OCT 21 2009

D³ FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit

K092882

Section 05, 510(k) Summary

Applicant:

DIAGNOSTIC HYBRIDS, INC.
1055 East State Street
Suite 100
Athens, OHIO 45701

Contact Information:

Ronald H. Lollar, Senior Director Product Realization,
Management, and Marketing
1055 East State Street
Suite 100
Athens, Ohio 45701
740-589-3300 – Corporate number
740-589-3373 – Desk phone
740-593-8437 – Fax
lollar@dhiusa.com

Date of preparation of 510(k) summary:

September 14, 2009

Device Name:

Trade name – **D³ FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit**
Common name – Influenza A/B virus DFA assay
Classification name – Antisera, Cf, Influenza Virus A, B, C
Product Code – GNW
Regulation – 21 CFR 866.3330, Class I, Influenza virus serological reagents; Panel Microbiology (83)

Legally marketed devices to which equivalence is claimed:

D³ *Ultra* DFA Respiratory Virus Screening & ID Kit (k061101)

Intended Use: The Diagnostic Hybrids, Inc. D³ *Ultra* DFA (direct fluorescent antibody) Respiratory Virus Screening & ID Kit (D³ *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 BSL 3+ facility is available to receive and culture specimens.

Device Description:

The D³ FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit (D³ FastPoint A/B Kit) uses a blend (called a "L-DFA Reagent") of viral antigen-specific murine monoclonal antibodies that are directly labeled with either R-PE (influenza A virus) or fluorescein (influenza B virus) for the rapid identification of influenza A virus and influenza B virus in nasal and nasopharyngeal swabs and aspirates/washes specimens from patients with signs and symptoms of respiratory infection.

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 influenza A virus will exhibit golden-yellow fluorescence due to the PE. Cells infected with influenza B virus 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.

Kit Components:

1. **D³ FastPoint L-DFA Influenza A/Influenza B Reagent**, 4.0-mL. One dropper bottle containing a mixture of PE-labeled murine monoclonal antibodies directed against influenza A virus antigens and FITC-labeled murine monoclonal antibodies directed against influenza B virus 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 Influenza A/Influenza B 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 influenza A virus, or influenza B virus. The negative wells contain non-infected cells. Each slide is intended to be stained only one time.

Intended Use:

The Diagnostic Hybrids, Inc. device, D³ FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit is intended for the qualitative identification of influenza A virus and influenza B virus 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 influenza A or influenza B virus after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude influenza A or influenza B 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. Since influenza strains display antigenic drift and shift from year to year, performance characteristics may vary. If infection with a novel influenza A virus is suspected, based on clinical and epidemiological screening criteria communicated by public health authorities, collect specimens following appropriate infection control precautions and submit to state or local health departments, for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility[1] is available to receive and culture specimens[2] .

Technological Characteristics, Compared to Predicate Device:

Table 5.1: Characteristics of the D³ FastPoint L-DFA Influenza A/Influenza B Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D³ FastPoint A/B Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928
Intended Use	The Diagnostic Hybrids, Inc. device, D³ FastPoint L-DFA Influenza A/ Influenza B Virus Identification Kit is intended for the qualitative identification of influenza A virus and influenza B virus in nasal and	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,	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,

[1] www.cdc.gov

[2] FDA Guidance Document: In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path; Issued 4/10/2006

Table 5.1: Characteristics of the D³ FastPoint L-DFA Influenza A/Influenza B Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D³ FastPoint A/B Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928
	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 influenza 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.	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.	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.
Target Viruses	influenza A virus, influenza B virus	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
Monoclonal antibodies (MAbs)	The L-DFA Reagent contains 4 MAbs to influenza A virus, influenza B virus	The Respiratory Virus DFA Screening Reagent contains 15 MAbs to 7 different	The RSV/Respiratory Virus DFA Screening Reagent contains 15 MAbs to 7 different respiratory viruses

Table 5.1: Characteristics of the D³ FastPoint L-DFA Influenza A/Influenza B Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D³ FastPoint A/B Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928
		respiratory viruses (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), plus 2 MAbs to respiratory syncytial virus.
Labeling method	Direct labeling, - using R-Phycoerythrin (R-PE) to label the MAbs to influenza A virus. - using fluorescein isothiocyanate (FITC) to label influenza B virus, MAbs.	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 (FITC) to label all other MAbs with fluorescein.
R-Phycoerythrin-labeled MAbs	influenza A virus	None	respiratory syncytial virus
Fluorescein-labeled MAbs	influenza B virus	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
Cell Fixative	Proprietary Non-Acetone based system	Acetone	Acetone
Cell Counter-stain	Propidium Iodide, Evans Blue	Evans Blue	Evans Blue
Performance characteristics			
Staining patterns	**Influenza A and B:** The fluorescence is cytoplasmic or bright nuclear or both. Cells appear	**Influenza A and B:** The fluorescence is cytoplasmic, nuclear or both. Cytoplasmic	**Influenza A and B:** The fluorescence is cytoplasmic, nuclear or both. Cytoplasmic staining is often

Table 5.1: Characteristics of the D³ FastPoint L-DFA Influenza A/Influenza B Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D³ FastPoint A/B Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928
	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.	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 fluorescence is cytoplasmic and punctate or bright nuclear or both. **Negative:** Cells fluoresce red due to the Evans Blue counter-stain.	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 fluorescence is cytoplasmic and punctate or bright nuclear or both. **Negative:** Cells fluoresce red due to the Evans Blue counter-stain.
Analytical specificity (for influenza A virus strains; MAbs are reactive with all listed strains)	13 influenza A strains: Influenza A Mexico/4108/2009 (H1N1) from CDC*, Influenza A California/07/2009 (H1N1) from CDC*, Aichi (H3N2), Mal (H1N1), Hong Kong (H3N2), Denver (H1N1), Port Chalmers (H3N2), Victoria (H3N2), New Jersey (H1N1), WS (H1N1), PR (H1N1), Wisconsin (H3N2), WS (H1N1),	10 influenza A strains: Aichi (H3N2), Mal (H1N1), Hong Kong (H3N2), Denver (H1N1), Port Chalmers (H3N2), Victoria (H3N2), New Jersey (H1N1), WS (H1N1), PR,(H1N1), A/NWS/33 (H1N1)	10 influenza A strains: Aichi (H3N2), Mal (H1N1), Hong Kong (H3N2), Denver (H1N1), Port Chalmers (H3N2), Victoria (H3N2), New Jersey (H1N1), WS (H1N1), PR (H1N1), A/NWS/33 (H1N1)

Table 5.1: Characteristics of the D³ FastPoint L-DFA Influenza A/Influenza B Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices				
Characteristics		**D³ FastPoint A/B Kit (Subject Device)**	**D³ *Ultra* Kit 510(k) #k061101**	**D³ *Duet* RSV Kit 510(k) # k081928**
		A/NWS/33 (H1N1)		
Analytical specificity (for Influenza B virus strains; MAbs are reactive with all listed strains)		7 influenza B strains: Hong Kong, Maryland, Mass, GL, Taiwan, B/Lee/40, Russia	7 influenza B strains: Hong Kong, Maryland, Mass, GL, Taiwan, B/Lee/40, Russia	7 influenza B strains: Hong Kong, Maryland, Mass, GL, Taiwan, B/Lee/40, Russia
Analytical specificity (cross-reactivity studies; various strains of microorganisms and cell lines)	Viruses	22	31	32
	Bacteria	22	18	25
	Chlamydia spp.	1	1	3
	Yeast	1	0	1
	Protozoan	1	0	1
	Cell lines	N/A	17	17

*Although the D³ FastPoint L-DFA Influenza A/Influenza B Reagent has been shown to detect the 2009 H1N1 virus in two culture isolates, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The D³ FastPoint L-DFA Influenza A/Influenza B DFA Reagent can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

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 Influenza A/B panel consisted of the following:

a. Low level influenza A (Victoria strain) infected cells.
b. Low level influenza B (Taiwan strain) infected cells.
c. Low level influenza A (Victoria strain) infected cells mixed with mid level influenza B (Taiwan strain) infected cells.
d. Low level influenza B (Victoria strain) infected cells mixed with mid level influenza A (Victoria 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 x10^5 to 3.5 x10^5 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 influenza A virus by the R-PE labeled MAbs and reproducible detection of influenza B virus by the FITC-labeled MAbs. The presence of influenza A virus infected cells was reported in 100% (120/120) of the wells in which the infected cells were expected. The presence of influenza B virus 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 95% (38/40) of the wells in which infected cells were not present. The total percent agreement for the L-DFA Reagent was 99.3% (278/280):

Table 5.2: Reproducibility Study Results using the L-DFA Reagent

Site	Panel Member	Negative	Flu A Low Level	Flu B Low Level	Mixed Infection		Mixed Infection		Total % Agreement
					Flu A Mid Level	Flu B Low Level	Flu A Low Level	Flu B 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	8/10 (80%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**68/70 (97.1%)**
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		38/40 (95%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	**278/280 (99.3%)**
95% CI		83.1 – 99.4%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	91.2 – 100%	**97.4 – 99.9%**

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 influenza A virus

(ATCC Victoria strain), influenza B virus (ATCC Taiwan 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
Influenza A (ATCC Victoria strain)	500	10/10	50 infected cells/mL
	100	10/10	
	50	**10/10**	
	25	5/10	
	12.5	3/10	
	6	2/10	
	3	0/10	
	1.5	2/10	
	0.8	0/10	
	0.4	0/10	
Influenza B (ATCC Taiwan strain)	2000	10/10	50 infected cells/mL
	400	10/10	
	200	10/10	
	100	10/10	
	50	**10/10**	
	25	7/10	
	12.5	4/10	
	6	2/10	
	3	0/10	
	1.5	0/10	

Analytical reactivity (inclusivity)

Analytical reactivity (inclusivity) of the L-DFA Reagent was evaluated using 13 influenza A virus and 7 influenza B virus strains. Low concentration infected cell suspensions (approximately 4% cells infected, 25-50 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 influenza A virus and influenza B virus strains

Influenza Strains	Infected Cell Concentration (as multiples of the respective established LoD concentration	L-DFA Reagent Results
Influenza A Mexico/4108/2009 (H1N1) from CDC*	20x LoD	19 Golden-yellow fluorescent cells
Influenza A California/07/2009 (H1N1) from CDC*	20x LoD	26 Golden-yellow fluorescent cells
Influenza A Wisconsin/56/2005 (H3N2)	20x LoD	39 Golden-yellow fluorescent cells
Influenza A WS, VR-1520 (H1N1)	20x LoD	67 Golden-yellow fluorescent cells
Influenza A Hong Kong, VR-544 (H3N2)	20x LoD	13 Golden-yellow fluorescent cells
Influenza A New Jersey, VR-897 (H1N1)	20x LoD	15 Golden-yellow fluorescent cells
Influenza A A/NWS/33 (H1N1)	20x LoD	10 Golden-yellow fluorescent cells
Influenza A Victoria, VR-822 (H3N2)	20x LoD	10 Golden-yellow fluorescent cells
Influenza A PR, VR-95 (H1N1)	20x LoD	20 Golden-yellow fluorescent cells
Influenza A Port Chalmers, VR-810 (H3N2)	20x LoD	8 Golden-yellow fluorescent cells
Influenza A Aichi, VR-547 (H3N2)	20x LoD	28 Golden-yellow fluorescent cells
Influenza A Denver, VR-546 (H1N1)	20x LoD	30 Golden-yellow fluorescent cells
Influenza A Mal, VR-98 (H1N1)	20x LoD	21 Golden-yellow fluorescent cells
Influenza B GL/1739/54, VR-103	20x LoD	13 Apple-green fluorescent cells
Influenza B Taiwan/2/62, VR-295	20x LoD	44 Apple-green fluorescent cells
Influenza B Hong Kong/5/72, VR-823	20x LoD	21 Apple-green fluorescent cells
Influenza B Maryland/1/59, VR-296	20x LoD	22 Apple-green fluorescent cells
Influenza B Russia, VR-790	20x LoD	36 Apple-green fluorescent cells
Influenza B B/Lee/40	20x LoD	41 Apple-green fluorescent cells
Influenza B Massachusetts, VR-523	20x LoD	67 Apple-green fluorescent cells

* Although the D³ FastPoint L-DFA Influenza A/Influenza B Reagent has been shown to detect the 2009 H1N1 influenza virus in two culture isolates, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The D³ FastPoint L-DFA Influenza A/Influenza B DFA Reagent can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

Clinical Performance:

Performance of the D³ FastPoint A/B 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 A/B Kit was assessed and compared to a predetermined algorithm that used composite comparator methods. The composite comparator methods for 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). "True" positive was defined as any sample that either tested positive by the comparator DSFA test or viral culture. "True" negative was defined as any sample that tested negative by both the comparator DSFA test and viral culture.

Prevalence of Influenza A/B viruses within this population as determined by the D³ FastPoint A/B Kit direct specimen testing is noted in Table 5.5 below:

Table 5.5: Influenza A/B Virus Prevalence

Age	Total Specimens Evaluated	Flu A # positive (prevalence)	Flu B # positive (prevalence)
0 – 1 month	55	0	0
> 1 month to 2 years	577	27 (4.7%)	20 (3.5%)
> 2 years to 12 years	391	43 (11.0%)	104 (26.6%)
> 12 years to 21 years	173	19 (11.0%)	41 (23.7%)
22 years to 30 years	57	3 (5.3%)	14 (24.6%)
31 years to 40 years	71	9 (12.7%)	9 (12.7%)
41 years to 50 years	52	5 (9.6%)	5 (9.6%)
51 years to 60 years	46	3 (6.5%)	3 (6.5%)
61 years to 70 years	33	2 (6.1%)	2 (6.1%)
71 years to 80 years	16	2 (12.5%)	1 (6.3%)
81 years and above	7	0	0
Age Not Reported	41	2 (4.9%)	14 (34.1%)
Total	1519	115 (7.6%)	213 (14.0%)

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

Table 5.6: Influenza A			
Fresh nasal/nasopharyngeal wash/aspirate	Comparator DSFA (negatives followed by culture with DFA)		
DHI DSFA	Positive	Negative	Total
Positive	56	3	59
Negative	10	568	578
Total	66	571	637
			95% CI
Sensitivity	56/66	84.8%	73.9-92.5%
Specificity	568/571	99.5%	98.5-99.9%

Table 5.7: Influenza B			
Fresh nasal/nasopharyngeal wash/aspirate	Comparator DSFA (negatives followed by culture with DFA)		
DHI DSFA	Positive	Negative	Total
Positive	9	0	9
Negative	2	617	619
Total	11	617	628
			95% CI
Sensitivity	9/11	81.8%	48.2-97.7%
Specificity	617/617	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: Influenza A			
Fresh nasal/nasopharyngeal swab	Comparator DSFA (negatives followed by culture with DFA)		
DHI DSFA	Positive	Negative	Total
Positive	57	1	58
Negative	8	624	632
Total	65	625	690
			95% CI
Sensitivity	57/65	87.7%	77.2-94.5%
Specificity	624/625	99.8%	99.1-100%

Table 5.9: Influenza B			
Fresh nasal/nasopharyngeal swab	Comparator DSFA (negatives followed by culture with DFA)		
DHI DSFA	Positive	Negative	Total
Positive	203	1	204
Negative	28	479	507
Total	231	480	711
			95% CI
Sensitivity	203/231	87.9%	83.7-92.1%
Specificity	479/480	99.8%	98.8-100%

Overall at the four Study Sites, the performance results of the D^3 FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit, when compared to those of the comparator devices, D^3 *Ultra* Kit, and D^3 *Duet* RSV Kit, demonstrate that the devices detect influenza A virus and influenza B virus antigens in a similar manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

OCT 2 1 2009

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

Re: K092882
Trade/Device Name: D^3 FastPoint L-DFA Influenza A/ Influenza B Virus Identification Kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX
Dated: September 14, 2009
Received: September 18, 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.

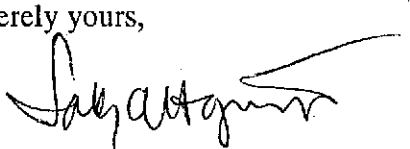
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

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) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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 (if known): k092882

Device Name: D^3 FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit

Indications For Use:

The Diagnostic Hybrids, Inc. device, D^3 FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit is intended for the qualitative identification of influenza A virus and influenza B virus 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 influenza A or influenza B virus after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude influenza A or influenza B 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. Since influenza strains display antigenic drift and shift from year to year, performance characteristics may vary. If infection with a novel influenza A virus is suspected, based on clinical and epidemiological screening criteria communicated by public health authorities, collect specimens following appropriate infection control precautions and submit to state or local health departments, for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility[1] is available to receive and culture specimens[2] .

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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) k092882

[1] www.cdc.gov

[2] FDA Guidance Document: In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path; Issued 4/10/2006