K 122189

Section 05, 510(k) Summary

Applicant:

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MAR 8 2013

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Date of preparation of 510(k) summary:

July 20, 2012

Device Name:

Trade name – **Quidel Molecular RSV + hMPV Assay**
Classification name – Respiratory viral panel multiplex nucleic acid assay
Product Code – OEM, OCC
Regulation – 21 CFR 866.3980

Legally marketed devices to which equivalence is claimed:

Gen-Probe Prodesse ProFlu+ (k092500)

The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.

Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative RSV results be confirmed by culture.

Performance characteristics for Influenza A Virus 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 department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Gen-Probe Prodesse Pro hMPV+ (k082688)

The Pro hMPV+ Assay is a Real Time RT-PCR *in vitro* diagnostic test for the qualitative detection of human Metapneumovirus (hMPV) nucleic acid isolated and purified from nasopharyngeal swab (NP) specimens obtained from individuals exhibiting signs and symptoms of acute respiratory infection. This assay targets a highly conserved region of the Nucleocapsid gene of hMPV. The detection of hMPV nucleic acid from symptomatic patients aids in the diagnosis of human respiratory hMPV infection if used in conjunction with other clinical and laboratory findings. This test is not intended to differentiate the four genetic sub-lineages of hMPV.

Negative results do not preclude hMPV infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Intended Use:

The Quidel Molecular RSV + hMPV assay is a multiplex Real Time RT-PCR assay for the *in vitro* qualitative detection and identification of respiratory syncytial virus and human metapneumovirus viral RNA extracted from nasal and nasopharyngeal swabs specimens from patients with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of respiratory syncytial virus and human metapneumovirus infections. This test is not intended to differentiate the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Device Description:

The Quidel Molecular RSV + hMPV Assay detects viral nucleic acids that have been extracted from a patient sample using the NucliSENS® easyMAG® automated extraction platform. A multiplex RT-PCR reaction is carried out under optimized conditions in a single tube generating amplicons for each of the target

viruses present in the sample. This reaction is performed utilizing either the Cepheid SmartCycler® II or the Applied Biosystems 7500 Fast DX. Identification of RSV and hMPV and the PRC occurs by the use of target-specific primers and fluorescent-labeled probes that hybridize to conserved regions in the genomes of RSV and hMPV and the PRC.

The following is a summary of the procedure:

1. **Sample Collection:** Obtain nasal or nasopharyngeal swabs specimens using standard techniques from symptomatic patients. Transport, store, and process these specimens according to established laboratory procedures.[i]

2. **Nucleic Acid Extraction:** Extract Nucleic Acids from the specimens with the NucliSENS® easyMAG® System following the manufacturer's instructions and using the appropriate reagents (See **Materials Required but Not Provided**).

   Prior to the extraction procedure, add 20 µL of the Process Control (PRC) to each 180 µL aliquot of specimen. The PRC serves to monitor inhibitors in the extracted specimen, assures that adequate amplification has taken place, and confirms that the nucleic acid extraction was sufficient.

3. **Rehydration of Master Mix:** Rehydrate the lyophilized Master Mix using the Rehydration Solution. The Master Mix contains oligonucleotide primers, fluorophore and quencher-labeled probes targeting conserved regions of RSV and hMPV, as well as the process control sequence.

4. **Nucleic Acid Amplification and Detection:** Add 15 µL of the rehydrated Master Mix to each reaction tube or plate well. Then add 5 µL of extracted nucleic acids (specimen with PRC) to the plate well or appropriately labeled reaction tube. Place the tube or plate into either the SmartCycler® II or 7500 Fast Dx instruments, respectively.

   Once the reaction tube or plate is added to the instrument, initiate the assay protocol. This protocol initiates reverse transcription of the RNA targets generating complementary DNA, and the subsequent amplification of the target amplicons occurs. The Quidel Molecular RSV + hMPV assay is based on TaqMan® chemistry and uses an enzyme with reverse transcriptase, DNA polymerase, and 5'-3' exonuclease activities. During DNA amplification, this enzyme cleaves the probe bound to the complementary DNA sequence, separating the quencher dye from the reporter dye. This step generates an increase in fluorescent signal upon excitation by a light source of the appropriate wavelength. With each cycle, additional dye molecules are separated from their quenchers resulting in additional signal. If sufficient

fluorescence is achieved by 50 cycles on the SmartCycler® II or 35 cycles on the ABI 7500 Fast Dx, the sample is reported as positive for the detected nucleic acid.

Device Comparison

The Quidel Molecular RSV + hMPV assay will be compared to legally marketed RT-PCR assays. The characteristics of Quidel Molecular RSV + hMPV assay ("Subject Device") and the Prodesse ProFlu + and Pro hMPV+ ("Predicate Devices") are described in the table below:

Subject Device and Comparator Device Comparison

Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+	**Predicate Device** Prodesse ProhMPV+
Intended Use	The Quidel Molecular RSV + hMPV assay is a multiplex Real Time RT-PCR assay for the *in vitro* qualitative detection and identification of respiratory syncytial virus and human metapneumovirus viral RNA extracted from nasal and nasopharyngeal swabs specimens with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of respiratory syncytial virus and human metapneumovirus infections. This test is not intended to	The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.	The Pro hMPV+ Assay is a Real Time RT-PCR *in vitro* diagnostic test for the qualitative detection of human Metapneumovirus (hMPV) nucleic acid isolated and purified from nasopharyngeal swab (NP) specimens obtained from individuals exhibiting signs and symptoms of acute respiratory infection. This assay targets a highly conserved region of the Nucleocapsid gene of hMPV. The detection of hMPV nucleic acid from symptomatic patients aids in the diagnosis of human respiratory hMPV infection if

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+	**Predicate Device** Prodesse ProhMPV+
	differentiate the four genetic sub-lineages of hMPV. Negative results do not preclude RSV or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.	Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative RSV results be confirmed by culture. Performance characteristics for Influenza A Virus 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	used in conjunction with other clinical and laboratory findings. This test is not intended to differentiate the four genetic sub-lineages of hMPV. Negative results do not preclude hMPV infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+	**Predicate Device** Prodesse ProhMPV+
		with appropriate infection control precautions for novel virulent Influenza viruses and sent to 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.	
Assay Target	respiratory syncytial virus, hMPV	Influenza A virus, influenza B virus, respiratory syncytial virus	hMPV
Sample Types	nasal swab, nasopharyngeal swab	nasopharyngeal swab	nasopharyngeal swab
Extraction Methods	bioMérieux easyMAG Automated Magnetic Extraction Reagents	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit or the bioMérieux easyMAG Automated Magnetic Extraction Reagents	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit or the bioMérieux easyMAG Automated Magnetic Extraction Reagents
Assay Methodology	PCR-based system for detecting the presence or absence of viral RNA in clinical specimens	PCR-based system for detecting the presence or absence of viral RNA in clinical specimens	PCR-based system for detecting the presence or absence of viral RNA in clinical specimens
Detection Techniques	Multiplex assay using different reporter dyes for each target	Multiplex assay using different reporter dyes for each target	Multiplex assay using different reporter dyes for each target
Viral Targets	RSV: L viral polymerase and NS2 genes	Influenza A: Matrix Gene; Influenza B: Non-	Nucleocapsid

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+	**Predicate Device** Prodesse ProhMPV+
	hMPV: RNA polymerase gene	structural NS1 and NS2	
LoD	The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular hMPV assay was determined using quantified ($TCID_{50}$/mL) cultures of 2 RSV strains and 4 hMPV strains (A1, A2, B1, B2) serially diluted in negative nasopharyngeal matrix. Each dilution was extracted using the NucliSENS easyMAG System and tested in replicates of 20 per concentration of virus on both the Applied Biosystems® 7500 Fast Dx platform. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive, ranged from 10^{-1} to 10^{1} $TCID_{50}$/mL.	The analytical sensitivity (limit of detection or LoD) of the ProFlu+ Assay was determined using quantified ($TCID_{50}$/mL) cultures of 4 Influenza A (2 H1N1 and 2 H3N2), 2 Influenza B, 2 Respiratory Syncytial Virus Type A, and 2 Respiratory Syncytial Virus Type B strains serially diluted in nasopharyngeal clinical matrix. Each viral strain was extracted using the Roche MagNA Pure LC instrument and tested in replicates of 20 per concentration of virus. Analytical sensitivity (LoD), as defined as the lowest concentration at which 95% of all replicates tested positive, ranged from 10^{2} to 10^{-1} $TCID_{50}$/mL.	The analytical sensitivity (limit of detection or LoD) of the Pro hMPV+ Assay was determined using quantified (TCID50/mL) cultures of 2 hMPV (subtype A2 and subtype B2) strains serially diluted in nasopharyngeal clinical matrix. Each viral strain was extracted using the Roche MagNA Pure LC instrument and tested in replicates of 20 per concentration of virus. Analytical sensitivity (LoD) as defined as the lowest concentration at which ≥ 95% of all replicates tested positive, ranged from 10^{2} – 10^{1} $TCID_{50}$/mL.

Analytical Performance:

Reproducibility:

The reproducibility of the Quidel Molecular Influenza RSV + hMPV assay was evaluated at 3 laboratory sites. Reproducibility was assessed using a panel of 4 simulated samples that include medium (5x LoD) and low (2x LoD), high negative (0.3x LoD) RSV, hMPV and negative samples. Panels and controls were tested at each site by 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 are based on the values obtained in the LoD study. The panels and controls were extracted using the bioMérieux easyMAG system and tested on the Cepheid SmartCycler® II and the Applied Biosystems® 7500 Fast DX.

Reproducibility Results – Cepheid SmartCycler										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
RSV High Negative 0.06x LoD	18/30	43.15	9.84	18/30	41.9	11.0	7/30	45.3	11.8	43/90
RSV Low Positive 2x LoD	29/29	31.79	6.32	30/30	31.2	4.1	30/30	31.9	4.4	89/89
RSV Med Positive 5x LoD	30/30	30.35	9.57	30/30	29.7	2.5	30/30	29.2	9.1	90/90
RSV Negative	1/30	48.50	N/A	0/30	N/A	N/A	1/30	43.0	N/A	2/90
RSV Negative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
RSV Positive Control	30/30	28.25	5.31	30/30	27.5	2.9	30/30	26.8	9.7	90/90
hMPV High Negative 0.06x LoD	25/30	37.27	10.75	20/30	40.43	7.75	11/30	42.3	5.4	56/90
hMPV Low Positive 2x LoD	30/30	32.35	7.68	30/30	31.55	3.19	30/30	32.2	3.5	90/90
hMPV Med Positive 5x LoD	30/30	30.19	4.01	30/30	29.95	2.02	30/30	30.4	1.7	90/90
hMPV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
hMPVNegative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
hMPV Positive Control	30/30	27.51	2.53	30/30	26.83	2.37	30/30	27.0	1.1	90/90

Reproducibility Results – Applied Biosystems 7500 Fast Dx										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
RSV High Negative 0.06x LoD	4/30	26.4	18.2	5/30	34.6	1.0	7/30	31.7	9.1	16/90
RSV Low Positive 2x LoD	30/30	24.5	6.64	30/30	22.8	7.3	30/30	24.5	8.8	90/90
RSV Med Positive 5x LoD	30/30	21.02	5.57	30/30	20.8	6.2	30/30	21.5	8.4	90/90
RSV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
RSV Negative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
RSV Positive Control	30/30	19.2	3.75	30/30	7.21	2.8	30/30	7.8	8.0	90/90
hMPV High Negative 0.06x LoD	6/30	28.5	20.9	2/30	31.6	0.67	10/30	27.3	13.2	18/90
hMPV Low Positive 2x LoD	27/30	24.5	11.07	30/30	24.6	12.4	30/30	24.6	12.8	87/90
hMPV Med Positive 5x LoD	29/30	23.1	7.58	30/30	23.3	4.9	30/30	21.7	6.4	89/90
hMPV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
hMPVNegative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
hMPV Positive Control	30/30	18.89	2.49	30/30	11.8	2.5	30/30	11.4	4.2	90/90

The data from the combined sites indicates that the Quidel Molecular RSV + hMPV assay generates reproducible results for RSV and hMPV when tested with the Cepheid SmartCycler® II and the Applied Biosystems® 7500 Fast Dx.

Limit of Detection

The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular RSV + hMPV assay was determined using quantified ($TCID_{50}$/mL) cultures of 2 RSV strains and 4 hMPV strains (1 A1, 1 A2, 1 B1, 1B2) serially diluted in negative nasopharyngeal matrix. Each dilution was extracted in replicates of 20 per concentration of virus using the NucliSENS easyMAG System and tested on both the 7500 Fast Dx or Cepheid SmartCycler® II platforms. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive.

LoD Value Summary for the 7500 Fast Dx & SmartCycler		
Virus	**LoD $TCID_{50}$/mL 7500 Fast Dx**	**LoD $TCID_{50}$/mL SmartCycler**
RSV A	6.29E-01	1.89E+00
RSV B	7.5E-01	7.5E-01
hMPV-A1	1.7E+01	2.645E+01
hMPV-A2	2.91E+00	2.91E+00
hMPV-B1	1.05E+00	7.88E+00
hMPV-B2	2.25E+00	2.25E+00

Analytical reactivity (inclusivity)

The reactivity of the Quidel Molecular RSV + hMPV assay was evaluated against multiple strains of RSV and hMPV. The clinical panel consisted of 13 RSV strains and 12 hMPV strains (3 A-1, 2 A-2, 3 B-1, and 4 B-2). Each panel member was extracted using the NucliSens easyMAG instrument and tested in triplicate.

RSV Inclusivity Panel				
Subtype	**Strain**	**$TCID_{50}$/mL**	**(7500 Dx)**	**(SmartCycler)**
A	Long	1.89E+0	Positive	Positive
A	A-2	9.38E-1	Positive	Positive
B	Washington	1.58E0	Positive	Positive
B	9320	1.95E+0	Positive	Positive
NA	WC-026	NA	Positive	Positive
NA	WC-189	NA	Positive	Positive
NA	MHIA - 0022	NA	Positive	Positive
NA	MHIA - 0020	NA	Positive	Positive
NA	MHIA - 0016	NA	Positive	Positive
NA	Chile - 424	NA	Positive	Positive
NA	Chile - 457	NA	Positive	Positive
NA	WC - 229	NA	Positive	Positive
NA	WC - 192	NA	Positive	Positive

hMPV Inclusivity Panel				
Subtype	**Strain**	**$TCID_{50}$/mL**	**(7500 Dx)**	**(SmartCycler)**
A1	Italy	1.11E+2	Positive	Positive
B1	Italy	2.20E+0	Positive	Positive
B2	Italy	4.50E+1	Positive	Positive
B1	Peru2-2002 G Gene	4.17E+2	Positive	Positive
B2	Peru1-2002 G Gene	1.26E+2	Positive	Positive
B1	Peru3-2003 G Gene	1.26E+2	Positive	Positive
B2	Peru6-2003	5.01E+2	Positive	Positive
A1	IA3-2002 G Gene	1.51E+2	Positive	Positive
A1	IA10-2003	3.80E+2	Positive	Positive
B2	IA18-2003 G Gene	6.61E+2	Positive	Positive
A2	IA14-2003 G Gene	1.95E+2	Positive	Positive
A2	Clinical Isolate	1.05E+2	Positive	Positive

Analytical specificity (cross-reactivity)

The analytical specificity of the Quidel Molecular RSV + hMPV assay was evaluated by testing a panel consisting of 27 viruses, 24 bacteria and 1 yeast strain representing common respiratory pathogens or flora commonly present in nasopharynx. Samples were extracted using the NucliSENS easyMAG instrument and tested in triplicate. Analytical specificity of the Quidel Molecular RSV + hMPV assay was 100%.

Organisms used for the study were the following:

Viruses

Influenza A/Mexico/4108/2009, Influenza B/Florida/04/2006, Adenovirus 1/Adenoid 71, Adenovirus 2, Adenovirus 3, Adenovirus 4, Adenovirus 5, Adenovirus 7, Adenovirus 11, Adenovirus 14, Adenovirus 31, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Coxsackievirus B4, Coxsackievirus B5/10/2006, Cytomegalovirus, Echovirus 7, Echovirus 9, Echovirus 6, Echovirus

11, Enterovirus 71, Enterovirus 70, Epstein Barr Virus, HSV Type 1 Maclnytre strain, Human Rhinovirus, HSV Type 2 G strain, Measles virus, Mumps virus, Parainfluenza Type 1, Parainfluenza Type 2, Parainfluenza Type 3, Parainfluenza Type 4, Varicella Zoster Virus

Bacteria

Bordetella pertussis, , Bordetella bronchiseptica, Chlamydophila pneumonia, Chlamydia trachomatis, Legionella pneumophila, Mycobacterium intracellulare, Mycobacterium tuberculosis, Mycobacterium avium, Mycoplasma pneumoniae, Haemophilus influenza, Pseudomonas aeruginosa, Proteus vulgaris, Proteus mirabilis, Neisseria gonorrhoeae, Neisseria menigitidis, Neisseria mucosa, Klebsiella pneumonia, Escherichia coli, Moraxella catarrhalis, Corynebacterium diptheriae, Lactobacillus plantarum, Streptococcus pneumonia, Streptococcus pyogenes, Streptococcus salivarius, Staphylococcus epidermidis, Staphylococcus aureus

Yeast
Candida albicans

Clinical Performance:

Performance characteristics of the Quidel Molecular RSV + hMPV assay using the Cepheid SmartCycler® II instrument and the Applied Biosystems® 7500 Fast Dx platform were established during a prospective study during the 2012 respiratory virus season (January to March 2012). Samples used for this study were fresh (414) and frozen (600) swab specimens that were collected for routine respiratory virus testing four sites across the United States. A single specimen was collected per patient and tested (direct specimen DFA and culture with DFA) for RSV immediately after collection. The specimens were extracted with the bioMériuex easyMAG and tested with Quidel Molecular RSV + hMPV assay. Aliquots of each specimen were sent to a central location for testing with a FDA Cleared hMPV molecular test.

Cepheid SmartCycler® II

One thousand and fourteen (1014) specimens were tested by both the subject and comparative methods for RSV. Five specimens were contaminated in cell culture (0.5%). Results for the remaining 1009 specimens are detailed in the table below.

Combined Site - Respiratory syncytial virus								
		DSFA & Cell Culture w/DFA					95% CI	
		POS	NEG	Total	Sensitivity	97.9%	93.9%	99.3%
QM RSV + hMPV	POS	137	21*	158	Specificity	97.6%	96.3%	98.4%
	NEG	3	848	851				
	Total	140	869	1009	Prevalence	13.9%		

* All originally discordant specimens were positive for RSV by an FDA-cleared RT-PCR assay. All specimens were also positive for RSV by bi-directional sequence analysis.

Nine hundred and sixty (960) specimens were tested by both the subject and comparative devices for hMPV (the comparator device was unavailable to complete comparison testing). Nine specimens were invalid in the comparative device (0.9%). Results for the remaining 951 specimens are detailed in the table below.

Combined Site - Human metapneumovirus								
		Pro hMPV+					95% CI	
		POS	NEG	Total	Positive percent agreement	96.7%	92.4%	98.6%
QM RSV + hMPV	POS	145	3*	148	Negative percent agreement	99.6%	98.9%	99.9%
	NEG	5	798	803				
	Total	150	801	951	Prevalence	15.8%		

* All originally discordant specimens were positive for hMPV by bi-directional sequence analysis.

Applied Biosystems® 7500 Fast Dx

One thousand and fourteen (1014) specimens were tested by both the subject and comparative methods for RSV. Five specimens were contaminated in cell culture (0.5%). Two specimens were invalid in the subject methods (0.2%). Results for the remaining 1,007 specimens are detailed in the table below.

Combined Site - Respiratory syncytial virus								
		DSFA & Cell Culture w/DFA					95% CI	
		POS	NEG	Total	Sensitivity	98.6%	94.9%	99.6%
QM RSV + hMPV	POS	138	28*	166	Specificity	96.8%	95.4%	97.8%
	NEG	2	839	841				
	Total	140	867	1007	Prevalence	13.9%		

*25 of 28 originally discordant specimens were positive for RSV by a FDA-cleared RT-PCR assay. 27 of 28 specimens were positive for RSV by bi-directional sequence analysis.

Nine hundred and fifty seven (957) specimens were tested by both the subject and comparative devices for hMPV (the comparator device was unavailable to complete comparison testing). Nine (9) specimens were invalid in the comparative device (0.9%). Two (2) specimens were invalid in the subject methods (0.2%). Results for the remaining 946 specimens are detailed in the table below.

Combined Site - Human metapneumovirus								
		Pro hMPV+					95% CI	
		POS	NEG	Total	Positive percent agreement	98.0%	94.3%	99.3%
QM RSV + hMPV	POS	147	6*	153	Negative percent agreement -	99.3%	98.4%	99.7%
	NEG	3	790	793				
	Total	150	796	946	Prevalence	15.9%		

* All originally discordant specimens were positive for hMPV by bi-directional sequence analysis.

Conclusions

Quidel Molecular RSV + hMPV Assay yielded good sensitivity and specificity for RSV with nasal and nasopharyngeal swabs when compared to a direct specimen DFA and cell culture with DFA.

Quidel Molecular RSV + hMPV Assay yielded good positive and negative percent agreement with nasal and nasopharyngeal swabs compared to a 510(k) cleared molecular device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Quidel Corporation
C/O Ronald H. Lollar
1055 East State Street, Suite 100
Athens, Ohio 45701

March 8, 2013

Re: k122189
Trade/Device Name: Quidel® Molecular RSV + hMPV Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OEM, OCC
Dated: January 28, 2013
Received: January 29, 2013

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 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 Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Uwe Scherf -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

510(k) Number (if known): k122189

Device Name: Quidel® Molecular RSV + hMPV Assay

Indication for Use:

The Quidel Molecular RSV + hMPV assay is a multiplex Real Time RT-PCR assay for the qualitative detection and identification of respiratory syncytial virus and human metapneumovirus RNA extracted from nasal and nasopharyngeal swabs specimens from patients with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of respiratory syncytial virus and human metapneumovirus infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Tamara V. Feldblyum -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) ___K122189___