DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 30, 2017

BioFire Diagnostics, LLC
Kristen J. Kanack, Ph.D.
Vice President, Regulatory and Clinical Affairs
515 Colorow Drive
Salt Lake City, UT 84108

Re: K170604
Trade/Device Name: FilmArray® Respiratory Panel 2 (RP2)
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: II
Product Code: OCC, OEM, OEP, OOU, OTG, OZE, OZX, OZY, OZZ, OOI, NSU
Dated: February 28, 2017
Received: March 1, 2017

Dear Dr. Kanack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Steven R. Gitterman -S

for Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170604

Device Name

The FilmArray® Respiratory Panel 2 (RP2)

Indications for Use *(Describe)*

The FilmArray® Respiratory Panel 2 (RP2) is a multiplexed nucleic acid test intended for use with FilmArray® 2.0 or FilmArray® Torch systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray® RP2:

- Adenovirus
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A, including subtypes H1, H1-2009, and H3
- Influenza B
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus

- *Bordetella parapertussis* (IS*1001*)
- *Bordetella pertussis* (*ptxP*)
- *Chlamydia pneumoniae*
- *Mycoplasma pneumoniae*

The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, or lower respiratory tract infection that may not be detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other organisms: the agent(s) detected by the FilmArray® RP2 may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray® RP2 cannot reliably differentiate them. A positive FilmArray® RP2 Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Performance characteristics for Influenza A were established when Influenza A H1-2009 and A H3 were the predominant Influenza A viruses in circulation. Performance of detecting Influenza A may vary if other Influenza A strains are circulating or a novel Influenza A virus emerges. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
BioFire Diagnostics, LLC

FilmArray Respiratory Panel 2 (RP2)

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108

Telephone: 801-736-6354
Facsimile: 801-588-0507

Contact: Kristen J. Kanack, ext. 330

Date Submitted: February 28, 2017

Device Name and Classification:

Trade Name: FilmArray Respiratory Panel 2 (RP2)

Regulation Number: 21 CFR 866.3980

Classification Name: Respiratory viral panel multiplex nucleic acid assay

Predicate Device:

K160068 – FilmArray Respiratory Panel (RP)

Intended Use:

The FilmArray® Respiratory Panel 2 (RP2) is a multiplexed nucleic acid test intended for use with FilmArray® 2.0 or FilmArray® Torch systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray RP2:

- Adenovirus
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43

- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A, including subtypes H1, H1-2009, and H3
- Influenza B
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus
- *Bordetella parapertussis* (IS*1001*)
- *Bordetella pertussis* (*ptxP*)
- *Chlamydia pneumoniae*
- *Mycoplasma pneumoniae*

The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, or lower respiratory tract infection that may not be detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other organisms: the agent(s) detected by the FilmArray RP2 may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP2 cannot reliably differentiate them. A positive FilmArray RP2 Rhinovirus/Enterovirus result should be followed up using an alternate method (e.g., cell culture or sequence analysis) if differentiation is required.

Performance characteristics for Influenza A were established when Influenza A H1-2009, A H1, and A H3 were the predominant Influenza A viruses in circulation. Performance of detecting Influenza A may vary if other Influenza A strains are circulating or a novel Influenza A virus emerges. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Description:

The FilmArray Respiratory Panel 2 (RP2) is designed to simultaneously identify 21 different potential pathogens (see Table 1) of respiratory tract infection from a single NPS specimen in a

time frame (~45 minutes) that allows the test results to be used in determining appropriate patient treatment and management. FilmArray RP2 is compatible with BioFire Diagnostics' (BioFire) PCR-based *in vitro* diagnostic FilmArray 2.0 and FilmArray Torch systems for infectious disease testing. A specific software module (i.e. FilmArray RP2 pouch module) is used to perform FilmArray RP2 testing on these systems.

Table 1. Pathogens Detected by the FilmArray RP2

Viral Targets Detected	Bacterial Targets Detected
Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A, including subtypes H1, H3 and H1-2009 Influenza B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus	*Bordetella parapertussis* (IS*1001*) *Bordetella pertussis* (*ptxP*) *Chlamydia pneumoniae* *Mycoplasma pneumoniae*

A test is initiated by loading Hydration Solution into one port of the FilmArray pouch and an NPS sample (in transport media) mixed with the provided Sample Buffer into the other port of the FilmArray RP2 pouch and placing it in a FilmArray instrument. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the FilmArray Software guides the user though the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray instrument contains a coordinated system of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically-controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical and chemical lysis followed by purification using standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the FilmArray performs a nested multiplex PCR that is executed in two stages. During the first stage, the FilmArray performs a single, large volume, highly multiplexed reverse transcription PCR (rt-PCR) reaction. The products from first

stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green® Plus, BioFire Diagnostics). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism on the panel.

Substantial Equivalence:

The FilmArray Respiratory Panel 2 is substantially equivalent to the FilmArray Respiratory Panel (K160068), which was most recently cleared on February 8, 2016 and determined to be a Class II device.

Table 2 compares the FilmArray Respiratory Panel 2 (RP2) to the FilmArray Respiratory Panel (RP) and outlines the similarities and differences between the two tests.

Table 2. Comparison of the FilmArray Respiratory Panel 2 (RP2) and the FilmArray Respiratory Panel (RP)

Element	New Device: FilmArray Respiratory Panel 2 (RP2)	Predicate: FilmArray Respiratory Panel (RP) (K160068)
Specimen Types	NPS in VTM	Same
Organisms Detected	Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*	Does not detect *Bordetella parapertussis* Reports *Chlamydia pneumoniae* by alternate name: *Chlamydophila pneumoniae*
Analyte	DNA/RNA	Same
Technological Principles	Multiplex nucleic acid	Same
Instrumentation	FilmArray 2.0 or FilmArray Torch	FilmArray, FilmArray 2.0, or FilmArray Torch
Time to result	About 45 minutes	About 1 hour
Reagent Storage	Room temperature	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same

Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Same
User Complexity	Moderate/Low	Same

Summary of Performance Data

Clinical Performance

The clinical performance of the FilmArray RP2 was established during a multi-center study conducted at three geographically distinct U.S. study sites during portions of the 2015-2016 and 2016-2017 respiratory illness seasons. A total of 1635 residual NPS specimens in viral transport media (VTM) were acquired for the prospective clinical study. Between January and March 2016, specimens were prospectively collected from all comers meeting the study eligibility criteria and immediately frozen (N=695 specimens) for later testing as prospective archived/frozen (Category II) specimens. Between September and November 2016, specimens were prospectively collected from all comers meeting the study eligibility criteria and tested fresh (N=940 specimens) as prospective fresh (Category I) specimens. Category II specimens were distributed to study sites beginning in September 2016. Study sites also began testing Category I specimens at this time. At each site, Category II specimens were thawed and tested according to the study procedures as time permitted over the remaining duration of the clinical study. A total of 23 prospective specimens (Category I and II specimens) were excluded from the final performance data analysis due to incompliance with the study protocol. The most common reasons for specimen exclusion were that a valid external control was not completed on the day of testing, that specimens were tested outside the 3-day refrigerated storage window, or that the specimen was found to not meet the inclusion criteria after the specimen had been enrolled. The final data set consisted of 1612 prospective specimens. Table 3 provides a summary of demographic information for the 1612 specimens included in the prospective study.

Table 3. Demographic Summary for Prospective FilmArray RP2 Clinical Evaluation

		Overall	Site 1	Site 2	Site 3
Sex	Male	867 (54%)	331 (57%)	271 (51%)	265 (53%)
	Female	745 (46%)	250 (43%)	256 (49%)	239 (47%)
Age	≤ 5 years	885 (55%)	379 (65%)	170 (32%)	336 (67%)
	6 - 21 years	331 (21%)	132 (23%)	89 (17%)	110 (22%)
	22 - 49 years	128 (8%)	27 (5%)	79 (15%)	22 (4%)
	50+ years	268 (17%)	43 (7%)	189 (36%)	36 (7%)
Status	Outpatient	329 (20%)	77 (13%)	66 (13%)	186 (37%)
	Hospitalized	640 (40%)	229 (39%)	197 (37%)	214 (42%)
	Emergency	643 (40%)	275 (47%)	264 (50%)	104 (21%)
Total		**1612**	**581**	**527**	**504**

The performance of the FilmArray RP2 was evaluated by comparing the FilmArray RP2 test results with those from an FDA-cleared multiplexed respiratory pathogen panel (the main comparator method) as well as with results from two analytically-validated PCR assays followed by bi-directional sequencing for *B. parapertussis* (this analyte is not detected by the FDA-cleared multiplexed respiratory pathogen panel). The *B. parapertussis* comparator assays were designed to amplify a different sequence than that amplified by the FilmArray RP2. Any specimen that had bi-directional sequencing data meeting pre-defined quality acceptance criteria that matched organism-specific sequences deposited in the NCBI GenBank database (www.ncbi.nlm.nih.gov) with acceptable E-values was considered Positive. Any specimen that tested negative by both of the comparator assays was considered Negative.

Positive Percent Agreement (PPA) for each analyte was calculated as 100% x (TP / (TP + FN)). True positive (TP) indicates that both the FilmArray RP2 and the comparator method had a positive result for this specific analyte, and false negative (FN) indicates that the FilmArray RP2 result was negative while the comparator result was positive. Negative Percent Agreement (NPA) was calculated as 100% x (TN / (TN + FP)). True negative (TN) indicates that both the FilmArray RP2 and the comparator method had negative results, and a false positive (FP) indicates that the FilmArray RP2 result was positive but the comparator result was negative. The exact binomial two-sided 95% confidence interval was calculated. Samples for which false positive and/or false negative results (i.e., discrepant results) were obtained when comparing the FilmArray RP2 results to the comparator method results were further investigated. The discrepancy investigation was mainly conducted by performing independent molecular methods with primers that are different from that of the FilmArray RP2 and/or comparator method retesting. The prospective clinical study results are summarized in Table 4.

Table 4. FilmArray RP2 Prospective Clinical Performance Summary

Analyte		Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Viruses							
Adenovirus[a]	Fresh	36/38	94.7	82.7-98.5	850/880	96.6	95.2-97.6
	Frozen	34/36	94.4	81.9-98.5	640/658	97.3	95.7-98.3
	Overall	***70/74***	***94.6***	***86.9-97.9***	***1490/1538***	***96.9***	***95.9-97.6***
CoV-229E[b]	Fresh	5/5	100	56.6-100	909/913	99.6	98.9-99.8
	Frozen	6/7	85.7	48.7-97.4	686/687	99.9	99.2-100
	Overall	***11/12***	***91.7***	***64.6-98.5***	***1595/1600***	***99.7***	***99.3-99.9***
CoV-HKU1[c]	Fresh	1/1	100	-	917/917	100	99.6-100
	Frozen	42/42	100	91.6-100	640/652	98.2	96.8-98.9
	Overall	***43/43***	***100***	***91.8-100***	***1557/1569***	***99.2***	***98.7-99.6***
CoV-NL63[d]	Fresh	0/0	-	-	917/918	99.9	99.4-100
	Frozen	40/40	100	91.2-100	645/654	98.6	97.4-99.3
	Overall	***40/40***	***100***	***91.2-100***	***1562/1572***	***99.4***	***98.8-99.7***
CoV-OC43[e]	Fresh	11/13	84.6	57.8-95.7	904/905	99.9	99.4-100
	Frozen	22/28	78.6	60.5-89.8	662/666	99.4	98.5-99.8
	Overall	***33/41***	***80.5***	***66.0-89.8***	***1566/1571***	***99.7***	***99.3-99.9***
hMPV[f]	Fresh	5/5	100	56.6-100	913/913	100	99.6-100

Analyte		Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
	Frozen	68/70	97.1	90.2-99.2	616/624	98.7	97.5-99.3
	Overall	***73/75***	***97.3***	***90.8-99.3***	***1529/1537***	***99.5***	***99.0-99.7***
HRV/EV[g]	Fresh	320/328	97.6	95.3-98.8	532/590	90.2	87.5-92.3
	Frozen	105/108	97.2	92.1-99.1	567/586	96.8	95.0-97.9
	Overall	***425/436***	***97.5***	***95.5-98.6***	***1099/1176***	***93.5***	***91.9-94.7***
FluA[h]	Fresh	3/3	100	43.9-100	915/915	100	99.6-100
	Frozen	75/75	100	95.1-100	616/616	100	99.4-100
	Overall	***78/78***	***100***	***95.3-100***	***1531/1531***	***100***	***99.7-100***
FluA H1	Fresh	0/0	-	-	918/918	100	99.6-100
	Frozen	0/0	-	-	691/691	100	99.4-100
	Overall	***0/0***	***-***	***-***	***1609/1609***	***100***	***99.8-100***
FluA H1-2009	Fresh	0/0	-	-	918/918	100	99.6-100
	Frozen	74/74	100	95.1-100	617/617	100	99.4-100
	Overall	***74/74***	***100***	***95.1-100***	***1535/1535***	***100***	***99.8-100***
FluA H3	Fresh	3/3	100	43.9-100	915/915	100	99.6-100
	Frozen	1/1	100	-	690/690	100	99.4-100
	Overall	***4/4***	***100***	***51.0-100***	***1605/1605***	***100***	***99.8-100***
FluB[i]	Fresh	0/0	-	-	918/918	100	99.6-100
	Frozen	14/14	100	78.5-100	678/680	99.7	98.9-99.9
	Overall	***14/14***	***100***	***78.5-100***	***1596/1598***	***99.9***	***99.5-100***
MERS-CoV	Fresh	0/0	-	-	918/918	100	99.6-100
	Frozen	0/0	-	-	694/694	100	99.4-100
	Overall	***0/0***	***-***	***-***	***1612/1612***	***100***	***99.8-100***
PIV1[j]	Fresh	5/5	100	56.6-100	913/913	100	99.6-100
	Frozen	4/4	100	51.0-100	689/690	99.9	99.2-100
	Overall	***9/9***	***100***	***70.1-100***	***1602/1603***	***99.9***	***99.6-100***
PIV2[k]	Fresh	46/47	97.9	88.9-99.6	863/871	99.1	98.2-99.5
	Frozen	0/0	-	-	694/694	100	99.4-100
	Overall	***46/47***	***97.9***	***88.9-99.6***	***1557/1565***	***99.5***	***99.0-99.7***
PIV3[l]	Fresh	40/42	95.2	84.2-98.7	867/876	99.0	98.1-99.5
	Frozen	3/3	100	43.9-100	690/691	99.9	99.2-100
	Overall	***43/45***	***95.6***	***85.2-98.8***	***1557/1567***	***99.4***	***98.8-99.7***
PIV4[m]	Fresh	6/6	100	61.0-100	910/912	99.8	99.2-99.9
	Frozen	3/3	100	43.9-100	686/691	99.3	98.3-99.7
	Overall	***9/9***	***100***	***70.1-100***	***1596/1603***	***99.6***	***99.1-99.8***
RSV[n]	Fresh	44/45	97.8	88.4-99.6	867/873	99.3	98.5-99.7
	Frozen	131/131	100	97.2-100	545/563	96.8	95.0-98.0
	Overall	***175/176***	***99.4***	***96.9-99.9***	***1412/1436***	***98.3***	***97.5-98.9***
Bacteria							
***B. parapertussis* (IS*1001*)[o]**	Fresh	4/5	80.0	37.6-96.4	913/913	100	99.6-100
	Frozen	2/2	100	34.2-100	692/692	100	99.4-100
	Overall	***6/7***	***85.7***	***48.7-97.4***	***1605/1605***	***100***	***99.8-100***
***B. pertussis* (*ptxP*)[p]**	Fresh	2/2	100	34.2-100	915/916	99.9	99.4-100
	Frozen	0/1	0.0	-	693/693	100	99.4-100

Analyte		Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
	Overall	***2/3***	***66.7***	***20.8-93.9***	***1608/1609***	***99.9***	***99.6-100***
***C. pneumoniae*[q]**	Fresh	2/2	100	34.2-100	915/916	99.9	99.4-100
	Frozen	3/3	100	43.9-100	691/691	100	99.4-100
	Overall	***5/5***	***100***	***56.6-100***	***1606/1607***	***99.9***	***99.6-100***
***M. pneumoniae*[r]**	Fresh	17/17	100	81.6-100	897/901	99.6	98.9-99.8
	Frozen	6/7	85.7	48.7-97.4	686/687	99.9	99.2-100
	Overall	***23/24***	***95.8***	***79.8-99.3***	***1583/1588***	***99.7***	***99.3-99.9***

[a] Adenovirus was detected in 3/4 FN specimens using an independent molecular method. Adenovirus was detected in 38/48 FP specimens using an independent molecular method; an additional two FP specimens were indicated to have been collected from subjects with an acute history of adenovirus infection.

[b] The single FN specimen was negative for CoV-229E when tested using an independent molecular method. All five FP specimens were negative for CoV-229E when tested using an independent molecular method.

[c] CoV-HKU1 was detected in 3/12 FP specimens upon comparator method retest.

[d] CoV-NL63 was detected in 3/10 FP specimens during discrepancy investigation; two were detected using an independent molecular method and one was detected upon comparator method retest.

[e] Of the eight FN specimens, six were TP for CoV-HKU1. They were confirmed to be due to a known cross-reactivity with CoV-HKU1 by the comparator method; All six specimens were negative for CoV-OC43 when tested with two independent PCR assays; the remaining two FN specimens were negative for CoV-OC43 when tested using an independent molecular method. CoV-OC43 was detected in 2/5 FP specimens upon comparator method retest.

[f] Both FN specimens were negative for hMPV when tested using an independent molecular method. hMPV was detected in 6/8 FP specimens during discrepancy investigation; one was detected using an independent molecular method and five were detected upon comparator method retest.

[g] HRV/EV was detected in 5/11 FN specimens during discrepancy investigation; one was detected using an independent molecular method and four were detected upon FilmArray RP2 retest. HRV/EV was detected in 33/77 FP specimens during discrepancy investigation; four were detected using an independent molecular method and 29 were detected upon comparator method retest.

[h] Three specimens were excluded from influenza A analysis: one with a comparator method result of Influenza A (No Subtype Detected) and two FilmArray RP2 Influenza A (Equivocal) detections.

[i] FluB was detected in both FP specimens during discrepancy investigation; one was detected using an independent molecular method and one was detected upon comparator method retest.

[j] The single FP specimen was negative for PIV1 when tested using an independent molecular method.

[k] The single FN specimen was negative for PIV2 when tested using an independent molecular method. PIV2 was detected in 5/8 FP specimens during discrepancy investigation; one was detected using an independent molecular method and four were detected upon comparator method retest.

[l] PIV3 was detected in both FN specimens during discrepancy investigation; one was detected using an independent molecular method and one was detected upon FilmArray RP2 retest. PIV3 was detected in 4/10 FP specimens during discrepancy investigation; two were detected using an independent molecular method and two were detected upon comparator method retest.

[m] PIV4 was detected in 1/7 FP specimens using an independent molecular method.

[n] The single FN specimen was negative for RSV when tested using an independent molecular method. RSV was detected in 8/24 FP specimens during discrepancy investigation; three were detected using an independent molecular method and five were detected upon comparator method retest.

[o] *B. parapertussis* was detected in the single FN specimen upon FilmArray RP2 retest.

[p] *B. pertussis* was detected in the both the FN and FP specimens using an independent molecular method.

[q] *C. pneumoniae* was detected in the single FP specimen using an independent molecular method.

[r] *M. pneumoniae* was detected in the single FN specimen upon FilmArray RP2 retest. *M. pneumoniae* was detected in all five FP specimens during discrepancy investigation; three were detected using an independent molecular method and two were detected upon comparator method retest.

FilmArray RP2 reported a total of 245 specimens with discernible multiple organism detections (15.2% of all specimens, 245/1612; and 24.0% of positive specimens, 245/1020; Table 5). The majority of multiple detections (190/245; 77.6%) contained two organisms, while 20.0% (49/245) contained three organisms, 1.6% (4/245) contained four organisms, 0.4% (1/245) contained five organisms, and 0.4% (1/245) contained six organisms. Out of the 245 specimens with multiple detections, 124 specimens (50.6%; 124/245) were concordant with the comparator methods. One hundred twenty-one (121) specimens (49.4%; 121/245) contained one or more organisms that had not been detected by the comparator methods (i.e. false positive results).

The three organisms that were most prevalent in multiple detections were also the three most prevalent organisms in the study as a whole (i.e. HRV/EV, RSV, and adenovirus). The most prevalent multiple detections (≥5 instances) are shown in Table 6.

Table 5. Prevalence of Analytes in Multiple Detections as determined by the FilmArray RP2

Analyte	Prevalence in Multiple Detections (N=245)	
Viruses		
Adenovirus	85	34.7%
CoV-229E	6	2.4%
CoV-HKU1	41	16.7%
CoV-NL63	31	12.7%
CoV-OC43	19	7.8%
hMPV	33	13.5%
HRV/EV	150	61.2%
FluA H1	0	0%
FluA H1-2009	9	3.7%
FluA H3	2	0.8%
FluB	6	2.4%
PIV1	5	2.0%
PIV2	15	6.1%
PIV3	21	8.6%
PIV4	12	4.9%
RSV	105	42.9%
Bacteria		
B. parapertussis (IS*1001*)	6	2.4%
B. pertussis (*ptxP*)	0	0%
C. pneumoniae	1	0.4%
M. pneumoniae	7	2.9%

The most prevalent multiple detection was adenovirus with HRV/EV (1.9% of all specimens; 30/1612) followed by HRV/EV with RSV (1.4% of all specimens; 22/1612); as previously stated these were also the most prevalent organisms detected in the study.

Table 6. Multiple Detection Combinations (≥5 instances) as Determined by the FilmArray RP2

Distinct Co-Detection Combinations			Total Multiple Detections	Number of Specimens with False Positive Results	False Positive Analyte(s)[a]
Analyte 1	Analyte 2	Analyte 3			
Adenovirus	HRV/EV		30	15	Adenovirus (15), HRV/EV (1)
HRV/EV	RSV		22	7	HRV/EV (3), RSV (4)

CoV-HKU1	RSV		13	7	CoV-HKU1 (4), RSV (3)
CoV-NL63	RSV		13	3	CoV-NL63 (2), RSV (1)
HRV/EV	PIV2		11	7	HRV/EV (6), PIV2 (2)
HRV/EV	PIV3		11	6	HRV/EV (3), PIV3 (4)
Adenovirus	RSV		10	5	Adenovirus (4), RSV (1)
Adenovirus	HRV/EV	RSV	9	5	Adenovirus (2), HRV/EV (3), RSV (1)
CoV-NL63	HRV/EV		8	2	CoV-NL63 (2)
CoV-HKU1	HRV/EV		5	2	CoV-HKU1 (1), HRV/EV (1)
CoV-OC43	HRV/EV		5	3	HRV/EV (3)
hMPV	HRV/EV		5	1	HRV/EV

[a] Of the 67 discrepant analytes (out of 293 total analytes), 32 (47.8%) were observed as being present in the specimen during discrepancy investigation; 22/67 (32.8%) were observed using an independent molecular method and 13/67 (19.4%) were observed upon comparator method retest.

The overall success rate for initial specimen tests in the prospective study was 99.3% (1611/1623) (95% CI: 98.7% - 99.6%); 12 tests were unsuccessful (one due to an incomplete test, one due to an instrument error, and ten due to control failures). Two tests (2/1623; 0.1%) did not complete on the initial run, resulting in an instrument success rate of 99.9% (1621/1623) (95% CI: 99.6% - 100%) for initial specimen tests. Both specimens were able to be retested and valid results were produced after a single retest. Ten tests (10/1621; 0.6%) did not produce valid pouch controls, resulting in a pouch control success rate of 99.4% (1611/1621) (95% CI: 98.9% - 99.7%) for completed runs in the initial specimen tests. Nine of the 10 invalid specimens were able to be retested and produced valid control results after a single retest; one was not able to be retested due to insufficient specimen volume.

Testing of Preselected Archived Specimens

Some of the analytes on the FilmArray RP2 were of low prevalence and were not encountered in large enough numbers during the prospective study to adequately demonstrate system performance. To supplement the results of the prospective clinical study, an evaluation of preselected archived retrospective specimens was performed at BioFire. These specimens were archived NPS in VTM specimens that were selected because they had previously tested positive for one of the following analytes: coronavirus 229E, influenza A H1, influenza A H3, influenza B, parainfluenza virus 1, parainfluenza virus 4, *Bordetella parapertussis*, *B. pertussis*, and *Chlamydia pneumoniae.* Parainfluenza virus 2, parainfluenza virus 3, and *Mycoplasma pneumoniae* were also expected to be low prevalence based on BioFire data collected during the 2015-2016 respiratory season, therefore archived testing was performed for these analytes as well and included in the study data (although ultimately they were observed in larger numbers during the prospective clinical study).

A total of 217 preselected archived retrospective clinical specimens were initially received for testing in this retrospective study. Prior to testing with the FilmArray RP2, the composition/integrity of the specimens was first confirmed with confirmatory molecular methods (PCR followed by bi-directional sequencing for *B. parapertussis* or an FDA-cleared multiplexed respiratory pathogen panel.

The specimens were divided into two different groups for testing based on the method of confirmation testing performed: all specimens containing analytes on the FDA-cleared multiplexed respiratory pathogens panel comparator method were tested in Group 1 and specimens containing *B. parapertussis* were tested in Group 2. Negative NPS specimens were also included in each group for testing.

The FDA-cleared multiplexed respiratory pathogen panel comparator method was performed on 197 of the 217 preselected archived retrospective clinical specimens only (Group 1). One of the 197 specimens was excluded from performance analysis because of an invalid FilmArray RP2 run with insufficient volume to retest. Additionally, two of the 197 specimens were also excluded from performance analysis because a valid FDA-cleared multiplexed respiratory pathogens panel comparator method confirmation result was not obtained and there was insufficient specimen volume for retesting: one comparator run was incomplete and the other comparator run had a control failure. Valid comparator method and FilmArray RP2 results were obtained for 194 of these 197 archived specimens (Group 1).

The *B. parapertussis* PCR followed by bi-directional sequencing comparator assays were performed on 20 of the 217 preselected archived retrospective clinical specimens only (Group 2). The FDA-cleared multiplexed respiratory pathogens panel comparator method was not performed on Group 2 specimens. Valid comparator method and FilmArray RP2 results were obtained for 20 of these 20 archived specimens.

A summary of the available demographic information of these 214 valid archived specimens is provided in Table 7.

Table 7. Available Demographic Summary for All Valid Archived Specimens

Total Specimens		**214**
Sex	Female (%)	75 (35%)
	Male (%)	81 (38%)
	Unknown	58 (27%)
Age Range	≤ 5 years	78 (36%)
	6 - 21 years	46 (21%)
	22 - 49 years	13 (6%)
	50+ years	19 (9%)
	Unknown	58 (27%)

All Group 1 and Group 2 positive archived specimens (as determined at the source laboratory) that were not confirmed by the respective comparator method were further excluded from the performance calculation for each of the respective analytes.

The FilmArray RP2 retrospective specimens testing performance data against the comparator methods are provided in Table 8 by analyte.

Table 8. FilmArray RP2 Archived Specimen Performance Data Summary

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Viruses						
Adenovirus	0/0	0	N/A	189/194	97.4	94.1-98.9
CoV- 229E [a]	15/15	100	79.6-100	175/175	100	97.9-100
CoV-HKU1	0/0	0	N/A	194/194	100	98.1-100
CoV-NL63	2/2	100	34.2-100	192/192	100	98.0-100
CoV-OC43	0/0	0	N/A	194/194	100	98.1-100
hMPV	1/1	100	20.7-100	192/193	99.5	97.1-99.9
HRV/EV	18/19	94.7	75.4-99.1	168/175	96.0	92.0-98.0
Influenza A	22/22	100	85.1-100	172/172	100	97.8-100
Influenza A H1	3/3	100	43.9-100	191/191	100	98.0-100
Influenza A 2009-H1	1/1	100	20.7-100	193/193	100	98.0-100
Influenza A H3	18/18	100	82.4-100	176/176	100	97.9-100
Influenza B [b]	16/16	100	80.6-100	177/177	100	97.9-100
Parainfluenza Virus 1	16/16	100	80.6-100	178/178	100	97.9-100
Parainfluenza Virus 2 [c]	16/16	100	80.6-100	177/177	100	97.9-100
Parainfluenza Virus 3	17/17	100	81.6-100	175/177	98.9	96.0-99.7
Parainfluenza Virus 4	17/17	100	81.6-100	174/177	98.3	95.1-99.4
RSV	2/2	100	34.2-100	191/192	99.5	97.1-99.9
Bacteria						
Bordetella parapertussis (IS*1001*) [d]	16/16	100	80.6-100	4/4	100	51.0-100
Bordetella pertussis (*ptx*P) [e]	25/26	96.2	81.1-99.3	160/162	98.8	95.6-99.7
Chlamydia pneumoniae [f]	17/17	100	81.6-100	176/176	100	97.9-100
Mycoplasma pneumoniae [g]	16/16	100	80.6-100	171/173	98.8	95.9-99.7

[a] Four of 19 CoV-229E positive archived specimens by the source laboratory were not confirmed by the comparator method and therefore were excluded from the performance calculation for CoV-229E .

[b] One of the 17 Influenza B positive archived specimens by the source laboratory was not confirmed by the comparator method and therefore was excluded from the performance calculation for Influenza B.

[c] One of the 17 Parainfluenza Virus 2 positive archived specimens the source laboratory was not confirmed by the comparator method and therefore was excluded from the performance calculation for Parainfluenza Virus 2 .

[d] The comparator *B. parapertussis* PCR followed by sequencing assays were performed on 20 achieved specimens only (Group 2). The comparator method for the other analytes was not performed on these 20 specimens.

[e] Six of the 31 *B. pertussis* positive archived specimens by the source laboratory were not confirmed by the comparator method and therefore were excluded from the performance calculation for *B. pertussis*.

[f] One of the 17 *C. pneumoniae* positive archived specimens by the source laboratory was not confirmed by the comparator method and therefore was excluded from the performance calculation for *C. pneumoniae.*

[g] Five of the 21 *M. pneumoniae* positive archived specimens by the source laboratory were not confirmed by the comparator method and therefore were excluded from the performance calculation for *M. pneumoniae*.

Testing of Contrived Specimens

Influenza A H1 is of such rarity that that both prospective and retrospective archived testing efforts were insufficient to demonstrate system performance. To supplement the prospective and retrospective data, an evaluation of contrived specimens was performed at one of the three clinical testing sites participating in the prospective evaluation. Contrived clinical specimens were prepared using individual unique residual NPS specimens that had previously tested

negative by the FDA-cleared multiplexed respiratory pathogen panel (i.e., the same test as the comparator method employed in the prospective and retrospective clinical evaluations) at the source laboratory. Spiking was performed using multiple quantified isolates of Influenza A H1. The spiking scheme was such that at least 25 of the contrived positive specimens had analyte concentrations at 2 × the limit of detection (LoD), while the remaining 25 contrived positive specimens were at additional concentrations that spanned the clinically relevant range which was based on FilmArray® RP2 Cp observations of influenza A (A H1, A H-2009, and H3) from the prospective and archived specimen studies. Contrived positive specimens were prepared and randomized along with 50 un-spiked influenza A H1 negative specimens such that the analyte status of each contrived specimen was unknown to the users performing the testing. The results of the FilmArray RP2 testing contrived specimens are presented in Table 9.

Table 9. FilmArray RP2 Performance Using Contrived Specimens

Analyte	Positive Percent Agreement				Negative Percent Agreement		
	× LoD	**TP/(TP + FN)**	**%**	**95% CI**	**TN/(TN + FP)**	**%**	**95% CI**
Influenza A H1	2	22/23 [a]	95.7%	79.0-99.2	50/50	100	92.9-100
	10	10/10	100%	72.3-100			
	50	5/5	100%	56.6-100			
	200	5/5	100%	56.6-100			
	1000	5/5	100%	56.6-100			
	Combined	**47/48 [a]**	**97.9%**	**89.1-99.6**			

[a] The FN specimen was spiked with influenza A/Weiss/43; this strain was detected at all other concentrations. Two specimens (also spiked with strain A/Weiss/43) had a result of Influenza A Equivocal or Influenza A H1 Equivocal and were excluded from Influenza A H1 performance calculation.

Selected Analytical Studies

Limit of Detection

The limit of detection (LoD) for FilmArray RP2 analytes was estimated by testing dilutions of contrived samples containing known concentrations of organisms. Confirmation of LoD was achieved by testing 20 replicates on FilmArray 2.0 and 20 replicates on FilmArray Torch. LoD was confirmed when the organism was detected in at least 19 of the 20 replicates tested (19/20 = 95%). The confirmed LoD for each FilmArray RP2 analyte is listed in Table 10 in viable units. An equivalent DNA or RNA copies/mL was calculated based on an alternate quantitative PCR assay for each analyte. LoD is equivalent when testing on FilmArray 2.0 and FilmArray Torch systems.

Table 10. Summary of Limit of Detection (LoD) for FilmArray RP2 Analytes

RP2 Analyte	Isolate	LoD Concentration	FilmArray 2.0	FilmArray Torch
Viruses				
Adenovirus[a]	Species A, Serotype 18 ATCC VR-19	**5.0E+00 $TCID_{50}$/mL** 7.6E+03 copies/mL	**20/20** 100%	**19/20** 95%
	Species B, Serotype 7A Zeptometrix 0810021CF	**5.0E-02 $TCID_{50}$/mL** 3.9E+01 copies/mL	**20/20** 100%	**20/20** 100%
	Species C, Serotype 2 ATCC VR-846	**2.0E+00 $TCID_{50}$/mL** 3.7E+01 copies/mL	**19/20** 95%	**20/20** 100%
	Species D, Serotype 37 Zeptometrix 0810119CF	**5.0E-02 $TCID_{50}$/mL** 9.0E+00 copies/mL	**20/20** 100%	**20/20** 100%
	Species E, Serotype 4a S. Carolina/2004, UIRF	**1.0E+01 $TCID_{50}$/mL** 3.0E+03 copies/mL	**19/20** 95%	**19/20** 95%
	Species F, Serotype 41 Tak, ATCC VR-930	**1.0E+00 $TCID_{50}$/mL** 1.2E+02 copies/mL	**20/20** 100%	**20/20** 100%
Coronavirus 229E	ATCC VR-740	**4.0E-01 $TCID_{50}$/mL** 6.5E+01 copies/mL	**20/20** 100%	**20/20** 100%
Coronavirus HKU1	Clinical specimen	**2.0E+03 RNA copies/mL**[b]	**20/20** 100%	**20/20** 100%
Coronavirus NL63	BEI NR-470	**2.5E-01 $TCID_{50}$/mL** 5.4E+01 copies/mL	**20/20** 100%	**20/20** 100%
Coronavirus OC43	ATCC VR-759	**3.0E+01 $TCID_{50}$/mL** 5.6E+02 copies/mL	**19/20** 95%	**20/20** 100%
Human Metapneumovirus	16, Type A1 IA10-2003 Zeptometrix 0810161CF	**1.0E+01 $TCID_{50}$/mL** 1.2E+03 copies/mL	**20/20** 100%	**20/20** 100%
Human Rhinovirus/ Enterovirus[a]	Human Rhinovirus Type 1A Zeptometrix 0810012CFN	**1.0E-01 $TCID_{50}$/mL** 8E+01 copies/mL	**20/20** 100%	**20/20** 100%
	Enterovirus D68 ATCC VR-1823	**3.0E+02 $TCID_{50}$/mL** 2.6E+01 copies/mL	**20/20** 100%	**20/20** 100%
Influenza A H1	Influenza A H1N1 A/New Caledonia/20/99 Zeptometrix 0810036CF	**1.0E+03 $TCID_{50}$/mL** 1.4E+02 copies/mL	**20/20** 100%	**20/20** 100%
Influenza A H1-2009	Influenza A H1N1 pdm A/Swine/NY/03/2009 Zeptometrix 0810249CF	**5.0E-01 $TCID_{50}$/mL** 3.3E+02 copies/mL	**20/20** 100%	**20/20** 100%
Influenza A H3	Influenza H3N2 A/Port Chalmers/1/73 ATCC VR-810	**1.0E-01 $TCID_{50}$/mL** 2.1E+01 copies/mL	**20/20** 100%	**20/20** 100%
Influenza B	B/FL/04/06 Zeptometrix 0810255CF	**5.0E+00 $TCID_{50}$/mL** 3.4E+01 copies/mL	**20/20** 100%	**20/20** 100%

RP2 Analyte	Isolate	LoD Concentration	FilmArray 2.0	FilmArray Torch
Parainfluenza Virus 1	Type 1 Zeptometrix 0810014CF	**5.0E+00 $TCID_{50}$/mL** 1.0E+03 copies/mL	**20/20** 100%	**20/20** 100%
Parainfluenza Virus 2	Type 2 Zeptometrix 0810015CF	**5.0E-01 $TCID_{50}$/mL** 3.0E+01 copies/mL	**20/20** 100%	**20/20** 100%
Parainfluenza Virus 3	Type 3 Zeptometrix 0810016CF	**2.5E+00 $TCID_{50}$/mL** 3.8E+01 copies/mL	**19/20** 95%	**20/20** 100%
Parainfluenza Virus 4	Type 4a Zeptometrix 0810060CF	**5.0E+01 $TCID_{50}$/mL** 1.6E+03 copies/mL	**20/20** 100%	**20/20** 100%
Respiratory Syncytial Virus	Type A Zeptometrix 0810040ACF	**2.0E-02 $TCID_{50}$/mL** 9.0E+00 copies/mL	**19/20** 95%	**20/20** 100%
Bacteria				
***Bordetella parapertussis* (IS*1001*)**	A747 Zeptometrix 0801461	**4.1E+01 CFU/mL** 6.0E+01 IS*1001* copies/mL[c]	**20/20** 100%	**19/20** 95%
***Bordetella pertussis* (*ptxP*)**	A639 Zeptometrix 0801459	**1.0E+03 CFU/mL**	**20/20** 100%	**20/20** 100%
Chlamydia pneumoniae	TW183 ATCC VR-2282	**1.0E-01 $TCID_{50}$/mL** 6.6E+01 copies/mL	**20/20** 100%	**19/20** 95%
Mycoplasma pneumoniae	M129 Zeptometrix 0801579	**1.0E+01 $TCID_{50}$/mL** 4.6E+02 copies/mL[d]	**20/20** 100%	**20/20** 100%

[a] The differences in LoD concentration between Adenovirus species (5.0E-02 – 1.0E+01 $TCID_{50}$/mL) or between Human Rhinovirus and Enterovirus (1.0E-01 – 3.0E+02$TCID_{50}$/mL) may not indicate actual differences in detection of different species or serotypes, but rather the variability of the $TCID_{50}$ measurement method.

[b] A cultured isolate of Coronavirus HKU1 was not available for testing. LoD for Coronavirus HKU1 was therefore determined by testing dilutions of a clinical NPS specimen known to contain the virus. The amount of viral RNA in the specimen (in RNA copies/mL) was determined by real-time RT-PCR against a standard curve.

[c] IS*1001* sequences can be present in more than one copy per cell, so the relationship between CFU/mL and copies/mL may vary from strain to strain and culture to culture. LoD was determined based on the copy number of IS*1001* measured by an independent quantitative real-time PCR assay and for this culture.

[d] The copy number of *Mycoplasma pneumoniae* was determined by a multicopy assay (16S rRNA) and may not accurately reflect the number of copies detected by the single-copy FilmArray RP2 gene target.

Note: LoD concentrations of the cultured viruses and obligate intracelleular bacteria (*C. pneumoniae* and *M. pneumoniae*) are provided in units of $TCID_{50}$ (50% Tissue Culture Infectious Dose). $TCID_{50}$ is an indirect measure of viral or bacterial concentration based on infectivity and cytotoxicity and will therefore vary considerably depending on technique and methodology (including cell type, culture media and conditions, cytotoxicity of the virus, etc.). It is not appropriate to make determinations on relative sensitivity of different molecular assays for detection of viruses and bacteria based on LoD values measured in $TCID_{50}$/mL.

Inclusivity

Analytical reactivity (inclusivity) was evaluated with a collection of 177 isolates that represent temporal and geographic diversity of FilmArray RP2 analytes, including relevant species, strains, serotypes, or genotypes. All isolates tested were detected by the FilmArray RP2 at concentrations within 10× LoD. When possible, *in silico* analysis of sequence data was used to make predictions of assay reactivity for less common strains or serotypes that were not tested but that may be detected by the FilmArray RP2 (Table 11 - Table 22).

RP2 influenza A assays will react variably with non-human influenza A viruses and rarely encountered human influenza A viruses that are not H1, H1-2009 or H3; generally producing Influenza A Equivocal or Influenza A (no subtype detected) results.

Note: FilmArray RP2 Influenza A (subtype) and Influenza B assays are predicted to react with attenuated viruses used in vaccines.

Table 11. Adenovirus Isolates Tested and Detected by FilmArray RP2

Species[a]	Serotype	Isolate ID/Source	[Strain/Location/Year]	xLoD Dectected	Result
A	12	ATCC VR-863	[Huie/Massachusetts]	3x	Adenovirus Detected
	18	ATCC VR-19	[Washington DC/1954]	1x	
	31	Zeptometrix 0810073CF	-	3x	
B	3	Zeptometrix 0810062CF	-	3x	
	7A	Zeptometrix 0810021CF	-	1x	
	7d/d2	Univ of Iowa Research Foundation	[Iowa/2001]	3x	
	7h	Univ of Iowa Research Foundation	[Iowa/1999]	3x	
	11	Univ of Iowa Research Foundation	[Wisconsin/2005]	3x	
	14	Univ of Iowa Research Foundation	[Missouri/2005]	3x	
	16	ATCC VR-17	[CH.79/Saudia Arabia/1955]	3x	
	21	Univ of Iowa Research Foundation	[Missouri/2005]	3x	
	34	ATCC VR-716	[Compton/1972]	3x	
	35	ATCC VR-718	[Holden]	3x	
	50	ATCC VR-1602	[Wan/Amsterdam/1988]	3x	
C	1	Zeptometrix 0810050CF	-	3x	
	2	ATCC VR-846	[Adenoid 6]	1x	
	5	Zeptometrix 0810020CF	-	3x	
	6	ATCC VR-6	[Tonsil 99/Washington DC]	3x	
D	8	Zeptometrix 0810069CF	-	3x	
	20	Zeptometrix 0810115CF	-	3x	
	37	Zeptometrix 0810119CF	-	1x	
E	4a	Univ of Iowa Research Foundation	[S Carolina/2004]	1x	
	4	Zeptometrix 0810070CF	-	3x	
F	40	Zeptometrix 0810084CF	-	3x	
		NCPV 0101141v	-	3x	
	41	ATCC VR-930	[Tak/73-3544/Netherlands/1973]	1x	
		Zeptometrix 0810085CF	-	3x	

[a] In silico analysis of available sequences predicts that the FilmArray RP2 will also react with Adenovirus B55, C57, species D serotypes, and G52.

Table 12. Coronavirus Isolates/Specimens Tested and Detected by FilmArray RP2

Coronavirus Type	Isolate ID/Source	[Location/Year]	xLoD Dectected	Result
229E	ATCC VR-740	-	1x	Coronavirus 229E
	Zeptometrix 0810229CF	-	3x	
HKU1	Clinical Specimen	[Utah/2015]	1x	Coronavirus HKU1
	Clinical Specimen	[Utah/2015]	3x	
	Clinical Specimen	[Utah/2015]	3x	
	Clinical Specimen	[S. Carolina/2010]	3x	
	Clinical Specimen	[Detroit/2010]	3x	
NL63	BEI NR-470[a]	[Amsterdam/2003]	1x	Coronavirus NL63
	Zeptometrix 0810228CF	-	3x	
OC43	ATCC VR-759[b]	-	1x	Coronavirus OC43
	Zeptometrix 0810024CF	-	3x	

[a] Organism obtained through the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH: Human Coronavirus NL63, NR-470.

[b] Discontinued part number; see ATCC VR-1558.

Table 13. Human Metapneumovirus Isolates Tested and Detected by FilmArray RP2

Genotype	Serotype	Isolate ID/Source	[Location/Year]	xLoD Detected	Result
A1	16	Zeptometrix 0810161CF	[Iowa10/2003]	1x	Human Metapneumovirus
	9	Zeptometrix 0810160CF	[Iowa3/2002]	3x	
A2	20	Zeptometrix 0810163CF	[Iowa14/2003]	3x	
	27	Zeptometrix 0810164CF	[Iowa27/2004]	3x	
B1	3	Zeptometrix 0810156CF	[Peru2/2002]	3x	
	5	Zeptometrix 0810158CF	[Peru3/2003]	3x	
	13	Univ of Iowa Research Foundation	[Iowa7/2003]	3x	
B2	4	Zeptometrix 0810157CF	[Peru1/2002]	3x	
	8	Zeptometrix 0810159CF	[Peru6/2003]	3x	
	18	Zeptometrix 0810162CF	[Iowa18/2003]	3x	
	22	Univ of Iowa Research Foundation	[Iowa16/2003]	3x	

Table 14. Human Rhinovirus and Enterovirus Isolates Tested and Detected by FilmArray RP2

Species	Serotype	Isolate ID/Source	[Strain/Location/Year]	xLoD Detected	Result
Human Rhinovirus					
A	1	Zeptometrix 0810012CFN	[1A]	1x	Human Rhinovirus/ Enterovirus
	2	ATCC VR-482	[HGP]	3x	
	7	ATCC VR-1601	[68-CV11]	3x	
	16	ATCC VR-283	[11757/Washington DC/1960]	3x	
	34	ATCC VR-507[a]	[137-3]	3x	
	57	ATCC VR-1600	[Ch47]	3x	
	77	ATCC VR-1187	[130-63]	3x	
	85	ATCC VR-1195	[50-525-CV54]	3x	
B	3	ATCC VR-483	[FEB]	3x	
	14	ATCC VR-284	[1059/S Carolina/1959]	3x	
	17	ATCC VR-1663	[33342/N Carolina/1959]	3x	
	27	ATCC VR-1137	[5870]	3x	
	42	ATCC VR-338	[56822]	3x	
	83	ATCC VR-1193	[Baylor 7]	3x	
Enterovirus					
A	Coxsackievirus 10	ATCC VR-168	[NY/1950]	3x	Human Rhinovirus/ Enterovirus
	Enterovirus 71	ATCC VR-1432	[H]	3x	
B	Coxsackievirus A9	Zeptometrix 0810017CF	-	3x	
	Coxsackievirus B3	Zeptometrix 0810074CF	-	3x	
	Coxsackievirus B4	Zeptometrix 0810075CF	-	3x	
	Echovirus 6	Zeptometrix 0810076CF	-	3x	
	Echovirus 9	Zeptometrix 0810077CF	-	3x	
	Echovirus 11	Zeptometrix 0810023CF	-	3x	
C	Coxsackievirus A21	ATCC VR-850	[Kuykendall/California/1952]	3x	
	Coxsackievirus A24	ATCC VR-583	[DN-19/Texas/1963]	3x	
D	68	ATCC VR-1823	[US/MO/2014-18947]	1x	

[a] Discontinued part number; see ATCC VR-1365.

Table 15. Influenza A Isolates Tested and Detected by FilmArray RP2

Type	Isolate ID/Source		[Strain/Location/Year]	xLoD Detected	Result
H1N1	Human	Zeptometrix 0810036CF	[New Caledonia/20/1999]	1x	Influenza A H1
		ATCC VR-219	[NWS/1933]	3x	
		ATCC VR-95	[PR/8/1934]	10x[a]	
		ATCC VR-96	[Weiss/1943]	3x	
		ATCC VR-97	[FM/1/1947]	3x	
		ATCC VR-98	[Mal/302/1954]	3x	
		ATCC VR-546	[Denver/1/1957]	3x	
		Zeptometrix 0810036CFN	[Solomon Isl/03/2006]	3x	
		Zeptometrix 0810244CF	[Brisbane/59/2007]	3x	
	Swine	ATCC VR-333	[A/Swine/Iowa/15/1930]	3x	
		ATCC VR-99	[A/Swine/1976/1931]	3x	
		ATCC VR-897	[A/New Jersey/8/76 (Hsw1N1)]	10x[a]	
H1N2	Recombinant	BEI NR-9677[b]	[Kilbourne F63, A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA)]	3x	
H1N1 pdm09	Human	Zeptometrix 0810249CFN	[SwineNY/03/2009]	1x	Influenza A H1-2009
		Zeptometrix 0810248CFN	[SwineNY/01/2009]	3x	
		Zeptometrix 0810109CFN	[SwineNY/02/2009]	3x	
		Zeptometrix 0810109CFJ	[Canada/6294/2009]	3x	
		Zeptometrix 0810165CF	[California/07/2009]	3x	
		Zeptometrix 0810166CF	[Mexico/4108/2009]	3x	
		BEI NR-19823[c]	[Netherlands/2629/2009]	3x	
		BEI NR-44345[d]	[Hong Kong/H090-761-V1(0)/2009]	10x[e]	
		BEI NR-42938[f]	[Georgia/F32551/2012]	3x	
H3N2[g]	Human	ATCC VR-810	[Port Chalmers/1/1973]	1x	Influenza A H3
		ATCC VR-776	[Alice (live attenuated vaccine)]	3x	
		Zeptometrix 0810238CF	[Texas/50/2012]	3x	
		ATCC VR-547	[Aichi/2/1968]	3x	
		ATCC VR-544	[Hong Kong/8/1968]	3x	
		ATCC VR-822	[Victoria/3/1975]	3x	
		Zeptometrix 0810252CF	[Wisconsin/67/2005]	3x	
		Zeptometrix 0810138CF	[Brisbane/10/2007]	3x	
	Recombinant	ATCC VR-777	[MCR2(A/England/42/72xA/PR8/34)]	3x	
H3N2v	Human	Clinical Specimen	[Ohio/2012]	3x	
H2N2	Human	BEI NR-2775[h]	[Japan/305/1957]	10x[e]	Influenza A (no subtype detected)
	Recombinant	BEI NR-9679[i]	[Korea/426/1968xPuerto Rico/8/1934]	10x[e]	
H2N3	Avian	MRI Global[j]	[Mallard/Alberta/79/2003]	3x	Influenza A Equivocal
H5N1		MRI Global[j]	[A/Chicken/Yunnan/1251/2003]	3x	Influenza A (no subtype detected)
H5N2		MRI Global[j]	[A/Northern pintail/Washington/40964/2014]	3x	
H5N3		BEI NR-9682[k]	[A/Duck/Singapore/645/1997]	3x	
H5N8		MRI Global[j]	[A/Gryfalcon/Washington/41088-6/2014]	3x	
H7N7		MRI Global[j]	[A/Netherlands/219/2003]	3x	
H7N9		MRI Global[j]	[A/Anhui/01/2013]	3x	
H10N7		BEI NR-2765[l]	[Chicken/Germany/N/49]	3x	Influenza A Equivocal

[a] Reported as Influenza A (no subtype detected) at 3× LoD.
[b] Genomic RNA obtained through the NIH Biodefense and Emerging Infections Research Resources Respiratory NAID, NIH Kilbourne F63: A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA) (H1N2), Reassortant NWS-F, NR-9677.
[c] Organism obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Netherlands/2629/2009 (H1N1)pdm09, NR-19823.
[d] Organism obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Hong Kong/H090-761-V1(0)/2009 (H1N1)pdm09, NR-44345.
[e] Reported as Influenza A Equivocal or Influenza A (no subtype detected) at 3× LoD.
[f] Organism obtained through BEI Resources, NIAID, NIH: Influenza A Virus, A/Georgia/F32551/2012 (H1N1)pdm09, NR-42938.
[g] Human isolates of recent swine variant H3N2 viruses (H3N2v) were not available for testing, but reactivity near LoD is predicted by sequence analysis.
[h] Genomic RNA obtained through the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH: Genomic RNA from Influenza A Virus, A/Japan/305/1957 (H2N2), NR-2775.

[i] Genomic RNA obtained through the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH: Genomic RNA from Kilbourne F38: A/Korea/426/1968 (HA, NA) x A/Puerto Rico/8/1934 (H2N2), NR-9679.
[j] Isolate provided and tested by MRI Global, Kansas City, MO.
[k] Genomic RNA obtained through the NIH Biodefense and Emerging Infections Research Resources Repository NIAID, NIH: Genomic RNA from Kilbourne F181: A/duck/Singapore/645/1997 (H5N3), Wild Type, NR-9682.
[l] Genomic RNA obtained through the NIH Biodefense and Emerging Infections Research Resources Repository NIAID, NIH: Genomic RNA from Influenza A Virus, A/chicken/Germany/N/1949 (H10N7), NR-2765

Table 16. Influenza B Isolates Tested and Detected by FilmArray RP2

Lineage	Isolate ID/Source	[Strain/Location/Year]	xLoD Detected	Result
N/A	ATCC VR-101	[Lee/1940]	3x	Influenza B
	ATCC VR-102	[Allen/1945]	3x	
	ATCC VR-103	[GL/1739/1954]	3x	
	ATCC VR-296	[1/Maryland/1959]	3x	
	ATCC VR-295	[2/Taiwan/1962]	3x	
	ATCC VR-786	[Brigit/Russia/1969]	3x	
Victoria	ATCC VR-823	[5/Hong Kong/1972]	3x	
	Zeptometrix 0810258CF	[2506/Malaysia/2004]	3x	
	CDC 2005743348	[1/Ohio/2005]	3x	
Yamagata	Zeptometrix 0810256CF	[07/Florida/2004]	3x	
	Zeptometrix 0810255CF	[04/Florida/2006]	1x	
	Zeptometrix 0810241CF	[1/Wisconsin/2010]	3x	
	Zeptometrix 0810239CF	[2/Massachusetts/2012]	3x	

Table 17. Parainfluenza Virus Isolates Tested and Detected by FilmArray RP2

Type	Subtype	Isolate ID/Source	[Strain/Location/Year]	xLoD Detected	Result
1		Zeptometrix 0810014CF	-	1x	Parainfluenza Virus 1
		ATCC VR-94	[C-35/Washington DC/1957]	3x	
		BEI NR-3226[a]	[C39]	3x	
		BEI NR-48680[b]	[FRA/29221106/2009]	3x	
2		Zeptometrix 0810015CF	-	1x	Parainfluenza Virus 2
		ATCC VR-92	[Greer/Ohio/1955]	3x	
3		Zeptometrix 0810016CF	-	1x	Parainfluenza Virus 3
		ATCC VR-93	[C-243/Washington DC/1957]	3x	
		BEI NR-3233[c]	[NIH 47885, Wash/47885/57]	3x	
4	A	Zeptometrix 0810060CF	-	1x	Parainfluenza Virus 4
		ATCC VR-1378	[M-25/1958]	3x	
	B	Zeptometrix 0810060BCF	-	3x	
		ATCC VR-1377	[CH-19503/Washington DC/1962]	3x	

[a] Discontinued part number.
[b] Obtained through BEI Resources, NIAID, NIH: Human Parainfluenza Virus 1, HPIV1/FRA/29221106/2009, NR-48680.
[c] Obtained through BEI Resources, NIAID, NIH: Human Parainfluenza Virus 3, NIH 47885, NR-3233.

Table 18. Respiratory Syncytial Virus Isolates Tested and Detected by FilmArray RP2

Type	Source	[Strain/Location/Year]	xLoD Detected	Result
A	Zeptometrix 0810040ACF	[2006]	1x	Respiratory Syncytial Virus
	ATCC VR-26	[Long/Maryland/1956]	3x	
	ATCC VR-1540	[A2/Melbourne/1961]	3x	
B	Zeptometrix 0810040CF	[Ch-93 (18)-18]	3x	
	ATCC VR-1400	[WV/14617/1985]	3x	
	ATCC VR-955	[9320/Massachusetts/1977]	3x	
	ATCC VR-1580	[18537/Washington DC/1962]	10x	

Table 19. *Bordetella parapertussis* (and *Bordetella bronchiseptica*) Isolates Tested and Detected by FilmArray RP2

Species	Source	[Strain/Location/Year]	xLoD Detected	Result
Bordetella parapertussis	Zeptometrix 0801461	[A747]	1x	*Bordetella parapertussis* (IS*1001*)
	Zeptometrix 0801462	[E595]	3x	
	ATCC 15237	[NCTC 10853]	3x	
	ATCC 15311	[NCTC 5952]	3x	
	ATCC BAA-587	[12822/Germany/1993]	3x	
Bordetella bronchiseptica (containing IS*1001*)	NRRL B-59909	[MBORD849/ Pig/Netherlands]	3x	

[a] Reactivity with IS*1001* sequences in *B. bronchiseptica* represents the intended reactivity of the assay, however the analyte will be inaccurately reported as *B. parapertussis*. The assay does not react with IS*1001*-like sequences in *B. holmesii* (see *Analytical Reactivity*).

Table 20. *Bordetella pertussis* Isolates Tested and Detected by FilmArray RP2

Isolate ID/Source	[Strain]	xLoD Detected	Result
Zeptometrix 0801459	[A639]	1x	*Bordetella pertussis* (*ptxP*)
Zeptometrix 0801460	[E431]	3x	
ATCC 8467	[F]	3x	
ATCC 9340	[5,17921]	3x	
ATCC 9797	[18323/NCTC 10739]	3x	
ATCC 10380	[10-536]	3x	
ATCC 51445	[CNCTC Hp 12/63,623]	3x	
ATCC BAA-589	[Tohama]	3x	
ATCC BAA-1335	[MN2531]	3x	

Table 21. *Chlamydia pneumoniae* Isolates Tested and Detected by FilmArray RP2

Isolate ID/Source	[Strain/Location/Year]	xLoD Detected	Result
ATCC VR-2282	[TW-183/Taiwan/1965]	1x	*Chlamydia pneumoniae*
ATCC VR-1310	[CWL-029]	3x	
ATCC VR-1360	[CM-1/Georgia]	3x	
ATCC 53592	[AR-39/Seattle/1983]	3x	

Table 22. M*ycoplasma pneumoniae* Isolates Tested and Detected by FilmArray RP2

Type	Isolate ID/Source	[Strain]	xLoD Detected	Result
1	Zeptometrix 0801579	[M129]	1x	*Mycoplasma pneumoniae*
	ATCC 29342	[M129-B7]	3x	
	ATCC 29085	[PI 1428]	3x	
2	ATCC 15531	[FH strain of Eaton Agent [NCTC 10119]	3x	
	ATCC 15492	[Mac]	3x	
unknown	ATCC 15293	[M52]	3x	
	ATCC 15377	[Bru]	3x	
	ATCC 39505	[Mutant 22]	3x	
	ATCC 49894	[UTMB-10P]	3x	

Exclusivity

The potential for non-specific amplification and detection by the FilmArray RP2 assays was evaluated *in silico* by sequence analysis and testing of high concentrations of organisms in contrived samples. A total of 22 on-panel organisms were tested to assess the potential for intra-panel cross-reactivity and 50 off-panel organisms were tested to evaluate panel specificity. Off-panel organisms included normal respiratory flora and pathogens that may be present in NPS

specimens as well as near-neighbors or species genetically related to the organisms detected by the FilmArray RP2. The on-panel and off-panel organisms tested are shown in Table 23.

The final concentration of analyte in the sample (typically at least 1×10^6 CFU/mL for bacteria and fungi and at least 1×10^5 $TCID_{50}$/mL for viruses) represented levels ~70 - 400,000 fold higher than the LoD of the FilmArray RP2 assays. Some potential for intra-panel cross-reactivity with *Bordetella* species and Influenza A subtypes of swine origin was predicted by sequence analysis and observed when tested at high concentrations, as summarized in Table 24.

Table 23. Organisms Tested for Evaluation of FilmArray RP2 Analytical Specificity

Organisms with the potential for non-specific amplification by a FilmArray RP2 assay are shown in **bold**.

On-Panel Viruses			**On-Panel Bacteria**
Adenovirus	Human Rhinovirus	Influenza B	***Bordetella parapertussis***
Coronavirus 229 E	Human Metapneumovirus	Parainfluenza Virus 1	***Bordetella pertussis***
Coronavirus HKU1[a]	Influenza A H1N1	Parainfluenza Virus 2	*Chlamydia (Chlamydophila) pneumoniae*
Coronavirus NL63	Influenza A H3N2	Parainfluenza Virus 3	*Mycoplasma pneumoniae*
Coronavirus OC43	Influenza A H1N1pdm09	Parainfluenza Virus 4	
Enterovirus (Echovirus 6)	**Influenza A Hsw1N1**	Respiratory Syncytial Virus	
Off-Panel Bacteria			**Off-Panel Viruses**
Acinetobacter calcoaceticus	*Enterobacter aerogenes*	*Neisseria gonorrhoeae*	Bocavirus
Bordetella avium	*Escherichia coli*	*Neisseria meningitidis*	Cytomegalovirus (CMV)
Bordetella bronchiseptica	*Haemophilus influenzae*	*Proteus mirabilis*	Epstein-Barr Virus (EBV)
Bordetella hinzii	*Klebsiella oxytoca*	*Pseudomonas aeruginosa*	Herpes Simplex Virus 1
Bordetella holmesii	*Klebsiella pneumoniae*	*Serratia marcescens*	Measles Virus
Legionella bozemanii	*Lactobacillus acidophilus*	*Staphylococcus aureus*	Mumps
Legionella dumofii	*Lactobacillus plantarum*	*Staphylococcus epidermidis*	Middle East Respiratory Syndrome Coronavirus[b]
Legionella feeleii	*Moraxella catarrhalis*	*Stenotrophomonas maltophilia*	
Legionella longbeacheae	*Mycoplasma genitalium*	*Streptococcus pneumoniae*	**Off-Panel Fungi/Yeast**
Legionella micdadei	*Mycoplasma hominis*	*Streptococcus agalactiae*	*Candida albicans*
Legionella pneumophila	*Mycoplasma orale*	*Streptococcus pyogenes*	*Cryptococcus neoformans*
Chlamydia trachomatis	*Mycobacterium tuberculosis*	*Streptococcus salivarus*	*Aspergillus fumigatus*
Corynebacterium diphteriae	*Neisseria elongata*	*Ureaplasma urealyticum*	*Aspergillus flavus*

a Two different clinical specimens containing up to 8.9×10^8 RNA copies/mL of Coronavirus HKU1.

b Heat-inactivated viral culture obtained through BEI Resources, NIAID, NIH: Middle East Respiratory Syndrome Coronavirus (MERS-CoV), EMC/2012, Heat-Inactivated, NR-50171.

Table 24. Predicted and Observed Cross-Reactivity of the FilmArray RP2

Cross-reactive Organism(s)	FilmArrayRP2 Result	Description
Non-pertussis Bordetella species (e.g., Bordetella parapertussis Bordetella bronchiseptica[a])	***Bordetella pertussis* (*ptxP*)** [b,c]	The *Bordetella pertussis* (*ptxP*) assay can amplify pertussis toxin pseudogene sequences in *B. bronchiseptica* and *B. parapertussis* primarily when present at high concentration ((≥1.2E+09 CFU/mL).
Bordetella bronchiseptica[a] (with IS*1001* sequences)	***Bordetella parapertussis* (IS*1001*)**	Some strains of *B. bronchiseptica* carry IS*1001* insertion sequences identical to those carried by *B. parapertussis*. These sequences will be efficiently amplified by the IS1001 assay and reported by FilmArray RP2 as *Bordetella parapertussis* (IS*1001*).
Bordetella pertussis* *Bordetella parapertussis* *Bordetella bronchiseptica	**Human Rhinovirus/Enterovirus**[d,e]	The Human Rhinovirus/Enterovirus assay may amplify off-target sequences found in strains of B. pertussis, B. bronchiseptica, and B. parapertussis when present at high concentration. Cross-reactivity with *B. pertussis* was observed at a concentration of 4.5E+07 CFU/mL or higher.
Influenza A H1N1 (swine origin)	**Influenza A H1-2009**[f]	The Influenza A H1-2009 assay may react with H1 hemagglutinin gene sequences from viruses of swine origin. FilmArray RP2 will report either Influenza A H1 or Influenza A H1-2009, depending on the strain and concentration in the sample[f].

[a] *B. bronchiseptica* infection is rare in humans and more common in domesticated animals ('kennel cough').

[b] Cross-reactivity was observed only when tested at a high concentration (≥1.2E+09 CFU/mL).

[c] Cross-reactivity between the *Bordetella pertussis* (*ptxP*) assay and *B. parapertussis* will be reported as a co-detection (*Bordetella parapertussis* (IS*1001*) Detected and *Bordetella pertussis* (*ptxP*) Detected); while cross-reactivity with most strains of *B. bronchiseptica* (that do not carry IS*1001*) will be reported only as *Bordetella pertussis* (*ptxP*) Detected.

[d] Cross-reactivity with *B. pertussis* was observed when tested at a concentration of 4.5E+07 CFU/mL and higher. Cross-reactivity with *B. parapertussis* and *B. bronchiseptica* is predicted based on *in silico* analysis, but was not observed when tested at a concentration of 1.2E+09 CFU/mL.

[e] Cross-reactivity between the Human Rhinovirus/Enterovirus assays and *B. pertussis* or *B. parapertussis* will be reported as a co-detection (*Bordetella pertussis* (*ptxP*) Detected and Human Rhinovirus/Enterovirus Detected or *Bordetella parapertussis* (IS*1001*) Detected and Human Rhinovirus/Enterovirus Detected); while cross-reactivity with most strains of *B. bronchiseptica* (that do not carry IS*1001*) will be reported (falsely) only as Human Rhinovirus/Enterovirus Detected.

[f] Swine origin Hsw1N1 (A/New Jersey/8/1976 ; ATCC VR-897) was detected as either Influenza A H1 or Influenza A H1-2009 at a concentration of 8.9E+06 $CEID_{50}$/mL.

Interference

Potentially interfering substances that could be present in NPS specimens or introduced during specimen collection and testing were evaluated for their effect on FilmArray RP2 performance. Substances included endogenous substances that may be found in specimens at normal or elevated levels (e.g. blood, mucus/mucin, human genomic DNA), various commensal or infectious microorganisms, medications, washes or topical applications for the nasal passage, various swabs and transport media for specimen collection, and substances used to clean, decontaminate, or disinfect work areas.

Each substance was added to contrived samples containing representative organisms at concentrations near (2-3×) LoD. The concentration of substance added to the samples (Table 25) was equal to or greater than the highest level expected to be in NPS specimens.

None of the substances were shown to interfere with the FilmArray RP2 function. However, it was observed that exposure of samples to bleach prior to testing could damage the

organisms/nucleic acids in the sample, leading to inaccurate FilmArray RP2 test results (lack of analyte detection). The effect of bleach was dependent on the concentration and/or length of time the bleach was allowed to interact with the sample.

Table 25. Evaluation of Potentially Interfering Substances on the FilmArray RP2

Substance Tested	Concentration Tested	Result
Endogenous Substances		
Human Whole Blood	10% v/v	No Interference
Human Mucus (Sputum)	1 swab/mL sample	No Interference
Human Genomic DNA	20 ng/µL	No Interference
Competitive Microorganisms		
Coronavirus 229E	1.7E+04 $TCID_{50}$/mL	No Interference
Adenovirus A12	8.9E+05 $TCID_{50}$/mL	No Interference
Parainfluenza Virus 3	6.6E+05 $TCID_{50}$/mL	No Interference
Bordetella pertussis	5.8E+08 CFU/mL	No Interference
Enterovirus D68	1.6E+07 $TCID_{50}$/mL	No Interference
Echovirus 6	1.0E+07 $TCID_{50}$/mL	No Interference
Respiratory Syncytial Virus	4.2E+04 $TCID_{50}$/mL	No Interference
Staphylococcus aureus	2.5E+07 CFU/mL	No Interference
Streptococcus pneumoniae	1.7E+07 CFU/mL	No Interference
Haemophilus influenzae	6.2E+07 CFU/mL	No Interference
Candida albicans	1.0E+06 CFU/mL	No Interference
Herpes Simplex Virus 1	1.6E+06 $TCID_{50}$/mL	No Interference
Cytomegalovirus	1.2E+06 $TCID_{50}$/mL	No Interference
Exogenous Substances[a]		
Tobramycin (systemic antibiotic)	0.6 mg/mL	No Interference
Mupirocin (active ingredient in anti-bacterial ointment)	2% w/v	No Interference
Saline Nasal Spray with Preservatives (0.65% NaCl, Phenylcarbinol, Benzalkonium chloride)	1% v/v	No Interference
Nasal Decongestant Spray (Oxymetazoline HCl 0.05%, Benzalkonium chloride, phosphate)	1% v/v	No Interference
Analgesic ointment (Vicks®VapoRub®)	1% w/v	No Interference
Petroleum Jelly (Vaseline®)	1% w/v	No Interference
Snuff (Tobacco)	1% w/v	No Interference
Disinfecting/Cleaning Substances		
Bleach	1% and 2% v/v [up to 1024 ppm chlorine]	Interference[b]
Disinfecting wipes (ammonium chloride)	½ in^2	No Interference
Ethanol	7% v/v	No Interference
DNA*Zap* (Ambion™ AM9891G & AM9892G)	1% v/v	No Interference
RNase*Zap* (Ambion™ AM9782)	1% v/v	No Interference
Specimen Collection Materials		
Rayon Swabs (Copan 168C)	N/A	No Interference
Nylon Flocked Swabs (Copan 553C)	N/A	No Interference
Polyester Swabs (Copan 175KS01)	N/A	No Interference
Calcium Alginate Swabs (Puritan 25-801 A 50)	N/A	No Interference

Substance Tested	Concentration Tested	Result
M4® Transport Medium (Remel)	100%	No Interference
M4-RT® Transport Medium (Remel)	100%	No Interference
M5® Transport Medium (Remel)	100%	No Interference
M6™ Transport Medium (Remel)	100%	No Interference
Universal Viral Transport vial (BD)	100%	No Interference
Sigma-Virocult™ Viral Collection and Transport System (Swab and Transport Medium)	100%	No Interference
Copan ESwab™ Sample Collection and Delivery System (Swab and Liquid Amies Medium)	100%	No Interference

[a] Nasal influenza vaccines (e.g. FluMist) were not evaluated, but are predicted to be reactive with the FilmArray RP2 Influenza A (subtype) and Influenza B assays.
[b] Not Detected results were reported for several analytes after incubation of the sample with 2% bleach for 10 minutes or overnight. It was concluded that interference resulted primarily from damage to the organisms/nucleic acids in the sample, rather than inhibition or interference with pouch function(s).

Reproducibility

Reproducibility testing of contrived samples was performed at three test sites on a combination of FilmArray 2.0 and FilmArray Torch systems. The study incorporated a range of potential variation introduced by site, day, operator (at least two per site), system, instrument or Torch module (at least three per site/sample), and pouch lot (at least three). The samples contained various combinations of twelve different FilmArray RP2 analytes, each at three different concentrations (Negative, Low Positive (1×LoD), and Moderate Positive (3×LoD)). Frozen samples were repeatedly tested on five different days for 120 data points per sample (60 per system) over 480 total valid runs.

A summary of results (percent (%) agreement with the expected Detected or Not Detected result) for each analyte (by site and system) is provided in Table 26.

Table 26. Reproducibility of FilmArray RP2 Results on FilmArray Torch and FilmArray 2.0 Systems

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result						
			FilmArray Torch			FilmArray 2.0			All Sites/Systems (95% CI)
			Site A	Site C	System Sub-Total	Site B	Site C	System Sub-Total	
Viruses									
Adenovirus C2 ATCC VR-846	**Moderate Positive 3× LoD** 6.0E+00 $TCID_{50}$/mL (1.1E+02 copies/mL)	**Detected**	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**118/120 98.3%** (94.1%-99.8%)
	Low Positive 1× LoD 2.1E+00 $TCID_{50}$/mL (3.7E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**119/120 99.2%** (95.4%-100%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240 100%** (98.5%-100%)
Coronavirus 229E	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480 100%** (99.2%-100%)
Coronavirus HKU1	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480 100%** (99.2%-100%)

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result						
			FilmArray Torch			FilmArray 2.0			All Sites/Systems (95% CI)
			Site A	Site C	System Sub-Total	Site B	Site C	System Sub-Total	
Coronavirus OC43 ATCC VR-759	**Moderate Positive** **3× LoD** 9.0E+01 $TCID_{50}$/mL (1.7E+03 copies/mL)	**Detected**	**29/30** 96.7%	**29/30** 96.7%	**58/60** 96.7%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**117/120** **97.5%** (92.9%-99.5%)
	Low Positive **1× LoD** 3.0E+01 $TCID_{50}$/mL (5.6E+02 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**27/30** 90.0%	**57/60** 95.0%	**117/120** **97.5%** (92.9%-99.5%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Coronavirus NL63	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480** **100%** (99.2%-100%)
Human Metapneumovirus Type 16, A1 IA10-2003 Zeptometrix 0810161CF	**Moderate Positive** **3× LoD** 3.0E+01 $TCID_{50}$/mL (3.6E+03 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	Low Positive **1× LoD** 1.0E+01 $TCID_{50}$/mL (1.2E+03 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**28/30** 93.3%	**30/30** 100%	**58/60** 96.7%	**118/120** **98.3%** (94.1%-99.8%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Human Rhinovirus/ Enterovirus Rhinovirus 1A Zeptometrix 0810012CFN	**Moderate Positive** **3× LoD** 3.0E-01 $TCID_{50}$/mL (1.1E+02 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**28/30** 93.3%	**30/30** 100%	**58/60** 96.7%	**118/120** **98.3%** (94.1%-99.8%)
	Low Positive **1× LoD** 1.0E-01 $TCID_{50}$/mL (3.8E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Influenza A H3 Influenza A H3N2 A/Port Chalmers/1/73 ATCC VR-810	**Moderate Positive** **3× LoD** 3.0E-01 $TCID_{50}$/mL (6.3E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**119/120** **99.2%** (95.4%-100%)
	Low Positive **1× LoD** 1.0E-01 $TCID_{50}$/mL (2.1E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Influenza A H1-2009	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480** **100%** (99.2%-100%)

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result						
			FilmArray Torch			FilmArray 2.0			All Sites/Systems (95% CI)
			Site A	Site C	System Sub-Total	Site B	Site C	System Sub-Total	
Influenza A H1	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480** **100%** (99.2%-100%)
Influenza B B/FL/04/06 Zeptometrix 0810255CF	**Moderate Positive** **3× LoD** 1.5E+01 $TCID_{50}$/mL (1.0E+02 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	Low Positive **1× LoD** 5.0E+00 $TCID_{50}$/mL (3.4E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Parainfluenza Virus 1	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480** **100%** (99.2%-100%)
Parainfluenza Virus 2 Type 2 Zeptometrix 0810015CF	**Moderate Positive** **3× LoD** 1.5E+00 $TCID_{50}$/mL (9.0E+01 copies/mL)	**Detected**	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**118/120** **98.3%** (94.1%-99.8%)
	Low Positive **1× LoD** 5.0E-01 $TCID_{50}$/mL (3.0E+01 copies/mL)	**Detected**	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**30/30** 100%	**27/30** 90.0%	**57/60** 95.0%	**116/120** **96.7%** (91.7%-99.1%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Parainfluenza Virus 3	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480** **100%** (99.2%-100%)
Parainfluenza Virus 4 Type 4a Zeptometrix 0810060CF	**Moderate Positive** **3× LoD** 1.5E+02 $TCID_{50}$/mL (4.8E+03 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	Low Positive **1× LoD** 5.0E+01 $TCID_{50}$/mL (1.6E+03 copies/mL)	**Detected**	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**118/120** **98.3%** (94.1%-99.8%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240** **100%** (98.5%-100%)
Respiratory Syncytial Virus Type A Zeptometrix 0810040ACF	**Moderate Positive** **3× LoD** 6.0E-02 $TCID_{50}$/mL (2.7E+01 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120** **100%** (97.0%-100%)
	Low Positive **1× LoD** 2.0E-02 $TCID_{50}$/mL (9.0E+00 copies/mL)	**Detected**	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**30/30** 100%	**29/30** 96.7%	**59/60** 98.3%	**118/120** **98.3%** (94.1%-99.8%)

Analyte	Concentration Tested	Expected Result	Agreement with Expected Result						
			FilmArray Torch			FilmArray 2.0			All Sites/Systems (95% CI)
			Site A	Site C	System Sub-Total	Site B	Site C	System Sub-Total	
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240 100%** (98.5%-100%)
Bacteria									
Bordetella parapertussis (IS*1001*) A747 Zeptometrix 0801461	**Moderate Positive 3× LoD** 1.8E+02 IS*1001* copies/mL (1.2E+02 CFU/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**119/120 99.2%** (95.4%-100%)
	Low Positive 1× LoD 6.0E+01 IS*1001* copies/mL (4.1E+01 CFU/mL)	**Detected**	**24/30**[a] 80.0%	**29/30** 96.7%	**53/60**[a] 88.3%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**112/120 93.3%** (87.3%-97.1%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240 100%** (98.5%-100%)
Bordetella pertussis (ptxP) A639 Zeptometrix 0801459	**Moderate Positive 3× LoD** 3.0E+03 CFU/mL	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120 100%** (97.0%-100%)
	Low Positive 1× LoD 1.0E+03 CFU/mL	**Detected**	**28/30** 93.3%	**30/30** 100%	**58/60** 96.7%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**118/120 98.3%** (94.1%-99.8%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240 100%** (98.5%-100%)
Chlamydia (Chlamydophila) pneumoniae TW183 ATCC VR-2282	**Moderate Positive 3× LoD** 3.0E-01 $TCID_{50}$/mL (2.0E+02 copies/mL)	**Detected**	**30/30** 100%	**30/30** 100%	**60/60** 100%	**30/30** 100%	**30/30** 100%	**60/60** 100%	**120/120 100%** (97.0%-100%)
	Low Positive 1× LoD 1.0E-01 $TCID_{50}$/mL (6.6E+01 copies/ml)	**Detected**	**28/30** 93.3%	**30/30** 100%	**58/60** 96.7%	**29/30** 96.7%	**30/30** 100%	**59/60** 98.3%	**117/120 97.5%** (92.9%-99.5%)
	None (no analyte)	**Not Detected**	**60/60** 100%	**60/60** 100%	**120/120** 100%	**60/60** 100%	**60/60** 100%	**120/120** 100%	**240/240 100%** (98.5%-100%)
Mycoplasma pneumoniae	**None** (no analyte)	**Not Detected**	**120/120** 100%	**120/120** 100%	**240/240** 100%	**120/120** 100%	**120/120** 100%	**240/240** 100%	**480/480 100%** (99.2%-100%)
Overall Agreement with the Expected Result All Analytes and All Test Levels (95% Confidence Interval)			**9,562/9,600 99.6% (99.5% – 99.7%)**						

[a] Data from Site A were further reviewed by the unique site-specific variables including test day, Torch module, and operator. No correlation could be found between the Not Detected results and any one or more of these variables. The Not Detected results at Site A were found to be statistically non-significant (p>0.05 by Fisher's exact test) and therefore do not indicate a site- or system-dependent variance in precision of the FilmArray RP2 *Bordetella parapertussis* (IS*1001*) results.

The reproducibility (standard deviation) of melting temperature (Tm) for the amplification products generated by the FilmArray RP2 was also evaluated, with a Tm standard deviation for

each assay of ± 0.5°C or less observed within and between the FilmArray 2.0 and FilmArray Torch systems (Table 27).

Table 27. Reproducibility of Tm (°C) For Select FilmArray RP2 Assays on FilmArray Torch and FilmArray 2.0 Systems

Mean Tm values are calculated from a combination of Tm values obtained at the 3× LoD and 1× LoD concentrations.

Analyte	Assay	Tm Observed (°C)[a]									
		FilmArray Torch				FilmArray 2.0				All Sites/Systems	
		Site A		Site C		Site B		Site C			
		Mean	StDev	Mean	StDev	Mean	StDev	Mean	StDev	Mean	StDev
Controls	yeastRNA	**82.3**	± 0.3	**82.1**	± 0.2	**82.2**	± 0.3	**82.0**	± 0.2	**82.1**	± 0.3
	PCR2	**76.1**	± 0.2	**75.9**	± 0.2	**76.0**	± 0.2	**75.8**	± 0.2	**75.9**	± 0.2
VIRUSES											
Adenovirus C2 (ATCC VR-846)	Adeno2	**89.0**	± 0.2	**88.8**	± 0.1	**88.8**	± 0.3	**88.7**	± 0.2	**88.8**	± 0.2
	Adeno6	**89.6**	± 0.2	**89.4**	± 0.2	**89.4**	± 0.3	**89.2**	± 0.2	**89.4**	± 0.3
Coronavirus OC43 (ATCC VR-759)	CoV-OC43-2	**80.7**	± 0.2	**80.6**	± 0.1	**80.6**	± 0.3	**80.5**	± 0.2	**80.6**	± 0.2
Human Metapneumovirus (Zeptometrix 0810161CF)	hMPV	**78.2**	± 0.3	**78.0**	± 0.2	**78.0**	± 0.3	**77.8**	± 0.2	**78.0**	± 0.3
Rhinovirus (Zeptometrix 0810012CFN)	HRV/EV	**84.3**	± 0.2	**84.2**	± 0.2	**84.3**	± 0.3	**84.1**	± 0.2	**84.2**	± 0.2
Influenza A H3N2 (ATCC VR-810)	FluA-pan1	**84.2**	± 0.2	**84.0**	± 0.1	**84.0**	± 0.3	**83.8**	± 0.2	**84.0**	± 0.2
	FluA-pan2	**78.9**	± 0.2	**78.9**	± 0.1	**78.9**	± 0.2	**78.8**	± 0.2	**78.9**	± 0.2
	FluA-H3	**82.1**	± 0.2	**81.9**	± 0.2	**82.0**	± 0.3	**81.9**	± 0.2	**82.0**	± 0.2
Influenza B (Zeptometrix 0810255CF)	FluB	**80.4**	± 0.3	**80.3**	± 0.2	**80.4**	± 0.2	**80.2**	± 0.2	**80.3**	± 0.2
Parainfluenza virus 2 (Zeptometrix 0810015CF)	PIV2	**83.2**	± 0.2	**83.1**	± 0.2	**83.2**	± 0.2	**83.0**	± 0.2	**83.1**	± 0.2
Parainfluenza virus 4 (Zeptometrix 0810060CF)	PIV4	**77.1**	± 0.2	**77.0**	± 0.3	**77.2**	± 0.3	**77.0**	± 0.2	**77.1**	± 0.3
Respiratory Syncytial Virus (Zeptometrix 0810040ACF)	RSV	**81.2**	± 0.2	**81.1**	± 0.2	**81.1**	± 0.2	**81.0**	± 0.2	**81.1**	± 0.2
BACTERIA											
Bordetella parapertussis (Zeptometrix 0801461)	IS*1001*	**87.7**	± 0.2	**87.6**	± 0.2	**87.6**	± 0.3	**87.5**	± 0.2	**87.6**	± 0.2
Bordetella pertussis (Zeptometrix 0801459)	ptxP	**88.6**	± 0.2	**88.5**	± 0.2	**88.5**	± 0.3	**88.2**	± 0.2	**88.4**	± 0.3
Chlamydia pneumoniae (ATCC VR-2282)	Cpne	**79.6**	± 0.3	**79.5**	± 0.2	**79.5**	± 0.3	**79.3**	± 0.2	**79.5**	± 0.3

[a] Calculated from results at the 3× LoD and 1× LoD test concentrations combined.