	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Yersinia pestis		A1122	1.40E+08	ND	D[1]	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
VIRUSES																							
Crimean-Congo hemorrhagic fever virus		IbAr10200	4.20E+07	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Chikungunya virus		Culture fluidR80422	1.10E+08	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Dengue virus	DENV-1	Hawaii	4.40E+07	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	DENV-2	New Guinea C	5.90E+07	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	DENV-3	H87	5.00E+07	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	DENV-4	H241	1.30E+07	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Ebola virus		Zaire Makona-Guéckédou	2.60E+06	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Sudan Boniface	1.40E+08	ND	D[1]	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Bundibugyo	2.80E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Tai Forest	3.80E+08	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Reston (H-28)	6.00E+08	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Lassa fever virus		Josiah	5.60E+08	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND	ND
Marburg virus		Musoke	2.90E+08	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND
		Ravn	4.70E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND	ND
West Nile virus		B-956 Uganda	3.20E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND
		NY 2001-6263	6.80E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND
Yellow fever virus		17D Flavivirus	1.70E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND
Zika virus		PRVABC59	4.40E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND
		MR766	2.80E+08	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND
PROTOZOA																							
Leishmania spp.		donovani	1.00E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND
Plasmodium	*P. falciparum*	Pursat Cambodia 2011, IPC 4884	1.00E+07	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	D	ND	ND
	P. vivax	11 (Strain Chesson)	7.70E+05	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	D	ND
	P. ovale	Clinical Sample N8K9QK19	2.40E+06	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	D	ND

[1] Detected due to suspected contamination of organism stocks.

TABLE 3: SUBSET OF OFF-PANEL EXCLUSIVITY ORGANISMS

Organism		Species/Serotype/ Strain	Concentration Tested	Bacillus anthracis	CCHF	ChikV	Dengue	Ebola virus	F. tul	Leish	Lepto	LV	Marburg Virus	Plas. Sp	Plas. Falciprum	plas vivax/ovale	Paratyphi	Typhi	West Nile	Y. Pestis	Yellow Fever	Zika
BACTERIA																						
Borrelia burgdorferi		B31 Clone 5A1	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Babesia microti		strain GI	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		Nan-Hs-2011	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Clostridium botulism		VPI4404	1.5 µg/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Leptospira	*meyeri* (group III)	serovar Hardjo strain went 5	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	kmetyi (group III)	strain Bejo-Iso9T	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	biflexa (group III)	Patoc 1	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	Wolbachii (III)	Serovar Codice starin CDC	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	alstonii (group I)	Sichuan 79601	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	licerasiae (group II)	VAR 010	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Salmonella enterica subsp. *enterica*	Serovar Typhimurium	Outbreak 2004	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		LT2	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		isolate 4	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	Serovar Newport	S11975	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		SL317	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
		SL254	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
VIRUSES																						
Guanarito virus		INH-95551 (Venezuaela prototype)	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Hendra virus		strain 9409-30-1800 (Australia prototype)	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Hepatitis A virus		HM 175/18f	2.8E+06 TCID50/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Influenza A virus		A/WS/33 (H1N1)	7.4E+05 TCID50/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Machupo virus		strain Carvallo	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Measles virus		Edmonston Kamtek	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Rift Valley fever virus		strain ZH501	4.5E+05 Copies/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
PROTOZOA																						
Plasmodium	*inui*	Taiwan I	4.6E+05 Copies/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND
	berghei	Nk 65	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	ND	ND	ND	ND	ND	ND
	simiovale	30140	1:10 Dilution	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	D	ND	D	ND	ND	ND	ND	ND
Trypanosoma	*brucei*	gambiense STIB 386	8.7E+05 Cells/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	cruzi	TcVT-1 axenic epimastigote	1.0E+07 Cells/mL	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

SUMMARY

The development of a multiplex FilmArray panel would aid in rapid and actionable AFI diagnosis. The FilmArray GF Panel provides a broad spectrum analysis of target pathogens in a sensitive and specific manner.

- Estimated LoD values show sensitivity levels at or below clinically relevant concentrations.
- On- and off-panel exclusivity show no evidence of cross-reactivity.
- Preliminary inclusivity maintains expected coverage of relevant target pathogens.
- Full analytical and clinical studies for the FilmArray GF Panel are underway.

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Data presented are from assays that are Investigational Use Only (IUO) and have not been cleared or approved for diagnostic use.

Presented at the American Society of Tropical Medicine and Hygiene
(ASTMH) Annual Meeting, October 28 - November 1, 2018
Poster LB-5119