Section 05, 510(k) Summary

DEC - 4 2009

Applicant:

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Date of preparation of 510(k) summary:

October 5, 2009

Device Name:

Trade name – **D[3] FastPoint L-DFA RSV/MPV Identification Kit**
Common name – RSV/MPV DFA assay
Classification name – Respiratory viral panel multiplex nucleic acid assay
Product Code – OMG, LKT
Regulation – 21 CFR 866.3980
Regulatory Class – Class II
Panel Microbiology (83)

Legally marketed devices to which equivalence is claimed:

D[3] *Ultra* DFA Respiratory Virus Screening & ID Kit (k061101)

Intended Use: The Diagnostic Hybrids, Inc. D[3] *Ultra* DFA (direct fluorescent antibody) Respiratory Virus Screening & ID Kit (D[3] *Ultra*) is intended for the qualitative detection and identification of the influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus, parainfluenza 1, parainfluenza 2 and parainfluenza 3 virus in respiratory specimens, by either

direct detection or cell culture method, by immunofluorescence using fluoresceinated monoclonal antibodies (MAbs). It is recommended that specimens found to be negative after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

- Performance characteristics for influenza A were established when influenza A/H3 and A/H1 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 BSL3+ facility is available to receive and culture specimens.

D³ *Duet* DFA RSV/Respiratory Virus Screening Kit (k081928)

Intended Use: The Diagnostic Hybrids, Inc. device, D³ *Duet* DFA RSV/Respiratory Virus Screening Kit (D³ *Duet* RSV Kit), is intended for the qualitative detection and identification of respiratory syncytial virus, while screening for influenza A virus, influenza B virus, adenovirus, and parainfluenza virus types 1, 2 and 3 viral antigens, in nasal and nasopharyngeal swabs and aspirates or in cell culture. The assay detects viral antigens by immunofluorescence using monoclonal antibodies (MAbs), from patients with signs and symptoms of respiratory infection.

It is recommended that specimens found to be negative after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Performance characteristics for influenza A virus detection and identification were established when influenza A (H3N2) and influenza A (H1N1) were the predominant influenza A strains circulating in the United States. Performance characteristics for influenza A virus detection and identification were established when influenza A H3N2 and influenza A H1N1 were the predominant influenza A strains circulating in the United States. 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 a state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.

D³ DFA Metapneumovirus Identification Kit (k090073)

Intended Use: The Diagnostic Hybrids, Inc. device, D³ DFA Metapneumovirus Identification Kit (D³ MPV Kit), is intended for the qualitative detection and identification of human metapneumovirus (hMPV) in nasal and nasopharyngeal swabs and aspirates/washes or cell culture. The assay detects hMPV antigens by immunofluorescence using a blend of three monoclonal antibodies (MAbs), from patients with signs and symptoms of acute respiratory infection. This assay detects but is not intended to differentiate the four recognized genetic sub-lineages of hMPV.

Negative results do not preclude hMPV infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. It is recommended that specimens found to be negative after examination of the direct specimen results be confirmed by an FDA-cleared hMPV molecular assay.

Device Description:

The D³ FastPoint L-DFA RSV/MPV Identification Kit uses a blend (called a "L-DFA Reagent") of viral antigen-specific murine monoclonal antibodies that are directly labeled with either R-phycoerythin (PE) (respiratory syncytial virus) or fluorescein isothiocyanate (FITC) (human metapneumovirus) for the rapid identification of respiratory syncytial virus and human metapneumovirus in nasal and nasopharyngeal swabs and aspirates from patients with signs and symptoms of respiratory infection.

Kit Components:

1. **D³ FastPoint L-DFA RSV/MPV Reagent,** 4.0-mL. One dropper bottle containing a mixture of PE-labeled murine monoclonal antibodies directed against respiratory syncytial virus antigens and FITC-labeled murine monoclonal antibodies directed against human metapneumovirus antigens. The buffered, stabilized, aqueous solution contains Evans Blue and propidium iodide as counter-stains and 0.1% sodium azide as preservative.

2. **40X PBS Concentrate,** 25-mL. One bottle of 40X PBS concentrate containing 4% sodium azide (0.1% sodium azide after dilution to 1X using de-mineralized water).

3. **Re-suspension Buffer,** 6.0-mL. One bottle of a buffered glycerol solution and 0.1% sodium azide.

4. **D³ FastPoint L-DFA RSV/MPV Antigen Control Slides,** 5-slides. Five individually packaged control slides containing 2 wells with cell culture-derived positive and negative control cells. Each positive well contains cells infected with either respiratory syncytial virus or human metapneumovirus. The negative wells contain non-infected cells. Each slide is intended to be stained only one time.

5. **D³ FastPoint L-DFA Specimen Slides and Coverslips,** 50-slides with coverslips. Fifty pack of 3-well specimen slides.

The cells to be tested are derived from respiratory specimens from patients with signs and symptoms of respiratory infection. The cells are permeabilized and stained concurrently in a liquid suspension format with the L-DFA Reagent. After incubating at 35°C to 37°C for 5-minutes, the stained cell suspensions are rinsed with 1X PBS. The rinsed cells are pelleted by centrifugation and then re-suspended with the Re-suspension Buffer and loaded onto a specimen slide well. The cells are examined using a fluorescence microscope. Cells infected with RSV will exhibit golden-yellow fluorescence due to the PE. Cells infected with hMPV will exhibit apple-green fluorescence due to the FITC. Non-infected cells will exhibit red fluorescence due to the Evans Blue counter-stain. Nuclei of intact cells will exhibit orange-red fluorescence due to the propidium iodide.

Intended Use:

The Diagnostic Hybrids, Inc. device, D³ FastPoint L-DFA RSV/MPV Identification Kit is intended for the qualitative identification of respiratory syncytial virus and human metapneumovirus in nasal and nasopharyngeal swabs and aspirates/washes specimens from patients with signs and symptoms of respiratory infection by direct detection of immunofluorescence using monoclonal antibodies (MAbs).

It is recommended that specimens found to be negative for respiratory syncytial virus after examination of the direct specimen result be confirmed by cell culture. Specimens found to be negative for human metapneumovirus after examination of the direct specimen results should be confirmed by an FDA-cleared human metapneumovirus molecular assay. Negative results do not preclude respiratory syncytial virus and human metapneumovirus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Technological Characteristics, Compared to Predicate Device:

TABLE 5.1: Characteristics of the D³ FastPoint L-DFA Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D³ FastPoint RSV/MPV Identification Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928	D³ MPV Kit 510(k) # k090073
Intended Use	The Diagnostic Hybrids, Inc. device, D³ FastPoint L-DFA RSV/MPV Identification Kit is intended for the qualitative identification of respiratory syncytial virus and human metapneumovirus in nasal and nasopharyngeal swabs and aspirates/washes specimens from patients with signs and symptoms of respiratory infection by direct detection of immunofluorescence using monoclonal antibodies (MAbs). It is recommended that specimens found to be negative for respiratory syncytial virus after examination of the direct specimen result be confirmed by cell culture. Specimens found to be negative for human metapneumovirus after examination of the direct specimen results should be confirmed by an FDA-cleared human metapneumovirus molecular assay. Negative results do	The Diagnostic Hybrids, Inc. D³ *Ultra*™ DFA (direct fluorescent antibody) Respiratory Virus Screening & ID Kit is intended for the qualitative detection and identification of the influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus, parainfluenza 1, parainfluenza 2 and parainfluenza 3 virus in respiratory specimens, by either direct detection or cell culture method, by immunofluorescence using monoclonal antibodies (MAbs). It is recommended that specimens found to be negative after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.	The Diagnostic Hybrids, Inc. device, D³ *Duet* DFA RSV/Respiratory Virus Screening Kit, is intended for the qualitative detection and identification of respiratory syncytial virus, while screening for influenza A virus, influenza B virus, adenovirus, and parainfluenza virus types 1, 2 and 3 viral antigens, in nasal and nasopharyngeal swabs and aspirates or in cell culture. The assay detects viral antigens by immunofluorescence using monoclonal antibodies (MAbs), from patients with signs and symptoms of respiratory infection. It is recommended that specimens found to be negative after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other management	The Diagnostic Hybrids, Inc. device, D³ DFA Metapneumovirus Identification Kit, is intended for the qualitative detection and identification of human metapneumovirus (hMPV) in nasal and nasopharyngeal swabs and aspirates/washes or cell culture. The assay detects hMPV antigens by immunofluorescence using a blend of three monoclonal antibodies (MAbs), from patients with signs and symptoms of acute respiratory infection. This assay detects but is not intended to differentiate the four recognized genetic sub-lineages of hMPV. Negative results do not preclude hMPV infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. It is recommended that specimens found to be negative after examination of the direct specimen

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	not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.		decisions.	results be confirmed by an FDA-cleared hMPV molecular assay.
Target Viruses	respiratory syncytial virus, metapneumovirus	influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3	influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3	metapneumovirus
Monoclonal antibodies (MAbs)	The D³ FastPoint L-DFA RSV/MPV Reagent contain 5 MAbs to respiratory syncytial virus (2) and metapneumovirus (3)	The Respiratory Virus DFA Screening Reagent contains 15 MAbs to 7 different respiratory viruses (influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3)	The RSV/Respiratory Virus DFA Screening Reagent contains 15 MAbs to 7 different respiratory viruses (influenza A virus, influenza B virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3), plus 2 MAbs to respiratory syncytial virus.	The Metapneumovirus DFA Reagent contains 3 MAbs to metapneumovirus
Labeling method	Direct labeling - using R-Phycoerythrin (R-PE) to label the MAbs to RSV. - using fluorescein isothiocyanate	Direct labeling - using fluorescein isothiocyanate (FITC) to label all MAbs with fluorescein.	Direct labeling - using R-Phycoerythrin (R-PE) to label the MAbs to respiratory syncytial virus. - using fluorescein isothiocyanate	Direct labeling - using fluorescein isothiocyanate (FITC) to label all MAbs with fluorescein.

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	(FITC) to label the MAbs to metapneumovirus.		(FITC) to label all other MAbs with fluorescein.	
R-Phycoerythrin-labeled MAbs	respiratory syncytial virus	None	respiratory syncytial virus	None
Fluorescein-labeled MAbs	metapneumovirus	influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3	influenza A virus, influenza B virus, adenovirus, parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3	metapneumovirus
Cell Fixative	Proprietary Non-Acetone based system	Acetone	Acetone	Acetone
Cell Counter-stain	Propidium Iodide, Evans Blue	Evans Blue	Evans Blue	Evans Blue
Performance characteristics				
Staining patterns	**Respiratory Syncytial Virus:** The fluorescence is cytoplasmic. Cells appear round. **Metapneumovirus:** The fluorescence is cytoplasmic and punctate. Cells appear round. **Negative:** Cells fluoresce red due to the Evans Blue counter-stain. **Nuclei:** Cell Nuclei fluoresce orange-red due to the Propidium Iodide counter-stain.	**Influenza A and B:** The fluorescence is cytoplasmic, nuclear or both. Cytoplasmic staining is often punctate with large inclusions while nuclear staining is uniformly bright. **Respiratory Syncytial Virus:** The fluorescence is cytoplasmic and punctate with small inclusions in the syncytia. **Parainfluenza 1, 2, 3:** The fluorescence is cytoplasmic and punctate with irregular inclusions. Types 2 and 3 cause the formation of syncytia. **Adenovirus:** The	**Influenza A and B:** The fluorescence is cytoplasmic, nuclear or both. Cytoplasmic staining is often punctate with large inclusions while nuclear staining is uniformly bright. **Respiratory Syncytial Virus:** The fluorescence is cytoplasmic and punctate with small inclusions in the syncytia. **Parainfluenza 1, 2, 3:** The fluorescence is cytoplasmic and punctate with irregular inclusions. Types 2 and 3 cause the	**Metapneumovirus:** The fluorescence is cytoplasmic and punctate with small inclusions in the syncytia. **Negative:** Entire cell fluoresce red due to the Evans Blue counter-stain.

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			fluorescence is cytoplasmic and punctate or bright nuclear or both. **Negative:** Cells fluoresce red due to the Evans Blue counter-stain.	formation of syncytia. **Adenovirus:** The fluorescence is cytoplasmic and punctate or bright nuclear or both. **Negative:** Cells fluoresce red due to the Evans Blue counter-stain.	
Analytical specificity (cross-reactivity studies; various strains of microorganisms and cell lines)	**Device Reagents are not reactive with these numbers of microorganisms.**				
	Viruses	59	31	32	59
	Bacteria	22	18	25	25
	Chlamydia spp.	1	1	3	3
	Yeast	1	0	1	1
	Protozoan	0	0	1	1
	Cell lines	N/A	17	17	16

Analytical Performance:

Precision/Reproducibility:

Assay precision, intra-assay variability and inter assay variability were assessed with a reproducibility panel consisting of 5 randomized panel members.

The RSV/hMPV panel consisted of the following:

a. Low level RSV (Washington strain) infected cells.
b. Low level hMPV (A1 subtype) infected cells.
c. Low level RSV (Washington strain) infected cells mixed with mid level hMPV (A1 subtype) infected cells.
d. Low level hMPV (A1 subtype) infected cells mixed with mid level RSV (Washington strain) infected cells.
e. Mid level non-infected (negative) cells.

The low level is estimated to contain between 4 to 10% infected cells in the sample. The mid level is estimated to contain between 20 to 25% infected cells in the sample. Each sample contains 2.5×10^5 to 3.5×10^5 total cells.

Each panel was tested daily in two separate runs for 5-days by four different laboratories (40 total runs). The following results were recorded:

a. Presence or absence of golden-yellow fluorescence.
b. Percent of cells exhibiting golden-yellow fluorescence.
c. Presence or absence of apple-green fluorescence.
d. Percent of cells exhibiting apple-green fluorescence.

For the L-DFA Reagent, the combined data from the four Study Sites demonstrated reproducible detection of RSV by the R-PE labeled MAbs and reproducible detection of hMPV by the FITC-labeled MAbs. The presence of RSV infected cells was reported in 100% (120/120) of the wells in which the infected cells were expected. The presence of hMPV infected cells was reported in 100% (120/120) of the wells in which the infected cells were expected. The absence of infected cells was reported in 100% (40/40) of the wells in which infected cells were not present. The total percent agreement for the L-DFA Reagent was 100% (280/280):

TABLE 5.2: Reproducibilty Study Results using the L-DFA Reagent

Site	Panel Member	Negative	RSV Low Level	hMPV Low Level	Mixed Infection		Mixed Infection		Total % Agreement
					RSV Mid Level	hMPV Low Level	RSV Low Level	hMPV Mid Level	
	Concentration	No infected cells	4 to 10% infected cells	4 to 10% infected cells	20 to 30% infected cells	4 to 10% infected cells	4 to 10% infected cells	20 to 30% infected cells	
Site 1	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**70/70 (100%)**
Site 2	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**70/70 (100%)**
Site 3	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**70/70 (100%)**
Site 4	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**70/70 (100%)**
Total Agreement with Expected result		40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	**280/280 (100%)**
95% CI		91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	**98.7 – 100%**

Limit of Detection:

Analytical Limit of Detections (LoDs) of the L-DFA Reagent was addressed using dilution series of infected model cells. Model cells for respiratory syncytial virus (ATCC Washington strain) and human metapneumovirus

subtype A1 (clinical strain) were diluted with non-infected cells to produce a suspension equivalent to 1,000 infected cells per milliliter. This level theoretically yields approximately 25 infected cells per 25-µL of suspension. This suspension was then serially diluted to a theoretical level of less than 1 cell per milliliter. (NOTE: This level was the target to begin with a low positive level. Actual starting levels vary, however, and are within 1 dilution of the 25 infected cell target level). 25-µL aliquots from each dilution level were spotted onto 10 replicate microscope slides, and then stained according to the instructions for use described in this product insert. Each cell spot was examined at 200x magnification. Results were reported as numbers of positive replicates for each set of 10. Analytical detection limits for each of the 8 analytes were defined as the lowest dilutions at which at least 9 out of 10 replicates were detected. LoD study results are summarized in TABLE 5.3 below:

TABLE 5.3: Limit of Detections of the L-DFA Reagent

Virus Strain	Infected cells/mL	Number of replicates with positive cells	LOD determination
RSV (ATCC Washington strain)	1000	10/10	100 infected cells/mL
	200	10/10	
	100	**10/10**	
	50	7/10	
	25	7/10	
	12.5	6/10	
	6	1/10	
	3	0/10	
	1.5	0/10	
	0.8	0/10	
hMPV A1 (Clinical strain)	2000	10/10	100 infected cells/mL
	400	10/10	
	200	10/10	
	100	**10/10**	
	50	6/10	
	25	2/10	
	12.5	0/10	
	6	0/10	
	3	0/10	
	1.5	0/10	

Analytical reactivity (inclusivity):

Analytical reactivity (inclusivity) of the L-DFA Reagent was evaluated using 3-RSV virus and 4-hMPV virus strains. Low concentration infected cell suspensions (approximately 4% cells infected, 25 to 50 infected cells) were prepared for each viral strain. The suspensions were stained with the L-DFA Reagent.

TABLE 5.4: Analytical Reactivity (inclusivity) of the L-DFA Reagent on various RSV virus and hMPV virus strains		
RSV and hMPV Strains	**Infected Cell Concentration (as multiples of the respective established LoD concentration)**	**L-DFA Reagent Results**
RSV 9320	10x LoD	22 Golden-yellow fluorescent cells
RSV Washington	10x LoD	22 Golden-yellow fluorescent cells
RSV Long	10x LoD	32 Golden-yellow fluorescent cells
hMPV A1	10x LoD	25 Apple-green fluorescent cells
hMPV A2	10x LoD	25 Apple-green fluorescent cells
hMPV B1	10x LoD	25 Apple-green fluorescent cells
hMPV B2	10x LoD	37 Apple-green fluorescent cells

Clinical Performance:

Performance of the D³ FastPoint RSV/MPV Kit testing direct respiratory specimens were established during prospective studies at 4 geographically diverse U.S. clinical laboratories during the 2009 respiratory virus seasons (January 2009 – March 2009). All specimens used in the studies meeting the inclusion and exclusion criteria represented excess, remnants of respiratory specimens that were prospectively collected from symptomatic individuals suspected of respiratory infection, and were submitted for routine care or analysis by each site, and that otherwise would have been discarded. Individual specimens were delinked from all patient identifiers and given a study sample code. All clinical sites were granted waivers of informed consent by their IRBs for this study.

Performance of the D³ FastPoint RSV/MPV Kit was assessed and compared to a predetermined algorithm that used composite comparator methods. The composite comparator methods for respiratory syncytial virus consisted of Direct Specimen Fluorescent Antibody (DSFA) test with an FDA-cleared device and viral culture confirmation of all the negatives (as determined by the comparator DSFA test). For human metapneumovirus the composite comparator methods consisted of DSFA with an FDA-cleared device, and confirmation of all negative specimens (as determined by the comparator DSFA test) using a validated[1] hMPV real-time RT-PCR followed by bi-directional sequencing analysis comparator assay. The hMPV real-time RT-PCR comparator assay targets the hMPV Nucleocapsid gene. "True"

[1] Analytical validation of the real-time hMPV RT-PCR followed by bi-directional sequencing analysis comparator assay included analytical sensitivity and reactivity study, analytical specificity study, and extraction efficiency study. The analytical sensitivity (limit of detection or LoD) of the real-time hMPV RT-PCR followed by bi-directional sequencing analysis comparator assay was determined using quantified ($TCID_{50}$/mL) stocks of the 4 hMPV (subtypes A1, A2, B1 and B2) strains diluted in hMPV negative nasopharyngeal clinical matrix, and ranged from 10 – 50 $TCID_{50}$/mL.

positive was defined as any sample that either tested positive by the comparator DSFA test or viral culture, or had bi-directional sequencing data meeting pre-defined quality acceptance criteria that matched hMPV sequences deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov), with acceptable E-values.[2] "True" negative was defined as any sample that tested negative by both the comparator DSFA test and either viral culture or the hMPV real-time RT-PCR comparator assay.

Prevalence of RSV and hMPV within this population as determined by the D³ FastPoint RSV/MPV Kit direct specimen testing is noted in TABLE 5.5 below:

TABLE 5.5: RSV/hMPV Prevalence*

Age	Total Specimens Evaluated	RSV # positive (prevalence)	hMPV # positive (prevalence)
0 – 1 month	55	15 (27.3%)	2 (3.6%)
> 1 month to 2 years	577	154 (26.7%)	41 (7.1%)
> 2 years to 12 years	391	25 (6.4%)	17 (4.3%)
> 12 years to 21 years	173	4 (2.3%)	3 (1.7%)
22 years to 30 years	57	0	1 (1.8%)
31 years to 40 years	71	1 (1.4%)	3 (4.2%)
41 years to 50 years	52	0	1 (1.9%)
51 years to 60 years	46	1 (2.2%)	3 (6.5%)
61 years to 70 years	33	1 (3.0%)	1 (3.0%)
71 years to 80 years	16	1 (6.3%)	4 (25.0%)
81 years and above	7	1 (14.3%)	0
Age Not Reported	41	0	1 (2.4%)
Total	1519	203 (13.4%)	77 (5.1%)

* There were 2 - respiratory syncytial virus + metapneumovirus co-infections detected.

TABLES 5.6 and 5.7 below show the study results of the NP wash/aspirate specimen type (Sites 1, 2, and 3 combined):

[2] The E-values generated from the clinical trials range from a low of 5e-78 to a high of 1e-20. The E-Value from NCBI BLAST Alignment indicates the statistical significance of a given pair-wise alignment and reflects the size of the database and the scoring system used. The lower the E-Value, the more significant the hit. A sequence alignment that has an E-Value of 1e-3 means that this similarity has a 1 in 1000 chance of occurring by chance alone.
(http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=handbook.section.614).

TABLE 5.6: Respiratory syncytial virus			
Fresh nasal/nasopharyngeal wash/aspirate	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	204	1	205
Negative	3	462	465
Total	207	463	670
			95% CI
Sensitivity	204/207	98.6%	95.8-99.7%
Specificity	462/463	99.8%	98.8-100%

TABLE 5.7: Human metapneumovirus			
Fresh nasal/nasopharyngeal wash/aspirate	**Comparator DSFA (negatives confirmed by a validated hMPV real-time RT-PCR followed by bi-directional sequencing analysis comparator assay)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	55	0	55
Negative	25	614	639
Total	80	614	694
			95% CI
Sensitivity	55/80	68.8%	57.4-78.7%
Specificity	614/614	100.0%	99.4-100%

TABLES 5.8 and 5.9 below show the study results of the NP swab specimen type (Sites 3 and 4 combined):

TABLE 5.8: Respiratory syncytial virus			
Fresh nasal/nasopharyngeal swab	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	39	0	39
Negative	1	647	648
Total	40	647	687
			95% CI
Sensitivity	39/40	97.5%	86.8-99.9%
Specificity	647/647	100.0%	99.4-100%

TABLE 5.9: Human metapneumovirus			
Fresh nasal/nasopharyngeal swab	**Comparator DSFA (negatives confirmed by a validated hMPV real-time RT-PCR followed by bi-directional sequencing analysis comparator assay)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	24	0	24
Negative	20	632	652
Total	44	632	676
			95% CI
Sensitivity	24/44	54.5%	38.8-69.9%
Specificity	632/632	100.0%	99.4-100%

Overall at the four Study Sites, the performance results of the D³ FastPoint L-DFA RSV/MPV Identification Kit, when compared to those of the comparator devices, D³ *Ultra* DFA Respiratory Virus Screening & ID Kit, D³ *Duet* DFA RSV/Respiratory Virus Screening Kit and D³ DFA Metapneumovirus Identification Kit demonstrate that the devices detect RSV and hMPV antigens in a similar manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

DEC - 4 2009

Mr. Ronald H. Lollar
Senior Director Product Realization,
Management and Marketing
Diagnostic Hybrids, Inc
1055 East State Street, Suite 100
Athens, Ohio 45701

Re: k093233
Trade/Device Name: D^3 FastPoint L- DFA RSV/MPV Identification Kit
Regulation Number: 21 CFR § 866.3980
Regulation Name: Respiratory viral antigens (respiratory syncytial virus and human metapneumovirus)
Regulatory Class: II
Product Code: OMG, LKT
Dated: October 5, 2009
Received: October 14, 2009

Dear Mr. Lollar:

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 either class II (Special Controls) or class III (PMA), 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.

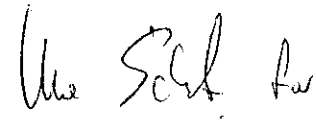
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5460. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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

510(k) Number (if known): k093233

Device Name: D^3 FastPoint L-DFA RSV/MPV Identification Kit

Indication for Use:

The Diagnostic Hybrids, Inc. device, D^3 FastPoint L-DFA RSV/MPV Identification Kit is intended for the qualitative identification of respiratory syncytial virus and human metapneumovirus in nasal and nasopharyngeal swabs and aspirates/washes specimens from patients with signs and symptoms of respiratory infection by direct detection of immunofluorescence using monoclonal antibodies (MAbs).

It is recommended that specimens found to be negative for respiratory syncytial virus after examination of the direct specimen result be confirmed by cell culture. Specimens found to be negative for human metapneumovirus after examination of the direct specimen results should be confirmed by an FDA-cleared human metapneumovirus molecular assay. Negative results do not preclude respiratory syncytial virus and human metapneumovirus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

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 Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k093233