# Analytical Performance of the FilmArray® Global Fever Panel

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## ABSTRACT

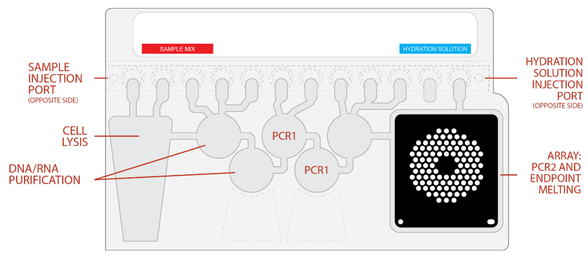
Acute Febrile Illness (AFI) can be caused by a large number of pathogens that include bacteria, viruses and parasites. BioFire Defense is developing the Global Fever (GF) Panel to be used on the FilmArray System in collaboration with the Department of Defense[a] and NIAID[b]. The FilmArray is an in vitro 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), Ebola virus, Lassa virus, Marburg virus, 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 36 copies/mL, Marburg virus Ravn at 26 copies/mL, Zika virus at 130 copies/mL, *Leishmania donovani* at 10 copies/mL, *Plasmodium* at 7 copies/mL, *Bacillus anthracis* at 640 copies/mL, and *Yersinia pestis* at 150 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. JPEO-MCS 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 Global Fever 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 detected 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* from *Plasmodium vivax* and *Plasmodium ovale*).

## Figure 1. FilmArray Global Fever Pouch




The FilmArray Global Fever 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 into 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 beading).
- 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 Global Fever array.

## ESTIMATED LIMIT OF DETECTION

The purpose of this study is to determine the estimated Limit of Detection (LoD) for the FilmArray Global Fever 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 Global Fever 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 vegetative | 6.3E+02 |
| ***Francisella tularensis*** | | BEI NR-15753 | 1.2E+04 |
| ***Leptospira* spp.** | | *Interrogans icterohaemorrhagiae* | 3.9E+02 |
| | | *broomii* | 1:10[6] dil |
| | | *wolffii* | 1:10[6] dil |
| ***Salmonella enterica*** | | Typhi | 1.2E+01 |
| | | Paratyphi | 1.2E+01 |
| ***Yersinia* pestis** | | CO92 / AGD0001227 | 1.5E+02 |
| **VIRUSES** | | | |
| **Chikungunya virus** | | R80422 | 5.5E+02 |
| **CCHF Virus** | | IbAr10200 | 6.4E+00 |
| **Dengue virus** | DENV-1 | Hawaii | 2.7E+01 |
| | DENV-2 | New Guinea C | 3.6E+01 |
| | DENV-3 | H87 | 1.6E+03 |
| | DENV-4 | H241 | 7.6E-01 |
| **Ebolavirus** | Bundibugyo | BEI NR-31813 | 1.4E+04 |
| | Ivory Coast | R4371s | 8.3E+01 |
| | Reston | BEI NR-44238 | 2.8E+03 |
| | Sudan | BEI NR-31810 | 1.1E+04 |
| | Mayinga | R3828S / AGD000125 | 1.1E+03 |
| **Lassa Virus** | | NR-31822 / 60428471 | 5.6E+03 |
| **Marburgvirus** | Ci 67 | BEI NR-31816 | 5.0E+01 |
| | Ravn | BEI NR-31819 | 2.6E+01 |
| **West Nile Virus** | | B-956 Uganda | 3.2E+03 |
| **Yellow Fever virus** | | 17D | 1.2E+02 |
| **Zika virus** | | PRVABC59 | 1.3E+02 |
| **PROTOZOA** | | | |
| ***Leishmania donovani*** | | NR-48822 / 62990853 | 1.0E+01 |
| ***Plasmodium* spp. Assay** | *falciparum* | MRA-1238 | 1.0E+02 |
| | *vivax/ovale* | MRA-383 | 7.7E+01 |
| ***Plasmodium*** | *Falciparum* Assay | MRA-1238 | 1.0E+03 |
| | *vivax/ovale* Assay | MRA-383 | 7.7E+01 |

## INCLUSIVITY

To ensure the Global Fever 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 Global Fever 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.


### 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+02 | 1 | 3/3 |
| | | Ames35 (genomic) | 1.9E+03 | 3 | 3/3 |
| | | Sterne (-pXO2) | | 3 | 3/3 |
| | | UM23-1 (genomic) | | 3 | 3/3 |
| *Francisella tularensis* | 1/1 | Schu S4 Ag | 1.2E+04 | 1 | 3/3 |
| *Leptospira* spp. | 6/8 | interrogans (icterohaemorrhagiae) | 3.9E+02 | 1 | 3/3 |
| | | kirschneri (bogvere) | 1.2E+03 | 3 | 3/3 |
| | | noguchi (LPT1E) | 1.2E+03 | 3 | 3/3 |
| | | borgpetersenii (LPT1D) | 3.9E+04 | 100 | 3/3 |
| | | broomii | 1:10[7] | N/A | 3/3 |
| | | wolffii | 1:10[8] | N/A | 3/3 |
| | | kmetyi Bejo-Iso9T | 3.9E+04 | 100 | 0/5 |
| | | weilii serotype celledoni I | | | 2/5 |
| *Salmonella enterica* serovar Paratyphi A | 2/4 | serovar Paratyphi-A | 1.2E+01 | 1 | 3/3 |
| | | Paratyphi A | 1.2E+03 | 3 | 3/3 |
| | | Paratyphi B* | | 100 | 0/5 |
| | | Paratyphi C* | | | |
| *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 | CO92 | 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+02 | 1 | 3/3 |
| | | VN/BID-V1002/2006 (2-1) | 1.1E+03 | 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 |
| Ebola virus | 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 |
| | | Zaire, Mayinga | 1.1E+03 | 1 | 3/3 |
| | | Zaire, Makona (Gueckedo) | 3.3E+03 | 3 | 3/3 |
| Lassa virus | 1/1 | Josiah | 5.6E+03 | 1 | 3/3 |
| Marburg virus | 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 | 5/5 | PRVABC59 | 3.9E+02 | 3 | 3/3 |
| | | Ibh 30656 | | | |
| | | MR 766 | | | |
| | | H/PAN/2016/BEI-259634 | | | |
| | | FLR | | | |
| **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[5] | N/A | 3/3 |
| | | *infantum* Nicolle | 1.1E+02 | 10 | 3/3 |
| *Plasmodium* | 9/9 | *falciparum*, Pursat | 1.0E+02 (spp.) 1.0E+03 (*falc.*) | 1 | 3/3 |
| | | *vivax*, 11 Strain Chesson | 7.7E+01 | 1 | 3/3 |
| | | *brasilianum* | 2.7E+02 | 3 | 3/3 |
| | | *cynomolgi* | 2.7E+02 | 3 | 3/3 |
| | | *fieldi* | 2.7E+02 | 3 | 3/3 |
| | | *inui* | 2.7E+02 | 3 | 3/3 |
| | | *falciparum* Tanzania | 3.0E+03 | 3 | 3/3 |
| | | *falciparum* SenTh021.09 | 3.0E+03 | 3 | 3/3 |
| | | *falciparum* St. Lucia | 3.0E+03 | 3 | 3/3 |

* Paratyphi B and C will be incorporated in upcoming exclusivity studies as they were not detected in inclusivity.

## EXCLUSIVITY

To determine whether the FilmArray Global Fever 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 20% 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* spp | *Plas falciprum* | *Plas vivax/ovale* |
| **BACTERIA** | | | | | | | | | | | | | | | | | | | | | | | |
| *Bacillus anthracis* | | Ames vegetative | 4.9E+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 | 8.7E+06 | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| *Leptospira* | | *interrogans* | 1.1E+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* | 1.4E+08 | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Typhi - Ty2 | 1.2E+09 | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| *Yersinia pestis* | | CO92 | 1.5E+09 | ND | ND | 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 | 4.2E+07 | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| Chikungunya virus | | Culture fluid R80422 | 1.1E+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 | 5.3E+06 | 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 | 3.6E+07 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | DENV-3 | H87 | 3.2E+07 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | DENV-4 | H241 | 3.8E+06 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| Ebola virus | | Zaire -76, Mayinga | 1.9E+07 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Sudan Boniface | 1.4E+08 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Bundibugyo | 2.8E+07 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Tai Forest | 3.8E+08 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Reston (H-28) | 6.0E+08 | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| Lassa fever virus | | Josiah | 5.6E+08 | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| Marburg virus | | Ci67 (Voege) | 1.2E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | | Ravn | 4.7E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| West Nile virus | | B-956 Uganda | 3.2E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND |
| Yellow fever virus | | 17D Flavivirus | 1.7E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND |
| Zika virus | | PRVABC59 | 4.4E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND |
| **PROTOZOA** | | | | | | | | | | | | | | | | | | | | | | | |
| *Leishmania* spp. | | donovani | 1.0E+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 | 1.0E+07 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | D | ND | |
| | *P. vivax* | 11 (Strain Chesson) | 7.7E+05 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | D | |
| | *P. ovale* | N/A* | | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

* Samples of *P. ovale* are currently unavailable. Efforts are in progress to acquire clinical samples of *P. ovale*.

### 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* spp | *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 |
| *Clostridium botulinum* | | 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 | 2.2E+07 Cells/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** | | | | | | | | | | | | | | | | | | | | | | |
| *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 |
| *Plasmodium* | *inui* | Tawain I | 4.6E+05 Copies/mL | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND |
| | *berghei* | Nk 65 | 1:10 Dilution | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | ND | ND | ND | ND | ND | ND | ND |
| | *simiovale* | 30140 | 1:10 Dilution | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | D | ND | D | ND | ND | ND | ND | ND | ND |
| *Trypanosoma* | *brucei* | gambiense STIB 386 | 8.7E+05 Parasites/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 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.
- Preparing for full analytical and clinical studies for the FilmArray GF Panel.

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