DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Quidel Corporation
Ronald H. Lollar
Senior Director, Clinical and Regulatory Affairs
2005 East State Street, Suite 100
Athens, OH 45701

October 9, 2014

Re: K141927
Trade/Device Name: Lyra™ Parainfluenza Virus Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OOU
Dated: July 15, 2014
Received: July 16, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely yours,

Tamara V. Feldblyum -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K141927

Device Name
Lyra™ Parainfluenza Virus Assay

Indications for Use *(Describe)*
The Lyra™ Parainfluenza Virus Assay is a Real-Time PCR assay for the qualitative detection and identification of human parainfluenza virus types 1, 2 and 3 viral RNA from nasal and nasopharyngeal swab specimens from symptomatic patients. It is intended for use as an aid in the differential diagnosis of parainfluenza virus types 1, 2 and 3. This test is not intended to detect Parainfluenza 4a or Parainfluenza 4b viruses.

Negative results do not preclude parainfluenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

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

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

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Applicant:

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Date of preparation of 510(k) summary:

July 15, 2014

Device Name:

Trade name – Lyra™ Parainfluenza Virus Assay
Classification name – Respiratory viral panel multiplex nucleic acid assay
Product Code – OOU
Regulation Section – 21CFR 866.3980

Substantial Equivalency

The Lyra™ Parainfluenza Virus Assay used direct specimen DFA and viral tissue culture with DFA as the reference comparator. The predicate device for the assay is the Prodesse ProParaflu™+ Assay. The characteristics of the Lyra™ Parainfluenza Virus Assay ("Subject Device") and the legally marketed device is described in the Table below:

Table 1. Comparison of New Device with Predicate Device		
Item	**Subject Device** Lyra™ Parainfluenza Virus Assay	**Predicate Device (K091053)** **Prodesse ProParaflu™+ Assay**
Intended Use	The Lyra™ Parainfluenza Virus Assay is a Real-Time PCR assay for the qualitative detection and identification of human parainfluenza type 1, 2 and 3 viral RNA from nasal and nasopharyngeal swab specimens from symptomatic patients. It is intended for use as an aid in the differential diagnosis of parainfluenza virus types 1, 2 and 3.This test is not intended to detect Parainfluenza 4a or Parainfluenza 4b Viruses. Negative results do not preclude parainfluenza infection and should not be used as the sole basis for treatment or other patient management decisions.	The ProParaflu+ Assay is a multiplex Real Time RT-PCR *in vitro* diagnostic test for the qualitative detection and discrimination of Parainfluenza I Virus, Parainfluenza 2 Virus and Parainfluenza 3 Virus (HPIV-1, HPIV-2 and HPIV-3) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of respiratory tract infections. This assay targets the conserved regions of the Hemagglutinin-Neuraminidase (HN) gene of HPIV-1, HPIV-2 and HPIV-3, respectively. The detection and discrimination of HPIV-I, HPIV-2 and HPIV-3 nucleic acids from symptomatic patients aid in the diagnosis of human respiratory tract parainfluenza infections if used in conjunction with other clinical and laboratory findings. This test is not intended to

Table 1. Comparison of New Device with Predicate Device		
Item	**Subject Device** Lyra™ Parainfluenza Virus Assay	**Predicate Device (K091053)** **Prodesse ProParaflu™+ Assay**
		detect Parainfluenza 4a or Parainfluenza 4b Viruses. Negative test results are presumptive and should be confirmed by cell culture. Negative results do not preclude Parainfluenza 1, 2 or 3 virus infections and should not be used as the sole basis for treatment or other management decisions.
DNA Amplification Technology	Real time polymerase chain reaction	Same
Target Sequence Detected	Parainfluenza type 1 nuclear protein gene Parainfluenza type 2 phosphate protein gene Parainfluenza type 3 phosphate protein gene	Conserved regions of the Hemagglutinin-Neuraminidase (HN) gene of HPIV-1, HPIV-2 and HPIV-3
Sample Types	Nasal and Nasopharyngeal swabs	Nasopharyngeal swabs
Extraction	NucliSENS® easyMAG™ (bioMérieux)	MagNA Pure LC System (Roche) NucliSENS® easyMAG™ (bioMérieux)
Amplification	Applied Biosystems 7500 Fast Dx	Cepheid SmartCycler II
Detection Techniques	Applied Biosystems 7500 Fast Dx	Cepheid SmartCycler II

Intended Use

The Lyra™ Parainfluenza Virus Assay is a Real-Time PCR assay for the qualitative detection and identification of human parainfluenza virus types 1, 2 and 3 viral RNA from nasal and nasopharyngeal swab specimens from symptomatic patients. It is intended for use as an aid in the differential diagnosis of parainfluenza virus types 1, 2 and 3. This test is not intended to detect Parainfluenza 4a or Parainfluenza 4b viruses.

Negative results do not preclude parainfluenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Methodology

The assay detects viral nucleic acids that have been extracted from a patient sample. A multiplex Real-time RT-PCR reaction is carried out under optimized conditions in a single tube generating amplicons for PIV-1, PIV-2, PIV-3 and the Process Control (PRC). Identification of PIV-1, PIV-2, PIV-3 and the PRC occurs by the use of target-specific primers and fluorescent-labeled probes that hybridize to conserved regions in the genomes of PIV-1, PIV-2, PIV-3 and the PRC.

Table 2. Lyra™ Probe Labels

Target	Dye
PIV-1	FAM
PIV-2	JOE
PIV-3	Tex Red
PRC	CY5

Performance Data

Precision/Reproducibility

Precision

For the Precision/Within Laboratory Repeatability study, a panel of four (4) simulated samples that include medium positive and low positive, high negative PIV-1, PIV-2, PIV-3 and negative samples was tested by two (2) operators, in triplicate for twelve (12) days.

Table 3. Applied Biosystems® 7500 Fast Dx Results Summary

Virus	Target	Ct Values and Percent Positive (%)					
		Pos. Control	**5X LoD**	**2X LoD**	**0.5X LoD**	**Neg. Matrix**	**Neg. Control**
PIV-1	Operator 1 Avg Ct	29.1	33.0	35.1	40.1	Neg	Neg
	Operator 2 Avg Ct	28.6	33.1	35.0	40.0	Neg	Neg
	Positivity	**100%**	**100%**	**100%**	**83%**	**0%**	**0%**
PIV-2	Operator 1 Avg Ct	29.6	32.6	34.6	40.2	Neg	Neg
	Operator 2 Avg Ct	29.1	32.6	34.6	40.5	Neg	Neg
	Positivity	**100%**	**100%**	**100%**	**83%**	**0%**	**0%**
PIV-3	Operator 1 Avg Ct	31.6	32.3	34.3	38.8	Neg	Neg
	Operator 2 Avg Ct	31.2	32.8	34.7	38.8	Neg	Neg
	Positivity	**100%**	**100%**	**100%**	**100%**	**0%**	**0%**

The Lyra™ Parainfluenza Virus Assay produces results that are highly reproducible.

Reproducibility

The reproducibility of the Lyra™ Parainfluenza Virus Assay was evaluated at three (3) laboratory sites. Reproducibility was assessed using a panel of four (4) simulated samples that include medium positive and low positive, high negative PIV-1, PIV-2, PIV-3 and negative samples. Panels and controls were tested at each site by two (2) operators for 5-days (triplicate testing x 2 operators x 5 days x 3 sites = 90 results per level for each virus). The LoD values were based on the values obtained in the LoD study. The panels and controls were extracted using the bioMérieux easyMAG system and tested on the Applied Biosystems 7500 Fast DX.

Table 4. Reproducibility Data

	Percent Agreement (CI95)	Percent Agreement (CI95)	Percent Agreement (CI95)	Percent Agreement (CI95)
	Site 1	Site 2	Site 3	Combined
PIV-1 High Negative	40% (CI95 24.6% to 57.7%)	76.6% (CI95 59.1% to 88.2%)	63.3% (CI95 45.5% to 78.1%)	60% (CI95 49.7% to 69.5%)
PIV-1 Low Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-1 Moderate Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-1 Negative	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100%* (CI95 88.3% to 100%)	100% (CI95 95.6% to 100%)
PIV-2 High Negative	20% (CI95 9.5% to 37.3%)	93.3% (CI95 78.7% to 98.2%)	80% (CI95 62.7% to 90.5%)	64.4% (CI95 54.1% to 73.6%)
PIV-2 Low Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-2 Moderate Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-2 Negative	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100%* (CI95 88.3% to 100%)	100% (CI95 95.6% to 100%)
PIV-3 High Negative	0% (CI95 0% to 11.4%)	3.3% (CI95 0.6% to 16.7%)	53.3% (CI95 36.1% to 69.8%)	18.9% (CI95 12.1% to 28.2%)
PIV-3 Low Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-3 Moderate Positive	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-3 Negative	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100%* (CI95 88.3% to 100%)	100% (CI95 95.6% to 100%)
PIV-1 Positive Control	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
PIV-2 Positive Control	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)

Table 4. Reproducibility Data				
	Percent Agreement (CI95)	Percent Agreement (CI95)	Percent Agreement (CI95)	Percent Agreement (CI95)
	Site 1	Site 2	Site 3	Combined
PIV-3 Positive Control	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)
Negative Control	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 88.6% to 100%)	100% (CI95 95.6% to 100%)

* One (1) replicate had an invalid PRC value and was removed for analysis.

The data from the combined sites indicates that the Lyra™ Parainfluenza Virus Assay, on the Applied Biosystems® 7500 Fast Dx, generates reproducible results for the detection of parainfluenza virus types 1, 2, 3, and the internal control.

Limit of Detection (LoD)

The analytical sensitivity (limit of detection or LoD) of the Lyra™ Parainfluenza Virus Assay was determined using quantified ($TCID_{50}$/mL) stocks of parainfluenza virus types 1, 2, and 3 diluted in a negative matrix. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive.

Table 5. Limit of Detection	$TCID_{50}$/mL
Parainfluenza virus type 1 (C-35 strain)	2.50×10^{0}
Parainfluenza virus type 2 (Greer strain)	2.50×10^{2}
Parainfluenza virus type 3 (C-243 strain)	8.00×10^{1}

Analytical Reactivity (Inclusivity)

To verify the Lyra™ Parainfluenza Virus Assay detects multiple strains of parainfluenza Type 1 (HPIV-1), Type 2 (HPIV-2) and Type 3 (HPIV-3). The number of characterized strains of parainfluenza is very limited. *In silico* analysis was performed to demonstrate that primers are representative of the genetic diversity in the chosen target region for each parainfluenza virus type identified by the assay.

All full-genome Genbank annotation files for Human Parainfluenza virus Types 1, 2, and 3 were downloaded from NCBI. A summary of the number of sequences evaluated for each virus type is in the table below.

Table 6. Summary of Parainfluenza Sequences Evaluated		
HPIV Type	***Subtyping HPIV Type***	***Total Number of Sequences***
HPIV1	HPIV2	308
	HPIV3	
	HPIV4	

HPIV2	HPIV1	458
	HPIV3	
	HPIV4	
HPIV3	HPIV1	509
	HPIV2	
	HPIV4	

Analytical Specificity/Cross-Reactivity

The analytical specificity with potentially cross-reactive organisms was evaluated by testing a panel consisting of 28 viral, 26 bacterial, and 1 yeast strains representing common respiratory pathogens or flora commonly present in the nasopharynx. The organisms were added to negative nasal matrix. The bacteria and yeast were tested at concentrations of 10^4 to 10^8 CFU/mL. Viruses were tested at concentrations of 10^4 to 10^8 $TCID_{50}$/mL. Samples were extracted using the NucliSens easyMAG instrument and tested in triplicate.

Table 7. Organisms Evaluated for Cross-Reactivity

Bordetella pertussis	*Candida albicans*	RSV A (Long)
Bordetella bronchiseptica	Adenovirus 1	RSV B (Wash/18537/62)
Chlamydophila pneumonia	Coronavirus 229E	Varicella Zoster Virus
Chlamydia trachomatis	Coronavirus NL63	
Legionella pneumophila	Coronavirus OC43	
Mycobacterium intracellualre	Coxsackievirus B4	
Mycobacterium tuberculosis	Coxsackievirus B5/10/2006	
Mycobacterium avium	Cytomegalovirus	
Mycoplasma pneumoniae	Echovirus 6	
Haemophilus influenzae	Echovirus 7	
Pseudomonas aeruginosa	Echovirus 9	
Proteus vulgaris	Echovirus 11	
Proteus mirabilis	Enterovirus 70	
Neisseria gonorrhoeae	Enterovirus 71	
Neisseria meningitidis	Epstein Barr Virus	
Neisseria mucosa	HSV Type 1 MacIntyre Strain	
Klebsiella pneumoniae	HSV Type 2 Strain G	
Escherichia coli	Human Metapneumovirus (A1)	
Moraxella catarrhalis	Human Rhinovirus 45	
Corynebacterium diptheriae	Human Rhinovirus 52	
Lactobacillus plantarum	Influenza A/Mexico/4108/2009	
Streptococcus pneumoniae	Influenza A/Port Chalmers	
Streptococcus pyogenes	Influenza B/Florida/04/2006	

Table 7. Organisms Evaluated for Cross-Reactivity		
Streptococcus salivarius	Measles/7/2000	
Staphylococcus epidermidis	Mumps Virus	
Staphylococcus aureus	Parainfluenza Type 4A	

No cross-reactivity was seen with any of the organisms tested.

Microbial Interference

The analytical specificity with interfering organisms of the Lyra™ Parainfluenza Virus Assay was evaluated by testing a panel consisting of 28 viral, 26 bacterial, and 1 yeast strains representing common respiratory pathogens or flora commonly present in the nasopharynx. The organisms were added to samples containing either parainfluenza virus types 1, 2, or 3 at 2 x LoD concentration. The bacteria and yeast were tested at concentrations of 10^4 to 10^8 CFU/mL. Viruses were tested at concentrations of 10^4 to 10^8 $TCID_{50}$/mL. Samples were extracted using the NucliSens easyMAG instrument and tested in triplicate.

Table 8. Organisms Evaluated for Interference		
Bordetella pertussis	*Candida albicans*	RSV A (Long)
Bordetella bronchiseptica	Adenovirus 1	RSV B (Wash/18537/62)
Chlamydophila pneumonia	Coronavirus 229E	Varicella Zoster Virus
Chlamydia trachomatis	Coronavirus NL63	
Legionella pneumophila	Coronavirus OC43	
Mycobacterium intracellualre	Coxsackievirus B4	
Mycobacterium tuberculosis	Coxsackievirus B5/10/2006	
Mycobacterium avium	Cytomegalovirus	
Mycoplasma pneumoniae	Echovirus 6	
Haemophilus influenzae	Echovirus 7	
Pseudomonas aeruginosa	Echovirus 9	
Proteus vulgaris	Echovirus 11	
Proteus mirabilis	Enterovirus 70	
Neisseria gonorrhoeae	Enterovirus 71	
Neisseria meningitidis	Epstein Barr Virus	
Neisseria mucosa	HSV Type 1 MacIntyre Strain	
Klebsiella pneumoniae	HSV Type 2 Strain G	
Escherichia coli	Human Metapneumovirus (A1)	
Moraxella catarrhalis	Human Rhinovirus 45	
Corynebacterium diptheriae	Human Rhinovirus 52	
Lactobacillus plantarum	Influenza A/Mexico/4108/2009	
Streptococcus pneumoniae	Influenza A/Port Chalmers	
Streptococcus pyogenes	Influenza B/Florida/04/2006	
Streptococcus salivarius	Measles/7/2000	
Staphylococcus epidermidis	Mumps Virus	
Staphylococcus aureus	Parainfluenza Type 4A	

No interference was seen with any of the organisms when the target viruses were tested at 2 x LoD concentrations.

Interfering Substances

A study was performed on the Applied Biosystems 7500 Fast Dx to evaluate the performance of the Lyra™ Parainfluenza Virus Assay in the presence of eleven (11) of potentially interfering/cross-reactive substances, at clinically relevant levels, that might be present in specimens. Each substance was tested in the presence of 2X LoD parainfluenza virus types 1, 2, and 3 samples and with negative matrix.

Table 9. Interfering/Cross-reactive Substances Summary

Substance Name	PIV-1		PIV-2		PIV-3		No Analyte		Inhibition (yes/no)
	Ct Avg.	SD	Ct Avg.	SD	Ct Avg.	SD	Ct Avg.	SD	
Controls	**35.1**	**0.3**	**36.8**	**2.9**	**33.4**	**0.6**	**Neg**	**N/A**	**N/A**
Mucin (Bovine Submaxillary Gland, type I-S)	35.8	0.4	35.6	0.7	34.4	0.3	Neg	N/A	No
Blood (human), EDTA anticoagulated	34.9	0.2	34.0	0.3	32.2	0.6	Neg	N/A	No
Neo-Synephrine	34.8	0.5	34.2	0.7	33.1	0.4	Neg	N/A	No
Afrin Nasal Spray	35.2	0.6	34.1	0.2	33.5	0.1	Neg	N/A	No
Zicam Homeopathic Non-Drowsy Allergy Relief No Drip Liquid Nasal Gel	34.9	0.8	34.2	0.1	34.0	0.4	Neg	N/A	No
Saline Nasal Spray	34.8	0.2	34.5	0.2	33.4	0.2	Neg	N/A	No
OTC Throat Lozenges: Ricola Action Cherry	34.7	0.2	34.2	0.4	34.0	0.2	Neg	N/A	No
Zanamivir	34.6	0.2	34.2	0.5	33.9	0.2	Neg	N/A	No
Tobramycin	34.9	0.3	34.1	0.5	34.5	1.6	Neg	N/A	No
Mupirocin	35.2	0.4	35.2	0.5	34.0	0.3	Neg	N/A	No
Oseltamivir phosphate	35.1	0.2	35.3	0.8	34.1	0.2	Neg	N/A	No

None of the eleven (11) of substances interferes with the detection of parainfluenza virus types 1, 2, and 3.
None of the eleven (11) of substances tested cross-reacts with the Lyra™ Parainfluenza Virus Assay.

Carry-Over and Cross Contamination

Studies were performed on the Applied Biosystems® 7500 Fast Dx using a 96-sample panel consisting of 48 high positives and 48 negative specimens. Each high positive specimen contained a concentration of 1.0×10^5 $TCID_{50}$/mL parainfluenza-1, parainfluenza-2, and parainfluenza-3 combined into one sample. The high positive samples were extracted and analyzed in series alternating with the negative samples. The negative samples were comprised of negative matrix. The testing was repeated over a 5-day period.

Over the course of 5 days, cross-contamination and amplicon carry-over did not occur with the Lyra™ Parainfluenza Virus Assay when extracted the NucliSens easyMAG automated nucleic acid extraction instrument and analyzed on the Applied Biosystems® 7500 Fast Dx.

Method Comparison

Prospective Study

The evaluation of the Lyra™™™ Parainfluenza Virus Assay occurred in two separate studies: a prospective multi-center study using one thousand two hundred and forty-one (1241) fresh specimens from the upper respiratory tract; and a retrospective study using one hundred five (105) frozen specimens from the upper respiratory tract. In both studies the specimens were processed the bioMérieux NucliSENS® easyMag® at all sites for the extraction of nucleic acids from the clinical specimens. The Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument was used with the Quidel assay for the amplification and detection of the target nucleic acids with the Lyra™ Parainfluenza Virus Assay. The prospective specimens were also processed and tested with direct specimen fluorescent antibody (DSFA) and cell culture with DFA (CCFA). The retrospective specimens were extracted and tested with an additional FDA-cleared molecular assay.

One thousand two hundred and forty-one (1241) fresh specimens were collected and transported to each laboratory for testing with the Lyra™ Parainfluenza Virus Assay. The specimens shipped daily with cold packs for DSFA and CCFA to the central location and were tested within 72-hours of collection. The table below details the PIV-1 results for the specimens.

Table 10. PIV-1			
Lyra™ Parainfluenza Virus Assay	**Comparator: DSFA and Culture with DFA**		
	Positive	Negative	Total
Positive	10	3*	13
Negative	0	1228	1228
Total	10	1231	1241
			95% CI
Sensitivity	10/10	100%	72.2% to 100%
Specificity	1228/1231	99.8%	99.3 % to 99.9%

* Two (2) of the three (3) positives were positive by an additional RT-PCR assay.

The table below details the PIV-2 results for the specimens.

Table 11. PIV-2			
Lyra™ Parainfluenza Virus Assay	**Comparator: DSFA and Culture with DFA**		
	Positive	Negative	Total
Positive	5	0	5
Negative	0	1236	1241
Total	5	1236	1246
			95% CI
Sensitivity	5/5	100%	56.6% to 100%
Specificity	1236/1236	100%	99.7% to 100%

The table below details the PIV-3 results for the specimens.

Table 12. PIV-3			
Lyra™ Parainfluenza Virus Assay	**Comparator: DSFA and Culture with DFA**		
	Positive	Negative	Total
Positive	17	5*	22
Negative	0	1219	1219
Total	17	1224	1241
			95% CI
Sensitivity	17/17	100%	81.6% to 100%
Specificity	1219/1224	99.6%	99.0% to 99.8%

* Five (5) of the five (5) positives were positive by an additional RT-PCR assay.

Retrospective Study

Due to the low prevalence of parainfluenza virus at the clinical sites during the study period, a retrospective study was conducted with specimens obtained from a pediatric hospital in the Southwest United States. One hundred five (105) frozen specimens from the upper respiratory tract were tested concurrently with the Lyra™ Parainfluenza Virus Assay and the Prodesse ProParaFlu+ assay (K091053).

Table 13. PIV-1			
Lyra™ Parainfluenza Virus Assay	**Comparator: Prodesse ProParaFlu+ assay**		
	Positive	Negative	Total
Positive	24	1*	25
Negative	0	80	80
Total	24	81	105
			95% CI
Positive Percent Agreement	24/24	100%	86.2% to 100%
Negative Percent Agreement	80/81	98.8%	93.3% to 99.8%

* One (1) of one (1) positive was positive by an additional RT-PCR assay.

Table 14. PIV-2			
Lyra™ Parainfluenza Virus Assay	**Comparator: Prodesse ProParaFlu+ assay**		
	Positive	Negative	Total
Positive	22	5*	27
Negative	0	78	78
Total	22	83	105
			95% CI
Positive Percent Agreement	22/22	100%	85.1% to 100%
Negative Percent Agreement	78/83	94.0%	86.7% to 97.4%

* Five (5) of five (5) positives were positive by an additional RT-PCR assay.

Table 15. PIV-3			
Lyra™ Parainfluenza Virus Assay	**Comparator: Prodesse ProParaFlu+ assay**		
	Positive	Negative	Total
Positive	24	0	24
Negative	0	81	81
Total	24	81	105
			95% CI
Positive Percent Agreement	24/24	100%	86.2% to 100%
Negative Percent Agreement	81/81	100%	95.5% to 100%

Statement of Safety and Effectiveness

When performed on the Applied Biosystems® 7500 Fast Dx, the Lyra™ Parainfluenza Virus Assay yielded good sensitivity and specificity when compared to the composite reference method of direct specimen fluorescent antibody (DSFA) and cell culture with DFA (CCFA).

When performed on the Applied Biosystems® 7500 Fast Dx, the Lyra™ Parainfluenza Virus Assay yielded good positive and negative percent agreement when compared to and FDA-cleared molecular device.