DEC 2 3 2009

Section 05, 510(k) Summary

Applicant:

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Date of preparation of 510(k) summary:

October 30, 2009

Device Name:

Trade name – D³ FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit
Common name – D³ FastPoint Parainfluenza Virus/Adenovirus Identification Kit
Classification name – Parainfluenza virus serological reagents, Adenovirus serological reagents
Product Code – GQS, GNY
Regulation – 21 CFR 866.3400, 21 CFR 866.3020
Regulatory Class – Class I
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 BSL3+ facility is available to receive and culture specimens.

Device Description:

The D³ FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit (D³ FastPoint PIV/ADV Kit) uses a blend (called an "L-DFA Reagent") of viral antigen-specific murine monoclonal antibodies that are directly labeled with either R-phycoerythin (PE) (parainfluenza virus types 1, 2 and 3) or fluorescein isothiocyanate (FITC) (adenovirus) for the qualitative identification of adenovirus and to screen for the presence of parainfluenza virus types 1, 2, and 3.

Kit Components:

1. **D³ FastPoint L-DFA PIV/Adenovirus Reagent,** 4.0-mL. One dropper bottle containing a mixture of PE-labeled murine monoclonal antibodies directed against parainfluenza virus types 1, 2, or 3 antigens and FITC-labeled murine monoclonal antibodies directed against adenovirus 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 Parainfluenza Virus/Adenovirus 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 parainfluenza virus type 3 or adenovirus. 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 parainfluenza virus types 1, 2 and 3 will exhibit golden-yellow fluorescence. Cells infected with adenovirus 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, D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit is intended for the qualitative identification of adenovirus and to screen for the presence of parainfluenza virus types 1, 2, and 3 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 parainfluenza virus and adenovirus after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude parainfluenza virus and adenovirus 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 D^3 FastPoint PIV/ADV Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices

Characteristics	D^3 FastPoint PIV/ADV Kit (Subject Device)	D^3 *Ultra* Kit 510(k) #k061101	D^3 *Duet* RSV Kit 510(k) # k081928
Intended Use	The Diagnostic Hybrids, Inc. device, D^3 FastPoint L-DFA Parainfluenza Virus/ Adenovirus Identification Kit is intended for the qualitative identification of adenovirus and to screen for the presence of parainfluenza virus types 1, 2, and 3 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 parainfluenza virus and adenovirus after examination of the direct specimen result be confirmed	The Diagnostic Hybrids, Inc. D^3 *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	The Diagnostic Hybrids, Inc. device, D^3 *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),

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	by cell culture. Negative results do not preclude parainfluenza virus and adenovirus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.	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.	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	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	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 D³ FastPoint L-DFA PIV/Adenovirus Reagent contains 9 MAbs to adenovirus (3) and parainfluenza virus (6)	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

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Characteristics	D³ FastPoint PIV/ADV Kit (Subject Device)	D³ *Ultra* Kit 510(k) #k061101	D³ *Duet* RSV Kit 510(k) # k081928
			syncytial virus.
Labeling method	Direct labeling - using R-Phycoerythrin (R-PE) to label the MAbs to parainfluenza virus types 1, 2, and 3. - using fluorescein isothiocyanate (FITC) to label the MAbs to adenovirus.	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	parainfluenza virus types 1, 2, and 3	None	respiratory syncytial virus
Fluorescein-labeled MAbs	adenovirus	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	**Parainfluenza 1, 2, 3:** The fluorescence is cytoplasmic. Cells appear round. **Adenovirus:** The fluorescence is cytoplasmic or bright nuclear or both. 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,**	**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.

TABLE 5.1: Characteristics of the D³ FastPoint PIV/ADV Kit are compared to those of the following Diagnostic Hybrids (DHI) predicate devices				
Characteristics		**D³ FastPoint PIV/ADV Kit (Subject Device)**	**D³ *Ultra* Kit 510(k) #k061101**	**D³ *Duet* RSV Kit 510(k) # k081928**
			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.	**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 (cross-reactivity studies; various strains of microorganisms and cell lines)	**Device Reagents are not reactive with these numbers of microorganisms**			
	Viruses	59	31	32
	Bacteria	22	18	25
	Chlamydia spp.	1	1	3
	Yeast	1	0	1
	Protozoan	0	0	1
	Cell lines	N/A	17	17

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 hPIV/adenovirus panel consisted of the following

a. Low level parainfluenza virus type 1 (C-35 strain) infected cells.
b. Low level adenovirus (ATCC type 1) infected cells.
c. Low level parainfluenza virus type 1 (C-35 strain) infected cells mixed with mid level adenovirus (ATCC type 1) infected cells.
d. Low adenovirus (ATCC type 1) infected cells mixed with mid level parainfluenza virus type 1 (C-35 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 x 10^5 to 3.5 x 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 D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit, the combined data from the four Study Sites demonstrated reproducible detection of parainfluenza virus type 1 (hPIV-1) by the R-PE labeled MAbs and reproducible detection of adenovirus by the FITC-labeled MAbs. The presence of hPIV-1 infected cells was reported in 100% (120/120) of the wells in which the infected cells were expected. The presence of adenovirus 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 D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit was 100% (280/280):

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

Site	Panel Member	Negative	Adenovirus Low Level	hPIV Low Level	Mixed Infection		Mixed Infection		Total % Agreement
					Adenovirus Mid Level	hPIV Low Level	Adenovirus Low Level	hPIV 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 Detection (LoD) of the L-DFA Reagent was addressed using dilution series of infected model cells. Model cells for parainfluenza virus types 1, 2, and 3 (ATCC strains C-35, Greer, and C243) and adenovirus (ATCC type 1) 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 4 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 D³ FastPoint L-DFA PIV/Adenovirus Reagent

Virus Strain	Infected cells/mL	Number of replicates with positive cells	LOD determination
Adenovirus (ATCC type 1)	1000	10/10	100 infected cells/mL
	200	10/10	
	100	**9/10**	
	50	5/10	
	25	1/10	
	12.5	0/10	
	6	0/10	
	3	0/10	
	1.5	0/10	
	0.8	0/10	
hPIV-1 (ATCC strain C-35)	500	10/10	100 infected cells/mL
	100	**10/10**	
	50	6/10	
	25	2/10	
	12.5	1/10	
	6	0/10	
	3	0/10	
	1.5	0/10	
	0.8	0/10	
	0.4	0/10	
hPIV-2 (ATCC strain Greer)	500	10/10	25 infected cells/mL
	100	10/10	
	50	10/10	
	25	**9/10**	
	12.5	6/10	
	6	5/10	
	3	3/10	
	1.5	1/10	
	0.8	0/10	
	0.4	0/10	

TABLE 5.3: Limit of Detections of the D³ FastPoint L-DFA PIV/Adenovirus Reagent			
Virus Strain	Infected cells/mL	Number of replicates with positive cells	LOD determination
hPIV-3 (ATCC strain C243)	1000	10/10	50 infected cells/mL
	200	10/10	
	100	10/10	
	50	**9/10**	
	25	6/10	
	12.5	2/10	
	6	0/10	
	3	0/10	
	1.5	0/10	
	0.8	0/10	

Analytical reactivity (inclusivity):

Analytical reactivity (inclusivity) of the D³ FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit was evaluated using 3 hPIV and 10 adenovirus 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 kit.

TABLE 5.4: Analytical Reactivity (inclusivity) of the D³ FastPoint L-DFA PIV/Adenovirus Reagent on various hPIV and adenovirus strains		
Parainfluenza and Adenovirus Strains	**Infected Cell Concentration (as multiples of the respective established LoD concentration**	**D³ FastPoint L-DFA PIV/Adenovirus Reagent Results**
Parainfluenza 1 C-35	10x LoD	9 Golden-yellow fluorescent cells
Parainfluenza 2 Greer	10x LoD	11 Golden-yellow fluorescent cells
Parainfluenza 3 C-243	10x LoD	22 Golden-yellow fluorescent cells
Adenovirus 1 VR-1	10x LoD	26 Apple-green fluorescent cells
Adenovirus 3 VR-3	10x LoD	17 Apple-green fluorescent cells
Adenovirus 5 VR-5	10x LoD	15 Apple-green fluorescent cells
Adenovirus 6 VR-6	10x LoD	22 Apple-green fluorescent cells
Adenovirus 7 VR-7	10x LoD	16 Apple-green fluorescent cells
Adenovirus 8 VR-1366	10x LoD	29 Apple-green fluorescent cells
Adenovirus 10 VR-1087	10x LoD	34 Apple-green fluorescent cells
Adenovirus VR-14	10x LoD	37 Apple-green fluorescent cells
Adenovirus Dewitt ATCC Strain	10x LoD	15 Apple-green fluorescent cells
Adenovirus 31 VR-1109	10x LoD	42 Apple-green fluorescent cells

Clinical Performance:

Performance of the D³ FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit testing direct respiratory specimens was established during prospective studies at 4 geographically diverse U.S. clinical laboratories during the 2009 respiratory virus seasons (January 2009 through 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 D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit was assessed and compared to a predetermined algorithm that used composite comparator methods. The composite comparator methods for parainfluenza virus and adenovirus 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 adenovirus and hPIV (human parainfluenza virus) within this population as determined by the D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit direct specimen testing is noted in Table 5.5 below:

TABLE 5.5: Parainfluenza Virus/Adenovirus Prevalence

Age	Total Specimens Evaluated	Adenovirus # positive (prevalence)	hPIV # positive (prevalence)
0 to 1 month	55	0	1 (1.8%)
> 1 month to 2 years	577	11 (1.9%)	29 (5.0%)
> 2 years to 12 years	391	1 (0.3%)	6 (1.5%)
> 12 years to 21 years	173	0	2 (1.2%)
22 years to 30 years	57	0	1 (1.8%)
31 years to 40 years	71	0	0
41 years to 50 years	52	0	0
51 years to 60 years	46	0	0
61 years to 70 years	33	0	0
71 years to 80 years	16	0	0
81 years and above	7	0	1 (14.3%)
Age Not Reported	41	1 (2.4%)	0
Total	1519	13 (0.9%)	40 (2.6%)

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

TABLE 5.6: Parainfluenza Virus			
Fresh nasal/nasopharyngeal wash/aspirate	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	23	4	27
Negative	2	599	601
Total	25	603	628
			95% CI
Sensitivity	23/25	92.0%	74.0-99.0%
Specificity	599/603	99.3%	98.3-99.8%

TABLE 5.7: Adenovirus			
Fresh nasal/nasopharyngeal wash/aspirate	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	12	0	12
Negative	1	619	620
Total	13	619	632
			95% CI
Sensitivity	12/13	92.3%	64.0-99.8%
Specificity	619/619	100%	99.4-100%

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

TABLE 5.8: Parainfluenza Virus			
Fresh nasal/nasopharyngeal swab	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	13	0	13
Negative	1	668	669
Total	14	668	682
			95% CI
Sensitivity	13/14	92.9%	66.1-99.8%
Specificity	668/668	100%	99.4-100%

TABLE 5.9: Adenovirus			
Fresh nasal/nasopharyngeal swab	**Comparator DSFA (negatives followed by culture with DFA)**		
DHI DSFA	**Positive**	**Negative**	**Total**
Positive	1	0	1
Negative	0	680	680
Total	1	680	681
			95% CI
Sensitivity	1/1	100%	N/A
Specificity	680/680	100%	99.5-100%

Note: The sensitivity performance of the D³ FastPoint PIV/ADV Kit detecting adenovirus from direct nasal/nasopharyngeal swab specimens has not been adequately established in the clinical study due to low adenovirus prevalence at the clinical study sites. However, the same MAb pool for adenovirus was validated in previous clinical trials for a number of FDA-cleared DSFA devices. Users may wish to further evaluate the sensitivity performance of this kit detecting adenovirus using prospective nasal/nasopharyngeal swab samples.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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DEC 2 3 2009

Re: k093415
Trade/Device Name: D^3 FastPoint L- DFA Parainfluenza Virus/Adenovirus Identification Kit
Regulation Number: 21 CFR § 866.3400
Regulation Name: Parainfluenza Virus Serological Reagents
Regulatory Class: I
Product Code: GQS, GNY
Dated: October 30, 2009
Received: November 2, 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.

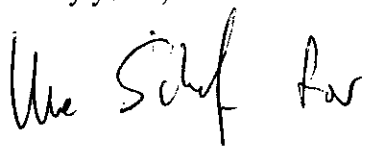
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 796-5461. 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): k093415

Device Name: D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit

Indication for Use:

The Diagnostic Hybrids, Inc. device, D^3 FastPoint L-DFA Parainfluenza Virus/Adenovirus Identification Kit is intended for the qualitative identification of adenovirus and to screen for the presence of parainfluenza virus types 1, 2, and 3 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 parainfluenza virus and adenovirus after examination of the direct specimen result be confirmed by cell culture. Negative results do not preclude parainfluenza virus and adenovirus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Prescription Use		Over-The-Counter Use
X	AND/OR	
(Part 21 CFR 801 Subpart D)		(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) k093415