K110764

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10 510(k) Summary

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Idaho Technology Inc.

Modification of
FilmArray RP Test System
To unmask results for PIV1, PIV2 and PIV4 assays in the FilmArray RP

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.

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Device Name and Classification:

Trade Name: FilmArray RP System

Regulation Number: 21 CFR 866.3980

Classification Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay

Predicate Device:

K063765, K081483, K091677 - Luminex® xTAG™ Respiratory Viral Panel (RVP).

Intended Use:

The FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with the FilmArray instrument for the simultaneous qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following virus types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus

HKU1, Coronavirus NL63, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza virus 3, Parainfluenza Virus 4, Rhinovirus/Enterovirus, and Respiratory Syncytial Virus. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. Negative results do not preclude respiratory infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. Positive results do not rule out bacterial infection or co-infection with other organisms. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory infection.

Due to seasonal prevalence, performance characteristics for Influenza A/H1, Influenza A/H3, Influenza A/2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4 were established primarily with retrospective clinical specimens.

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

The FilmArray RP detects Adenovirus species C serotype 2 and serotype 6 with reduced sensitivity. It is recommended that specimens found to be negative for Adenovirus after examination using FilmArray RP be confirmed by an alternate method (e.g. FDA-cleared molecular test or cell culture).

Performance characteristics for influenza A were established when influenza A/2009 H1N1, A/H1, and A/H3 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. 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 RP System is a multiplex nucleic acid test system composed of the FilmArray instrument, the FilmArray software (preinstalled on a laptop computer) and the FilmArray RP pouch. The FilmArray RP pouch contains freeze-dried reagents to perform nucleic acid purification, reverse transcription, and nested, multiplex PCR with DNA melt analysis. The Respiratory Panel (RP) pouch identifies 15 common and emerging viral respiratory pathogens (see Table 1).

Table 1. Viruses Detected by the FilmArray Respiratory Panel

Viral Respiratory Pathogens
Influenza A
H1 subtype
H3 subtype
2009 H1 subtype
Influenza B
Adenovirus
Coronavirus HKU1
Coronavirus NL63
Human Metapneumovirus
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus
Rhinovirus and Enterovirus

A test is initiated by loading Hydration Solution and an unprocessed patient nasopharyngeal swab (NPS) specimen (i.e. specimen mixed with Sample Buffer) into the FilmArray RP pouch. 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 reverse transcription reactions, the PCR reactions, and the melting curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical lysis and 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, Idaho Technology). This second master mix 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 second 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 melting curve analysis for the detection of signature amplicons denoting the presence of specific viral or bacterial targets A digital camera placed in front of the second stage PCR captures fluorescent images of the PCR reactions in real time.

The FilmArray software automatically interprets the results of each DNA melting 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 Luminex® xTAG™ RVP is a PCR-based system for detecting the presence of viral nucleic acid in nasopharyngeal swabs collected from individuals with signs and symptoms of respiratory illness. The similarities and differences between the xTAG RVP and the FilmArray RP are outlined below.

Table 2. Similarities between the xTAG RVP and the FilmArray RP

Element	FilmArray Respiratory Panel Test System	Luminex® xTAG™ RVP
Organisms Detected	Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Respiratory Syncytial Virus, human Metapneumovirus, Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, and Rhinovirus/Enterovirus	Same except the differences listed below
Analyte	RNA/DNA	Same
Technological Principles	multiplex nucleic acid	Same except the differences listed below
Specimen Types	Nasopharyngeal swabs	Same

Table 3. Differences between the xTAG RVP and the FilmArray RP

Element	FilmArray Respiratory Panel Test System	Luminex® xTAG™ RVP
Organisms Detected	Can distinguish Influenza A subtype 2009 H1 from Influenza A subtype H1. Also detects Coronavirus NL63, Coronavirus HKU1, and Parainfluenza 4.	Can distinguish Respiratory Syncytial Virus Type A from Respiratory Syncytial Virus Type B.
Technological Principles	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product.	Multiplex RT-PCR and multiplex TSPE followed by Fluorescence-activated sorting of labeled beads coupled to streptavidin-conjugated biotinylated products
Instrumentation	FilmArray Instrument	PCR Thermocycler Luminex® 100 IS or 200 system
Time to result	Less than 1 hour	Approximately 8 hours
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Semi-automated test interpretation. User must review all "no call" results to determine cause and retesting strategy.
Sample Preparation Method	Sample Processing is automated in the FilmArray instrument.	Up front sample processing is required to extract nucleic acid.
Reagent Storage	Reagents are stored at room temperature.	Reagents stored at 4°C and -20°C.
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Internal control added to each sample. External control processed with each batch of samples.
User Complexity	Moderate/Low	High

Summary of Performance Data for Parainfluenza Viruses 1, 2 and 4

The purpose of this 510(k) is to support unmasking of test results for the Parainfluenza Virus 1, 2 and 4 assays that are part of the FilmArray RP. Refer to the 510k summary for K103175 for performance data of the previously cleared assays (Adenovirus, Coronavirus HKU1, Coronavirus NL63, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 3, Rhinovirus/Enterovirus, and Respiratory Syncytial).

Clinical Performance

The clinical performance of the FilmArray RP system for Parainfluenza Viruses 1, 2, and 4 was established during a prospective study at 3 U.S. clinical sites where enrollment spanned an 11 month time period encompassing two respiratory seasons (December 2009 - May 2010 and September 2010 – January 2011). Subjects with signs and/or symptoms of respiratory infection were invited to participate. Upon obtaining informed consent, NPS samples were collected for FilmArray and comparator testing; a second respiratory

sample was collected from each subject for viral culture reference testing. A total of 1144 subjects were initially enrolled in the study (857, at 3 sites, between December 2009 and May 2010; 287, at 2 sites, between September 2010 and January 2011) and four were withdrawn. Specimens from 20 subjects were omitted from analysis due to improper storage prior to testing; and 3 specimens were omitted due to the lack of valid external control mix results on the day of testing. Table 4, provides a summary of demographic information for the remaining 1117 subjects that participated in the prospective study.

Table 4. Demographic Summary for FilmArray RP Prospective Study (All Specimens Analyzed for PIV1, PIV2, and PIV4)

Sex	Number of Subjects
Male	600 (54%)
Female	517 (46%)
Age	
≤5	724 (65%)
6-21	119 (11%)
22-49	190 (17%)
≥50	84 (8%)

Each NPS specimen was tested with the FilmArray RP. The performance of the FilmArray RP for Parainfluenza Viruses 1, 2, and 4 was evaluated by comparing the FilmArray RP test result for each virus with the appropriate comparator/reference methods shown in Table 5.

Table 5. Reference/Comparator Methods Used to Assess FilmArray RP Performance

Organism/Virus	Reference/Comparator Method(s)
Parainfluenza Virus 1	Viral culture followed by DFA identification[1]
Parainfluenza Virus 2	
Parainfluenza Virus 4	1 PCR test of viral culture with bi-directional sequence confirmation[2]

[1] Performance of the FilmArray RP system detecting Parainfluenza Virus 1 and Parainfluenza Virus 2 was compared to viral culture followed by fluorescent antibody identification. "True" Parainfluenza Virus 1or Parainfluenza Virus 2, positives, were considered as any sample that tested positive for Parainfluenza Virus 1 or Parainfluenza virus 2 by viral culture followed by DFA testing. "True" Parainfluenza Virus 1 or Parainfluenza Virus 2 negatives were considered as any sample that tested negative for Parainfluenza Virus 1 or Parainfluenza Virus 2, by viral culture followed by DFA testing.

[2] Performance of the FilmArray RP system detecting Parainfluenza Virus 4 was compared to viral culture followed by one analytically validated PCR assay with bi-directional sequence confirmation. The comparator assay was designed to amplify a different sequence from that amplified by the FilmArray assay. "True" Parainfluenza Virus 4 positives were considered as any sample that had bi-directional sequencing data meeting pre-defined quality acceptance criteria that matched Parainfluenza Virus 4 sequences deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov) with acceptable E-values, when tested from viral culture material. "True" Parainfluenza Virus 4 negatives were considered as any sample for which viral culture material tested negative for Parainfluenza Virus 4 by the specific comparator PCR assay.

A total of 1117 specimens were evaluated for Parainfluenza Viruses 1, 2, and 4 in this study. Clinical sensitivity or positive percent agreement (PPA) was calculated as 100% x (TP / TP + FN). True positive (TP) indicates that both the FilmArray RP and comparator method had a positive result for this specific analyte and false negative (FN) indicates that the FilmArray result was negative while the comparator result was positive. Specificity was calculated as 100% x (TN / TN + FP). True negative (TN) indicates that both the FilmArray RP and the comparator method had negative results and a false positive (FP) indicates that the FilmArray RP result was positive but the comparator results was negative. The exact binomial two-sided 95% confidence interval was calculated. The results are summarized in Table 6.

Table 6. Clinical Sensitivity and Specificity for the FilmArray RP Prospective Clinical Study

	Sensitivity		95% CI	Specificity		95% CI
Parainfluenza Virus 1	1/1	100%	n/a	1115/1116[a]	99.9%	99.5 – 100%
Parainfluenza Virus 2	7/8[b,d]	87.4%	47.4 – 99.7%	1107/1109[c,d]	99.8%	99.4 – 100%
Parainfluenza Virus 4	9/9	100%	66.4 -100%	1107/1108[e]	99.9%	99.5 – 100%

[a] PIV1 was identified in this specimen using bi-directional sequence analysis.
[b] PIV2 Virus was not detected in the single false negative specimen using PCR analysis.
[c] PIV2 Virus was detected in both false positive specimens using bi-directional sequencing analysis.
[d] Two adjacent specimens (one false positive and one false negative) may have been switched during the viral culture reference method testing as is evidenced by bi-directional sequence analysis of these specimens.
[e] A PIV4 Virus was detected in this false positive NPS specimen by bi-directional sequence analysis although it was not detected from viral culture.

A total of 103 co-infections (9% of all analyzed specimens; 103/1117) were detected by FilmArray during this study. The FilmArray detected 6 co-infections involving PIV1, 2, or 4 (Table 7), representing approximately 6% of all co-infections detected (6/103).

Table 7. Co-infections Involving Parainfluenza Viruses 1, 2, or 4 as Detected by FilmArray RP.

Distinct Co-infection Combinations Detected by FilmArray RP		Total Co-infections	Number of Discrepant Co-infections[a]	Discrepant Analyte(s)[a]
Analyte 1	**Analyte 2**			
hMPV	PIV 4	1	1	hMPV (1)
HRV/Entero	PIV 1	1	1	PIV 1 (1)[b]
HRV/Entero[a]	PIV 2	1	0	-
HRV/Entero[a]	PIV 4	3	0	-
Total Co-infections		6	**Total Analytes in 6 Co-infections = 12**	

a. HRV/Entero was not analyzed by a comparator method for the single HRV/Entero + PIV2 co-infection, or 1/3 of the HRV/Entero + PIV4 co-infections due to the HRV/Entero analyte being cleared (k103175) prior to testing of these specimens.
b. PIV1 virus was detected in this specimen using bi-directional sequence analysis.

Table 8 provides a summary of the FilmArray RP test results for PIV1, PIV2, and PIV4 obtained during this study, including the prevalence of each organism detected by the FilmArray RP System and distribution among the age groups. The majority of Parainfluenza 1, 2, and 4 Viruses were detected in children five years and younger (90%; 19/21). A single PIV1 and a single PIV4 were also detected in older children.

Table 8. Prevalence and Age Distribution of Analytes in the Clinical Study

Analyte	Total (Prevalence)	≤ 5 years	6-21 years	22-49 years	≥ 50 years
Parainfluenza Virus 1	2 (0.2%)	1	1	0	0
Parainfluenza Virus 2	9 (0.8%)	9	0	0	0
Parainfluenza Virus 4	10 (0.9%)	9	1	0	0

All three viruses were of low prevalence during the clinical study (0.2 – 0.9%). To supplement the results of the prospective clinical study, an evaluation of preselected archived samples was performed.

Testing of Preselected Archived Specimens

In addition to the prospective clinical study, archived clinical NPS specimens were also tested using the FilmArray RP. The specimens were selected because they had previously tested positive for Parainfluenza Virus 1, 2, or 4, or had been negative for these viruses by previous testing methods. Prior to testing with the FilmArray RP, the presence or absence of the analyte of interest was confirmed in each specimen using analyte specific PCR and bi-directional sequencing. Of 168 specimens, 147 were confirmed to contain the analyte of interest (or lack thereof for negative specimens). The specimens were organized into "test panels" and randomized such that the users testing the samples with the FilmArray RP were blinded as to the expected test result. Each panel contained specimens known to be positive and negative for the specific analyte being evaluated allowing the calculation of a positive percent agreement (PPA) and a negative percent agreement (NPA). A summary of the available demographic information of the tested samples is provided in Table 9 and the results of the FilmArray testing are presented in Table 10.

Table 9. Demographic Summary of FilmArray RP Archived Specimen Study

Total Specimens		147
Sex	Female (%)	46 (31.3%)
	Male (%)	49 (33.3%)
	Unknown	52 (35.4%)
Age	Avg	10.6
	Median	1.0
	Min	0.5
	Max	81.0
Age Range	≤5	75 (51%)
	6-21	5 (3.4%)
	22-49	5 (3.4%)
	≥50	10 (6.8%)
	Unknown[a]	52 (35.4%)

[a] Demographic information was not provided for specimens from one source. Because the specimens were provided by a pediatric hospital, it is understood that the age range of specimens was from <1 yrs to 21 yrs.

Table 10. FilmArray Archived Specimen Performance Data Summary for Parainfluenza Virus 1, 2, and 4

	Positive Percent Agreement (PPA)			Negative Percent Agreement (NPA)		
	TP/TP +FN	Percent	95% CI	TN/TN+FP	Percent	95% CI
PIV1	34/35	97.1%	85.1 - 99.9%	94/94	100.0%	96.2 - 100%
PIV2	28/28	100.0%	87.6 - 100%	101/101	100.0%	96.4 - 100%
PIV4	11/11	100.0%	71.5 - 100%	6/6	100.0%	54.1 - 100%

Selected Analytical Studies

Limit of Detection

The analytical sensitivity or Limit of Detection (LoD) for each FilmArray RP analyte (except for Coronavirus HKU1) was determined by testing limiting dilutions of live, quantified viruses. LoD is defined as the lowest concentration at which the analyte is consistently detected (detection in ≥95% of samples tested). Simulated NPS sample matrix (cultured human cells in VTM) was spiked with one or more analytes and at least 20 replicates were tested at the LoD concentration. The LoD for the FilmArray RP analytes Parainfluenza Viruses 1, 2, and 4 are listed in Table 11.

Table 11. LoD for Analytes Detected by FilmArray RP

Organism	Strain	Limit of Detection
Parainfluenza Virus 1	Type 1	500 $TCID_{50}$/mL
Parainfluenza Virus 2	Type 2	10 $TCID_{50}$/mL
Parainfluenza Virus 4	Type 4A	5000 $TCID_{50}$/mL

NOTE: Most analytes were re-grown and quantified in $TCID_{50}$ (50% Tissue Culture Infectious Dose). The unit $TCID_{50}$ is a measure of infectivity or cytotoxicity rather than number of organisms or copies of nucleic acid. Variability in $TCID_{50}$/mL may not accurately reflect differences in the relative sensitivity of detection between different organisms or different strains of the same organism.

Analytical Reactivity (Inclusivity)

The analytical reactivity of the FilmArray RP system assays was evaluated with an inclusivity panel consisting of 108 strains or isolates that represent the genetic, temporal, and geographic diversity of the FilmArray RP analytes. The tested organisms include: 17 Adenovirus, 4 Coronavirus (3 HKU1 and 1 NL63), 10 human Metapneumovirus, 12 Enterovirus, 14 Rhinovirus, 22 Influenza A (including 10 Influenza A/H1, 3 Influenza A/2009 H1 and 9 Influenza A/H3), 11 Influenza B, 3 Parainfluenza Viruses 1, 2 Parainfluenza Viruses 2, 3 Parainfluenza Viruses 3, 4 Parainfluenza Viruses 4 and 6 Respiratory Syncytial Virus. Each organism was initially tested in a simulated NPS sample matrix at or near the system LoD. Higher concentrations were tested if the analyte was not detected at LoD.

Results from inclusivity testing of Parainfluenza Viruses 1, 2, and 4 are presented below. The concentration and multiple of LoD at which each strain was detected by the FilmArray RP system is indicated.

Table 12. Results of Inclusivity Testing for Parainfluenza Viruses 1, 2 and 4

Type	Strain or Source	Concentration Detected	Multiple of LoD Detected
1	Zeptometrix #0810014CF	500	1x
	C-35 ATCC VR-94	500	1x
	C39 BEI NR-3226	500	1x
2	Zeptometrix #0810015CF	10	1x
	Greer ATCC VR-92	10	1x
4A	M25 ATCC VR-1378	5000 TCID50/mL	1x
	Zeptometrix #0810060CF	5000 TCID50/mL	1x
4B	CH-19503 ATCC VR-1377	5000 TCID50/mL	1x
	Zeptometrix #08010060BCF	5000 TCID50/mL	1x

Analytical Specificity (Cross-reactivity and Exclusivity)

The potential for cross-reactivity between assays contained in the FilmArray RP system was evaluated by testing simulated NPS samples containing high concentrations of respiratory panel viruses (tens to thousands-fold higher than LoD). No cross-reactivity was observed at the concentrations listed in **Error! Reference source not found.**13.

Table 13. Results of Testing for Cross-Reactivity with FilmArray RP Analytes

Virus or Bacterium	Type / Strain	Test Concentration	Multiple of LoD
Adenovirus	**Serotype 1** (Species C)	1.00×10^5 $TCID_{50}$/mL	333 x
Coronavirus	**HKU1 – Type B** Clinical specimen	2.78×10^9 copies/mL	1,463 x
	NL63 NR-470	5.67×10^3 TCID50/mL	1,134 x
Human Metapneumovirus	**Type A1 - hMPV-16** IA10-2003 A1	8.17×10^3 $TCID_{50}$/mL	4,085 x
Human Rhinovirus / Enterovirus	**Echovirus 6**	3.40×10^6 $TCID_{50}$/mL	113 x
	Rhinovirus A1	5.67×10^3 TCID50/mL	5,670 x
Influenza A H1N1	**A/Brisbane/59/07**	1.00×10^5 $TCID_{50}$/mL	500 x
	A/New Caledonia/20/99	1.00×10^5 $TCID_{50}$/mL	500 x
	A/PR/8/34	1.00×10^6 $TCID_{50}$/mL	5,000 x
	A1/FM/1/47	4.70×10^3 $TCID_{50}$/mL	24 x
	A/NWS/33	4.70×10^3 $TCID_{50}$/mL	24 x
	A1/Denver/1/57	4.70×10^3 $TCID_{50}$/mL	24 x
	A/Solomon Islands/3/2006	1.39×10^4 $TCID_{50}$/mL	70 x
	A/Weiss/43	4.70×10^3 $TCID_{50}$/mL	24 x
	A/Mal/302/54	1.39×10^4 $TCID_{50}$/mL	70 x
Influenza A H1N1-2009	**A/SwineNY/03/2009**	4.00×10^5 $TCID_{50}$/mL	4,000 x
Influenza A H3N2	**A/Wisconsin/67/2005**	8.17×10^3 $TCID_{50}$/mL	1634 x
	A/Victoria/3/75	4.70×10^3 $TCID_{50}$/mL	940 x
	A/Port Chalmers/1/73	5.67×10^3 $TCID_{50}$/mL	1,134 x
	A/Aichi/2/68	1.00×10^5 $TCID_{50}$/mL	20,000 x
	A/Hong Kong/8/68	1.00×10^5 $TCID_{50}$/mL	20,000 x
	A/Alice	4.70×10^3 $TCID_{50}$/mL	940 x
	A/MRC 2	8.17×10^3 $TCID_{50}$/mL	1,634 x
	A/Brisbane/10/07	8.17×10^3 $TCID_{50}$/mL	1,634 x
Influenza B	**B/FL/04/06**	1.67×10^4 $TCID_{50}$/mL	278 x
	B/Lee/40	8.17×10^3 $TCID_{50}$/mL	136 x
	B/Taiwan/2/62	5.03×10^4 $TCID_{50}$/mL	838 x
	B/GL/1739/54	8.17×10^3 $TCID_{50}$/mL	136 x
	B/Maryland/1/59	8.17×10^3 $TCID_{50}$/mL	136 x

Virus or Bacterium	Type / Strain	Test Concentration	Multiple of LoD
	B/Florida/07/04	$1.00x10^5$ $TCID_{50}$/mL	1,667 x
	B/Malaysia/2506/04	$5.67x10^3$ $TCID_{50}$/mL	95 x
	B/Allen/45	$1.00x10^5$ $TCID_{50}$/mL	1,667 x
	B/HongKong/5/72	$8.17x10^3$ $TCID_{50}$/mL	136 x
	B/Brigit	$3.50x10^4$ $TCID_{50}$/mL	583 x
Parainfluenza Virus	**Type 1** Zeptometrix # 0810014CF	1.39E+04 $TCID_{50}$/mL	28 x
	Type 2 Zeptometrix # 0810015CF	1.67E+04 $TCID_{50}$/mL	1,670 x
	Type 3 Zeptometrix # 0810016CF	$1.00x10^5$ $TCID_{50}$/mL	10,000 x
	Type 4 Zeptometrix #0810060CF	$5.67x10^3$ $TCID_{50}$/mL[a]	1.13 x[a]
Respiratory Syncytial Virus	**A**	$1.39x10^4$ $TCID_{50}$/mL	6,950 x
	B	$2.14x10^4$ $TCID_{50}$/mL	10,700 x

[a] Highest test concentration possible based on the concentration of virus in the stock culture fluid.

The potential for the FilmArray RP system to cross-react with non-FilmArray RP organisms was evaluated by testing an exclusivity panel consisting of 45 bacteria, 10 viruses, and 1 fungus. These organisms were selected based on their relatedness to FilmArray RP analytes, clinical relevance (cause respiratory symptoms or represent nasopharyngeal flora), or high prevalence within the population (e.g. Herpes Simplex Virus). Negative sample matrix was spiked with bacteria or fungi at a concentration of 10^6 CFU/mL and viruses at a concentration between 10^4 - 10^5 $TCID_{50}$/mL, or the highest concentration possible. The FilmArray RP system did not cross-react with the exclusivity panel organisms listed in Table 25. One measles virus strain was found to contain Adenovirus, which was detected by the FilmArray RP.

Table 14. Non-FilmArray RP Exclusivity Panel

Bacteria	Strain / Isolate	Viruses	Strain / Isolate
Bordetella bronchiseptica	clinical isolate	Bocavirus	Type 1 - Clinical specimen
Bordetella holmesii	F061	Coronavirus 229E	ATCC VR-740
Bordetella parapertussis	A747	Coronavirus SARS	Zeptometrix –Nucleic Acid
Bordetella pertussis	E431	Coronavirus OC43	ATCC VR-759
Bordetella pertussis	A639	Cytomegalovirus (CMV)	AD-169 (VR-538)
Bordetella pertussis	ATCC 8467	Epstein-Barr Virus (EBV)	B95-8
Bordetella pertussis	ATCC 9797	Herpes Simplex Virus	Type 1
Bordetella pertussis	ATCC 51445	Measles Virus	Edmonston
Bordetella pertussis	ATCC BAA-589	Measles Virus	Zeptometrix # 0810025CF[a]
Bordetella pertussis	ATCC 9340	Mumps	Zeptometrix # 0810079CF
Bordetella pertussis	ATCC 10380	**Fungi**	**Strain / Isolate**
Bordetella pertussis	ATCC BAA-1335	*Candida albicans*	Zeptometrix #0801504

Bacteria	Strain / Isolate	Viruses	Strain / Isolate
Chlamydia trachomatis	D-UW3		
Chlamydophila pneumoniae	TW183		
Corynebacterium diptheriae	ATCC14779		
Escherichia coli	O157:H7		
Haemophilus influenzae	MinnA		
Lactobacillus acidophilus	Type strain		
Lactobacillus plantarum	17-5		
Legionella longbeacheae	Long Beach 4		
Legionella micdadei	Tatlock		
Legionella pneumophilia	Philadelphia		
Moraxella catarrhalis	Ne 11 (type strain)		
Mycobacterium tuberculosis	H37Ra-1		
Mycoplasma hominis	ATCC 23114		
Mycoplasma genitalium	ATCC 33530		
Mycoplasma pneumoniae	M129		
Mycoplasma pneumoniae	ATCC 15531		
Mycoplasma pneumoniae	ATCC 15293		
Mycoplasma pneumoniae	ATCC 15377		
Mycoplasma pneumoniae	ATCC 15492		
Mycoplasma pneumoniae	ATCC 29085		
Mycoplasma pneumoniae	ATCC 29342		
Mycoplasma pneumoniae	ATCC 39505		
Mycoplasma pneumoniae	ATCC 49894		
Neisseria elongata	type strain		
Neisseria gonorrhoeae	ATCC 700825		
Neisseria meningitidis	M1027 (type strain)		
Pseudomonas aeruginosa	Zeptometrix #0801519		
Staphylococcus aureus	COL		
Staphylococcus epidermidis	RP62A		
Streptococcus pneumoniae	type 59		
Streptococcus pyogenes	Zeptometrix #0801512		
Streptococcus salivarius	ATCC 13419		
Ureaplasma urealyticum	ATCC 27618		

[a]This viral stock produced one false positive Adenovirus result. The false positive was confirmed to be caused by Adenovirus contamination of the viral stock and was not due to cross-reactivity between the Adenovirus assay and Measles virus.

Supplemental Analytical Exclusivity Testing for Influenza Strains of Avian Origin:

Additional analytical exclusivity testing was carried out with either live isolates or purified genomic RNA of avian host influenza A strains with the following results:

Table 15. Results of Exclusivity Testing of Virus or Nucleic Acid from Culture of Avian Influenza A

Host	Subtype	Isolate / Strain	Test Concentration [a]	FilmArray Result
Avian	H2N2	A/Japan/305/57	3.3 ng RNA	Influenza A (no subtype detected)
		Kilbourne F38 A/Korea/426/68 (HA, NA) x A/Puerto Rico/8/34	6.3 ng RNA	
	H5N1	A/Vietnam/1203/2004 R-H5	N/A [b]	
	H5N2	A/duck/Pennsylvania/10218/84	2.5 ng RNA	
	H5N3	Kilbourne F181 A/duck/Singapore/645/97	247 ng RNA	
	H7N2	A/NewYork/107/2003	N/A [b]	
	H7N3	A/Mallard/Netherlands/12/2000	N/A [b]	
	H10N7	A/chicken/Germany/N/49	68 ng RNA	

[a] Purified and quantified RNA from avian influenza cultures was obtained from BEI Resources

[b] Stock virus HA titre from CDC = 128. Twenty microliters of virus stock tested.

Precision (Reproducibility)

A multicenter reproducibility study was performed to determine between-site and overall reproducibility of the FilmArray RP system.

Reproducibility testing occurred at three test sites utilizing a panel of twelve simulated NPS specimens spiked with various combinations of live respiratory pathogens (analytes) at three different test levels (high negative (LoD/10), low positive (1X LoD), and medium positive (3X LoD)). On each testing day, two operators at each site tested two aliquots of specimens on two different FilmArray instruments (six specimens per operator per instrument per day). Every specimen was tested four times a day on five days at the three testing sites, for a total of 60 tests per analyte per concentration. A total of 26 lots of reagents and 20 FilmArray instruments were utilized in the reproducibility study. Summary results for each analyte are summarized below.

Results for Parainfluenza Viruses 1, 2, and 4 are summarized below:

Table 16. Summary of Positive Agreement, Negative Agreement, and Tm Results from Reproducibility Testing of Parainfluenza Virus 1

Parainfluenza Virus 1 Zeptometrix # Z0810014CFN		**# Positive**	**# Negative**	**% Agreement with Expected Result[a]**	**95% CI**	**Mean Tm**	**%CV Tm**	**Observed Tm Range**
Medium Positive (3x LoD) 1500 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	78.86	0.26	78.42 - 79.25
	Site B	20/20	0/20	100%	83.2% – 100%	79.32	0.28	78.83 - 79.78
	Site C	19/20	1/20	95.0%	75.1% - 99.9%	78.50	0.28	78.02 - 78.87
	All Sites	**59/60**	**1/60**	**98.3%**	**91.1% - 100%**	**78.91**	**0.50**	**78.02 - 79.78**
Low Positive (1x LoD) 500 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	78.60	0.31	77.99 - 79.05
	Site B	20/20	0/20	100%	83.2% – 100%	78.93	0.26	78.31 - 79.36
	Site C	20/20	0/20	100%	83.2% – 100%	78.50	0.38	77.90 - 79.16
	All Sites	**60/60**	**0/60**	**100%**	**94.0% - 100%**	**78.67**	**0.40**	**77.90 - 79.36**
High Negative[b] (LoD/10) 50 $TCID_{50}$/mL	Site A	15/20	5/20	75.0%	50.1% - 91.3%	78.54	0.25	78.10 - 78.94
	Site B	15/20	5/20	75.0%	50.1% - 91.3%	78.94	0.25	78.52 - 79.36
	Site C	13/20	7/20	65.0%	41.0% - 84.6%	78.41	0.35	77.87 - 79.02
	All Sites	**43/60**	**17/60**	**71.7%**	**58.6% - 82.6%**	**78.61**	**0.42**	**77.79 - 79.36**
Negative	Site A	0/180	180/180	100.0%	98.0% - 100%			
	Site B	0/180	180/180	100.0%	98.0% - 100%			
	Site C	0/180	180/180	100.0%	98.0% - 100%			
	All Sites	**0/540**	**540/540**	**100.0%**	**99.3% – 100%**			

[a] Expected results for the "Medium Positive", the "Low Positive", and the "High Negative" panel members are positive. Expected result for the "Negative" panel member is negative. [b] High negative samples are targeted to be positive 20-80% of the time.

Table 17. Summary of Positive Agreement, Negative Agreement, and Tm Results from Reproducibility Testing of Parainfluenza Virus 2

Parainfluenza Virus 2 Zeptometrix #0810015CF		# Positive	# Negative	% Agreement with Expected Result[a]	95% CI	Mean Tm	%CV Tm	Observed Tm Range
Medium Positive (3x LoD) 30 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	83.63	0.36	83.01 - 84.39
	Site B	20/20	0/20	100%	83.2% – 100%	84.06	0.40	83.44 - 84.79
	Site C	20/20	0/20	100%	83.2% – 100%	83.88	0.32	83.13 - 84.28
	All Sites	**60/60**	**0/60**	**100%**	**94.0% - 100%**	**83.85**	**0.42**	**83.01 - 84.79**
Low Positive (1x LoD) 10 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	83.56	0.28	82.94 - 84.08
	Site B	20/20	0/20	100%	83.2% – 100%	84.00	0.31	83.52 - 84.63
	Site C	20/20	0/20	100%	83.2% – 100%	83.79	0.32	82.92 - 84.25
	All Sites	**60/60**	**0/60**	**100%**	**94.0% - 100%**	**83.78**	**0.37**	**82.92 - 84.63**
High Negative[b] (LoD/10) 1 $TCID_{50}$/mL	Site A	12/20	8/20	60.0%	36.1% - 80.9%	83.43	0.34	82.71 - 83.96
	Site B	12/20	8/20	60.0%	36.1% - 80.9%	83.91	0.31	83.43 - 84.56
	Site C	11/20	9/20	55.0%	31.5% - 76.9%	83.71	0.36	82.91 - 84.30
	All Sites	**35/60**	**25/60**	**58.3%**	**44.9% - 70.9%**	**83.69**	**0.41**	**82.71 - 84.56**
Negative	Site A	0/180	180/180	100.0%	98.0% - 100%			
	Site B	0/180	180/180	100.0%	98.0% - 100%			
	Site C	0/180	180/180	100.0%	98.0% - 100%			
	All Sites	**0/540**	**540/540**	**100.0%**	**99.3% – 100%**			

[a] Expected results for the "Medium Positive", the "Low Positive", and the "High Negative" panel members are positive. Expected result for the "Negative" panel member is negative. [b] High negative samples are targeted to be positive 20-80% of the time.

Table 18. Summary of Positive Agreement, Negative Agreement, and Tm Results from Reproducibility Testing of Parainfluenza Virus 4

Parainfluenza Virus 4a Zeptometrix #0810060CF		# Positive	# Negative	% Agreement with Expected Result[a]	95% CI	Mean Tm	%CV Tm	Observed Tm Range
Medium Positive (3x LoD) 15,000 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	77.70	0.30	77.36 - 78.10
	Site B	20/20	0/20	100%	83.2% – 100%	78.09	0.56	77.48 - 78.74
	Site C	20/20	0/20	100%	83.2% – 100%	77.73	0.40	77.05 - 78.21
	All Sites	**60/60**	**0/60**	**100%**	**94.0% - 100%**	77.82	0.47	77.05 - 78.74
Low Positive (1x LoD) 5,000 $TCID_{50}$/mL	Site A	20/20	0/20	100%	83.2% – 100%	77.11	0.28	76.64 - 77.68
	Site B	20/20	0/20	100%	83.2% – 100%	77.65	0.41	76.73 - 78.71
	Site C	20/20	0/20	100%	83.2% – 100%	77.23	0.38	76.81 - 78.20
	All Sites	**60/60**	**0/60**	**100%**	**94.0% - 100%**	77.33	0.46	76.64 - 78.71

Parainfluenza Virus 4a Zeptometrix #0810060CF		# Positive	# Negative	% Agreement with Expected Result[a]	95% CI	Mean Tm	%CV Tm	Observed Tm Range
High Negative[b] (LoD/10) 500 $TCID_{50}$/mL	Site A	4/20	16/20	20.0%	5.7% - 43.7%	77.07	0.26	76.63 - 77.58
	Site B	5/20	15/20	25.0%	8.7% - 49.1%	77.59	0.27	77.05 - 78.00
	Site C	11/20	9/20	55.0%	31.5% - 76.9%	77.24	0.30	76.62 - 77.84
	All Sites	**20/60**	**40/60**	**33.3%**	**21.7% - 46.7%**	77.29	0.40	76.62 - 78.00
Negative	Site A	0/180	180/180	100.0%	98.0% - 100%			
	Site B	0/180	180/180	100.0%	98.0% - 100%			
	Site C	0/180	180/180	100.0%	98.0% - 100%			
	All Sites	**0/540**	**540/540**	**100.0%**	**99.3% – 100%**			

[a] Expected results for the "Medium Positive", the "Low Positive", and the "High Negative" panel members are positive. Expected result for the "Negative" panel member is negative. [b] High negative samples are targeted to be positive 20-80% of the time.

Precision (Repeatability)

The repeatability of the FilmArray RP System results was evaluated by repeated testing of the same 12 specimens tested in the reproducibility study while minimizing as many sources of variability as possible. The in-house repeatability testing was performed at Site C over the course of 12 testing days for a total of 48 test results per specimen. On each day, all 12 specimens were tested 4 times by two operators on two FilmArray instruments.

Table 19. Summary of Positive Agreement Results for Repeatability Testing of Parainfluenza Viruses 1, 2 and 4.

Spiked Organism	Moderate Positive (3x LoD)		Low Positive (1x LoD)		High Negative (0.1x LoD)	
	# Positive / Total	% Positive Results	# Positive / Total	% Positive Results	# Positive / Total	% Positive Results
Parainfluenza Virus 1	47/48	97.9%	48/48	100.0%	32/48	66.7%
Parainfluenza Virus 2	48/48	100.0%	47/48	97.9%	27/48	56.3%
Parainfluenza Virus 4	48/48	100.0%	48/48	100.0%	26/48	54.2%

Interference

Substances that could be present in NPS samples or introduced during sample handling were evaluated for their potential to interfere with assay performance. Four different organism mixes containing FilmArray RP analytes were spiked into a simulated NPS (sNPS) sample matrix (human epithelial cells in VTM) at 5x their respective LoDs. The 5x LoD organism concentration was chosen to be near the analyte LoD but also to provide consistent results for sample-to-sample comparison. Each FilmArray RP analyte was tested in the presence of each potentially interfering substance listed in Table 20. None of the substances tested were found to compete or interfere with the control or analyte assays in the FilmArray RP.

Table 20. List of Potentially Interfering Substances Evaluated

Endogenous Substances		**Competitive / Interfering Microorganisms**	
Human Blood (with Na Citrate) (1% v/v)		Respiratory Syncytial Virus A	2.8×10^4 $TCID_{50}$/mL
Mucin (bovine submaxillary gland) (1% v/v)		Human Rhinovirus	1.1×10^4 $TCID_{50}$/mL
Human Genomic DNA: 0.2 ng/µL		Influenza A 2009 H1N1	1.0×10^5 $TCID_{50}$/mL
2 ng/µL		*Staphylococcus aureus*	1.0×10^6 CFU/mL
20 ng/µL		*Neisseria meningitides*	1.0×10^6 CFU/mL
		Corynebacterium diptheriae	1.0×10^6 CFU/mL
Exogenous Substances			
Saline Nasal Spray with Preservatives (1% v/v)		Analgesic ointment (1% w/v)	
Nasal Decongestant Spray (Oxymetazoline HCl) (1%v/v)		Petroleum Jelly (1% w/v)	
Tobramycin (0.6 mg/mL)		Smokeless Tobacco (1% w/v)	
Mupirocin (2% w/v)			
Technique Specific Substances			
Laboratory Reagents:	**Viral Transport Media:**	**Swabs:**	
Bleach (1%, 2%, 5% v/v)	Remel M4	Copan 168C (rayon / twisted aluminum shaft)	
Disinfecting wipes	Remel M4-RT	Copan FloQ (flocked nylon / plastic shaft)	
Ethanol (7% v/v)	Remel M5	Copan 175KS01 (polyester / aluminum shaft)	
DNAzap (1% v/v)	Remel M6	Millipore 519CS01M (flocked nylon / plastic shaft)	
RNaseOut (1% v/v)	Copan UTM		

Evaluation of the FilmArray RP system was not performed using clinical NPS specimens obtained from individuals who had recently received the FluMist® nasal influenza vaccine (MedImmune). However, analytical testing was performed with simulated samples containing various concentrations of the 2009-2010 formulation of the vaccine material. The FilmArray RP assays react with the Influenza A H1, Influenza A H3 and Influenza B viral material contained in the vaccine. No cross-reactivity was observed with other, non-influenza FilmArray RP assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Idaho Technology Inc.
c/o Beth Lingenfelter
390 Wakara Way
Salt Lake City, UT 84108

APR 27 2011

Re: K110764
Trade/Device Name: FilmArray Respiratory Panel (RP) System
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OEM, OOU, OEP, OTG, NXD, OOI
Dated: March 17, 2011
Received: March 18, 2011

Dear Ms. Lingenfelter:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director,
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k110764
Device Name: FilmArray Respiratory Panel (RP) System

Indications for Use:

FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with the FilmArray instrument for the simultaneous qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following virus types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus HKU1, Coronavirus NL63, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Rhinovirus/Enterovirus, and Respiratory Syncytial Virus. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory viral infection if used in conjunction with other clinical and epidemiological information. Negative results do not preclude respiratory viral infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. Positive results do not rule out bacterial infection or co-infection with other organisms. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory infection.

Due to seasonal prevalence, performance characteristics for Influenza A/H1, Influenza A/H3, Influenza A/2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4 were established primarily with retrospective clinical specimens.

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

The FilmArray RP detects Adenovirus species C serotype 2 and serotype 6 with reduced sensitivity. It is recommended that specimens found to be negative for Adenovirus after examination using FilmArray RP be confirmed by an alternate method (e.g. FDA cleared molecular test or cell culture).

Performance characteristics for influenza A were established when influenza A/2009 H1N1, A/H1, and A/H3 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. 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.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K110764