Respiratory Panel 1.0

Instructions for Use

For Professional Use

CE IVD

For Use with FlashDx-1000-E System

For *In vitro* Diagnostic Use

Rev A. May 2022

Proprietary Name

Respiratory Panel 1.0

Common or Usual Name

Respiratory Panel 1.0

Packing Specification

10 tests/box

Intended Use

Respiratory Panel 1.0 is a rapid multiplexed nucleic acid microarray-qPCR test intended for *in vitro* qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus (ADV), parainfluenza virus 1, 2 & 3 (PIV1, PIV2, PIV3), human rhinovirus/enterovirus (HRV/HEV) and/or mycoplasma pneumoniae (MP) in nasopharyngeal, nasal or throat swabs collected from individuals with or without symptoms, or other epidemiological reasons to suspect of respiratory viral infection. The test is run using FlashDx-1000-E or other compatible FlashDx systems.

Positive results are indicative of the presence of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, adenovirus, parainfluenza virus, human rhinovirus/enterovirus and/or mycoplasma pneumoniae RNA or DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out co-infection with other pathogens. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, adenovirus, parainfluenza virus, human rhinovirus/enterovirus and/or mycoplasma pneumoniae infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

Principle of the Procedure

Respiratory Panel 1.0 is an *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, adenovirus, parainfluenza virus, human rhinovirus/enterovirus and/or mycoplasma pneumoniae. The test is performed on FlashDx-1000-E Automatic Nucleic Acid Detection System. The test is a single-use disposable

cartridge containing lyophilized and liquid reagents for sample processing, reverse transcription, cDNA amplification and detection. Once user closes the lid after sample is added, cartridge becomes self-contained and this can minimize cross-contamination between samples.

A microarray of specific probes is prepositioned on inner surface of amplification chamber to detect specific amplification products. When target cDNA is amplified, corresponding microarray spots can light up in an exponential manner similar to those during real-time qPCR such as TaqMan assay. This test targets specific conserved gene sequences in each pathogen. Within the cartridge, an Internal Control (IC) is also used to monitor the full process starting from sample processing to reverse transcription, amplification, microarray hybridization and signal detection.

User first transfers sample from recommended sample transport medium, universal transport medium (UTM) or 0.9% saline, where sampling swab has been stored, into sample chamber of cartridge and close lid of chamber. The cartridge is loaded into the instrument loading bay according to on-screen instruction. Once user clicks to start the process, system automatically handles sample processing, RT-amplification/amplification and detection process. The instrument collects fluorescence signals of each microarray spot in real-time during amplification and automatically generates test result through analysis of amplification curves (fluorescence signal change).

Main Components

Each box contains following components listed in Table 1:

Table 1：Main Components

Serial No.	Components	10 tests/Box		Main Ingredients
		Specification	Quantity	
1	Cartridge	1 test/bag	10 bags	Primers, probes, dNTPs, $MgCl_2$, reverse transcriptase, DNA polymerase and buffer.
2	Disposable Transfer Pipettes	/	10 - 12	/

Storage Conditions and Handling

1. Store Respiratory Panel 1.0 cartridge at 2-8°C.

2. Do not open cartridge pouch until you are ready to perform test. Do not use the cartridge if the pouch is broken. Once the pouch is open, use the cartridge within 15 minutes.

3. See production date and expiration date on the label.

Compatible Instrument

FlashDx-1000-E Automatic Nucleic Acid Detection System

Requirements for Samples

1. Specimen type: nasopharyngeal, nasal or throat swab

2. Specimen Collection, Transport, and Storage

2.1 Nasopharyngeal swab collection procedure

Gently holds the head of test subject with one hand and inserts a nasopharyngeal swab into either nostril with the other hand and slowly goes deep along the bottom of lower nasal passage. Since nasal passage is curved, excessive force should not be used to avoid traumatic bleeding. When swab reaches the posterior wall of nasopharyngeal cavity, gently rotate swab once (pause for a moment in case of reflex cough), then slowly and gently remove swab, and place swab in the tube containing 3mL or 5mL of recommended sample transport medium, UTM or saline. Rotate the swab 5 times rubbing it against the wall of the tube. Break swab at the indicated break line if necessary and cap the specimen collection tube tightly.

2.2 Nasal swab collection procedure

Insert a nasal swab 1cm to 1.5cm into a nostril. Rotate the swab against the inside of the nostril for 5 rounds while gently pressing a figure to the outside of the nostril. Repeat the same procedure on the other nostril with the same swab. Remove the swab and place it in the tube containing 3mL or 5mL of recommended sample transport medium, UTM or saline. Rotate the swab 5 times rubbing it against the wall of the tube. Break swab at the indicated break line if necessary and cap the specimen collection tube tightly.

2.3 Throat swab collection procedure

Insert a throat swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillar and posterior oropharynx and avoid touching the tongue, teeth and gums. Remove the swab and place it into the recommended sample transport medium, UTM or

saline. Rotate the swab 5 times rubbing it against the wall of the tube. Break swab at the indicated break line if necessary and cap the specimen collection tube tightly.

2.4 Requirements for sampling containers

Sampling swabs should be rayon swabs (polyester fiber, polyester or rayon head), flocking swabs (nylon fiber) or other non-cotton, non-calcium alginate swabs, and the handle should be made of non-wood materials. Collected samples can be preserved in validated sample transport medium or UTM. We recommend some commercially available swabs and sample transport medium. If customers choose to use other swabs and sample transport medium, please verify before using our products. It has been verified that preservation solutions such as saline solution and TE buffer can also be used.

Note: Inactivating UTM/VTM containing guanidine salt is NOT compatible with this test.

2.5 Sample transport and storage

As viral RNA will degrade over time, specimens should be tested soon after collection. Respiratory specimens should be tested within 30 minutes at room temperature and within 4 hours at 2-8°C. Specimens should not be stored for more than 48 hours at 2~8°C. If it is anticipated that specimens may be tested after 24 hours, specimens should be stored at -70°C (not more than 30 days) and shipped with dry ice. Avoid repeated freezing and thawing. If proper care is not taken with sample, it can lead to potential false negative result. Necessary information such as sample number, date of onset and sample collection date should be collected and attached to sample during sample collection, shipping and storage.

Detection Method

Test cartridge contains all reaction reagents needed, and no additional reagent preparation is required.

1. Sample testing

1.1 Preparation of test cartridge

Open the aluminum foil pouch and take out test cartridge.

Note: Please verify that test panel printed on pouch is for Respiratory Panel 1.0 before opening. Once the aluminum foil pouch is open, it is necessary to load sample and run test cartridge within 15 minutes. Extended storage can affect test performance.

1.2 Pipetting

1.2.1 Place test cartridge with label upright, barcode facing forward. Make sure that the white lyophilized pellet in sample chamber is located at the bottom. If not, please gently tap the cartridge on tabletop until the lyophilized pellet falls to the bottom.

1.2.2 Remove sealing aluminum foil on the top of sample chamber completely to fully expose opening. Then use a disposable transfer pipette (supplied) or a laboratory pipette to transfer 120µL of sample solution into the sample chamber and dissolve lyophilized reagent completely. Be careful not to introduce air bubbles during pipetting.

Figure 1. Left: Open cartridge showing the white lyo pellet at the bottom of sample chamber; Right: Make sure that there is no foil left on the top of sample chamber after peeling off the sample port foil.

Note: When using a disposable transfer pipette, squeeze its top bulb completely and then place the pipette tip well below the liquid surface in the specimen transport tube. Slowly release the top bulb to completely fill the pipette stem with sample before removing it from the specimen collection tube. Some liquid may also be in the overflow reservoir. Insert the tip of the pipette into the sample chamber without touching the lyophilized reagent, squeeze the top bulb of the transfer pipette completely again to empty the liquid in the pipette stem.

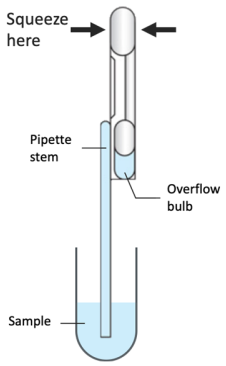

Figure 2. Transfer Pipette

1.2.3 Firmly close sample chamber lid until it is flush with the rest of test cartridge top surface. Make sure there is a tight seal and there should be no gap between chamber lid and cartridge body.

Note: It is important to remove foil completely to ensure a tight seal between lid and sample chamber.

1.3 Run test

Important note: This section only lists basic steps of running the test. Please refer to FlashDx-1000-E user manual for comprehensive instructions.

1.3.1 Input information: Sample information is entered by scanning sample barcode or manually through on-screen keyboard.

1.3.2 Load cartridge: Remove transparent protective cover of cartridge. Hold the test cartridge with chip side pointing leftwards (2-D barcode facing forward). Press button on the instrument's touchscreen and wait for the loading bay to move out. Put test cartridge into the loading bay and press it down to feel a soft click. The instrument should now detect a cartridge in place. Click button on the touchscreen again to retract the loading bay.

Figure 3. Left: Fully closed sample port lid is flush with the rest of the cartridge top. Right: Load the cartridge into the instrument's loading bay.

1.3.3 Start test: Instrument automatically recognizes QR code on the test cartridge and select the appropriate test. Select the corresponding sample type as needed. After confirming the program is correct, click button on the touchscreen to start the test. The instrument should start to run test automatically.

1.3.4 Test result: Test process takes about 55 minutes. On-screen display will show progress and test results will be saved after test is completed.

Result Report

Once test is completed, the instrument automatically reports the results as negative, positive, undetermined for each target or invalid.

Result Interpretation

Test result is interpreted automatically by the instrument according to internal reference controls and detected targets. Presence of a positive readout of internal control or at least one positive target is a prerequisite for the validity of test result. When the test result is valid, a target is either labelled as ⊕, ⊖, or "UD", which represents positive, negative or undetermined result, respectively.

Table 2. Respiratory Panel 1.0 Possible Results

Result		Interpretation
SARS-CoV-2	SARS-CoV-2 ⊕ Detected	SARS-CoV-2 target RNA is detected. The signal of at least one SARS-CoV-2 assay meets the target-specific positive criteria.

	SARS-CoV-2 ⊖ Not Detected	SARS-CoV-2 target RNA is not detected. None of the signal of the SARS-CoV-2 assays meets the target-specific positive criteria.
	SARS-CoV-2 UD Undetermined	The presence or absence of SARS-CoV-2 target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
Influenza A	FluA ⊕ Detected	Influenza A target RNA is detected. The signal of the Influenza A assay meets the target-specific positive criteria.
	FluA ⊖ Not Detected	Influenza A target RNA is not detected. The signal of Influenza A assay doesn't meet the target-specific positive criteria.
	FluA UD Undetermined	Presence or absence of Influenza A target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
Influenza B	FluB ⊕ Detected	Influenza B target RNA is detected. The signal of Influenza B assay meets the target-specific positive criteria.
	FluB ⊖ Not Detected	Influenza B target RNA is not detected. The signal of Influenza B assay doesn't meet the target-specific positive criteria.
	FluB UD Undetermined	Presence or absence of Influenza B target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
RSV	RSV ⊕ Detected	Respiratory syncytial virus target RNA is detected. The signal of at least one respiratory syncytial virus assay meets the target-specific positive criteria.
	RSV ⊖ Not Detected	Respiratory syncytial virus target RNA is not detected. None of the signal of respiratory syncytial virus assays meets the target-specific positive criteria.
	RSV UD Undetermined	Presence or absence of respiratory syncytial virus target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
ADV	ADV ⊕ Detected	Adenovirus target DNA is detected. The signal of at least one adenovirus assay meets the target-specific positive criteria.
	ADV ⊖ Not Detected	Adenovirus target DNA is not detected. None of the signal of the adenovirus assays meets the target-specific positive criteria.
	ADV UD Undetermined	Presence or absence of adenovirus target DNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
PIV	PIV ⊕ Detected	Parainfluenza virus target RNA is detected. The signal of at least one parainfluenza virus assay meets the target-specific positive criteria.

	PIV ⊖ Not Detected	Parainfluenza virus target RNA is not detected. None of the signal of parainfluenza virus assays meets the target-specific positive criteria.
	PIV UD Undetermined	Presence or absence of parainfluenza virus target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
HRV/HEV	HRV/HEV ⊕ Detected	Human rhinovirus/enterovirus target RNA is detected. The signal of the human rhinovirus/enterovirus assay meets the target-specific positive criteria.
	HRV/HEV ⊖ Not Detected	Human rhinovirus/enterovirus target RNA is not detected. The signal of human rhinovirus/enterovirus assay doesn't meet the target-specific positive criteria.
	HRV/HEV UD Undetermined	Presence or absence of human rhinovirus/enterovirus target RNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
MP	MP ⊕ Detected	Mycoplasma pneumoniae target DNA is detected. The signal of the mycoplasma pneumoniae assay meets the target-specific positive criteria.
	MP ⊖ Not Detected	Mycoplasma pneumoniae target DNA is not detected. The signal of mycoplasma pneumoniae assay doesn't meet the target-specific positive criteria.
	MP UD Undetermined	Presence or absence of mycoplasma pneumoniae target DNA cannot be determined. If clinically indicated, repeat the test with same sample or, if possible, collect new sample for testing.
Test Invalid		Presence or absence of SARS-CoV-2, Influenza A, Influenza B, respiratory syncytial virus, adenovirus, parainfluenza virus, human rhinovirus/enterovirus and/or mycoplasma pneumoniae target cannot be determined. None of the signal of all the assays, including the internal control, meets the target-specific positive criteria. Repeat the test with same sample or, if possible, collect new sample for testing.
[Error]. Test Aborted		Presence or absence of SARS-CoV-2, Influenza A, Influenza B, respiratory syncytial virus, adenovirus, parainfluenza virus, human rhinovirus/enterovirus and/or mycoplasma pneumoniae target RNA/DNA cannot be determined. Repeat the test with same sample or, if possible, collect new sample for testing.

Re-test

To retest a UD or invalid result, use a new cartridge. If feasible, collect a new sample, otherwise use the leftover sample from the original specimen. Follow testing procedure as previously described. Put on a clean pair of gloves and use a new transfer pipette.

If test result is still invalid, no further testing on this sample is recommended. Certain samples may contain too high level of inhibitors and interfere with test.

Performance Characteristics

1. Clinical Evaluation

Respiratory Panel 1.0 was evaluated with 205 frozen clinical specimens in sample transport media. Specimens were selected based on previously known result by independent CLIA lab or clinical institutes. All samples handling and analysis were performed in a double-blinded manner. The thawed sample were then analyzed with Respiratory Panel 1.0 by clinical lab's personnel independently in a blinded manner. The results were then unblinded and compared. Only valid samples were compared.

Sensitivity, Specificity, Overall Percent Agreement (OPA) and Kappa coefficient were determined by comparing the results of Respiratory Panel 1.0 test relative to the results of PacificDx Covid-19 Test, a SARS-CoV-2 FDA EUA RT-PCR test, for the SARS-CoV-2 target, Sansure Biotech six respiratory pathogens test, a Chinese NMPA-approved RT-PCR test, for the Flu A, Flu B, RSV, ADV, MP and HRV/HEV targets, and Hecin Health PIV tests, Chinese NMPA-approved RT-PCR tests, for PIV, respectively.

Table 3. Comparison Performance Results

SARS-CoV-2 Performance results								
Respiratory Panel 1.0	PacificDx Covid-19		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	35	1	36	Sensitivity	94.59%	82.30%	98.50%	
Negative	2	42	44	Specificity	97.67%	87.94%	99.59%	
Total	37	43	80	OPA	96.25%	89.55%	98.72%	0.925
FluA Performance results								
Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	17	0	17	Sensitivity	100.00%	81.57%	100.00%	
Negative	0	108	108	Specificity	100.00%	96.57%	100.00%	
Total	17	108	125	OPA	100.00%	97.02%	100.00%	1
FluB Performance results								
Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	

Positive	30	0	30	Sensitivity	100.00%	88.65%	100.00%	
Negative	0	95	95	Specificity	100.00%	96.11%	100.00%	
Total	30	95	125	OPA	100.00%	97.02%	100.00%	1

RSV Performance results

Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	38	0	38	Sensitivity	97.44%	86.82%	99.55%	
Negative	1	86	87	Specificity	100.00%	95.72%	100.00%	
Total	39	86	125	OPA	99.20%	95.61%	99.86%	0.981

ADV Performance results

Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	10	0	10	Sensitivity	100.00%	72.25%	100.00%	
Negative	0	115	115	Specificity	100.00%	96.77%	100.00%	
Total	10	115	125	OPA	100.00%	97.02%	100.00%	1

PIV Performance results

Respiratory Panel 1.0	Hecin Health PIV test		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	20	0	20	Sensitivity	100.00%	83.89%	100.00%	
Negative	0	29	29	Specificity	100.00%	88.30%	100.00%	
Total	20	29	49	OPA	100.00%	92.73%	100.00%	1

HEV/HRV Performance results

Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	10	0	10	Sensitivity	100.00%	72.25%	100.00%	
Negative	0	115	115	Specificity	100.00%	96.77%	100.00%	
Total	10	115	125	OPA	100.00%	97.02%	100.00%	1

MP Performance results

Respiratory Panel 1.0	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	19	0	19	Sensitivity	100.00%	83.18%	100.00%	
Negative	0	106	106	Specificity	100.00%	96.50%	100.00%	
Total	19	106	125	OPA	100.00%	97.02%	100.00%	1

For eight pathogens, Respiratory Panel 1.0 demonstrated a PPA and NPA of 87.50% and 97.5% for SARS-CoV-2, respectively; 100.0% and 100.0% for Flu A, respectively; 100.0% and 100.0% for Flu B, respectively; 97.44% and 100.0% for RSV, respectively; 100.0% and 100.0% for ADV,

respectively; 100.0% and 100.0% for PIV, respectively; 100.0% and 100.0% for HEV/HRV, respectively and 100.0% and 100.0% for MP, respectively.

Analytical Performance

1. Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical LoD of Respiratory Panel 1.0. The LoD was established using one lot of reagents and limiting dilutions of reference material for eight pathogens prepared in VTM. The concentrations were predefined for each dilution and the test for each concentration was repeated three times. The concentration level with observed detection rates 100% is regarded as estimated LoD. Then 3 levels of concentrations around the estimated LoD (higher and lower) were repeated for 20 times each. The concentration with the hit rate equal and greater than 95% was determined as LoD. After verification process, LoD was determined as listed in table below for eight pathogens respectively.

Table 4. LoD Determination

Pathogens	Limit of detection (copies/mL)
SARS-CoV-2	500
Flu A	2000
Flu B	2000
RSV	2000
ADV	1000
PIV	2000
HRV/HEV	4000
MP	1500

2. Reproducibility

The reproducibility was established at two sites using two samples, one negative and one Flu A positive sample with the concentration of 3 x LoD. Tests were conducted by two operators for fifteen consecutive days using three lots of cartridges. In total, 120 observations were yielded. All results were concordant with the expected.

3. Analytical specificity

3.1 Cross-reaction

The cross-reaction was evaluated using *in silico* analysis of primers and probes of eight pathogens with various other pathogens including endemic *measles virus, mumps virus,*

mycoplasma pneumoniae, legionella, bacillus pertussis, *haemophilus influenzae*, *staphylococcus aureus*, *streptococcus pneumoniae*, *streptococcus pyogenes*, *klebsiella pneumoniae* and *candida albicans*. In addition to *in silico* analysis, cross-reactivity was evaluated by experiments using different pathogens for three times at certain concentrations. No cross reaction was observed.

Table 5. Cross reactivity test results

Strain	Tested Concentration cp/mL	SARS-CoV-2	Flu A	Flu B	RSV	ADV	HRV /HEV	PIV	MP
measles virus	$1.0x10^6$	-	-	-	-	-	-	-	-
mumps virus	$1.0x10^6$	-	-	-	-	-	-	-	-
legionella	$1.0x10^6$	-	-	-	-	-	-	-	-
bacillus pertussis	$1.0x10^6$	-	-	-	-	-	-	-	-
haemophilus influenzae	$1.0x10^6$	-	-	-	-	-	-	-	-
staphylococcus aureus	$1.0x10^6$	-	-	-	-	-	-	-	-
streptococcus pneumoniae	$1.0x10^6$	-	-	-	-	-	-	-	-
streptococcus pyogenes	$1.0x10^6$	-	-	-	-	-	-	-	-
klebsiella pneumoniae	$1.0x10^6$	-	-	-	-	-	-	-	-
andida albicans	$1.0x10^6$	-	-	-	-	-	-	-	-

3.2 Interfering substances

Potentially interfering substances, including purified mucin, blood and other drugs listed in table below, have been tested in the samples at listed concentration. No significant interference was detected at the level tested, based on triplicate detection of reference material at 3 x LoD.

Table 6. Interfering Substance

Substance	Concentration
purified mucin	50 μg/mL
whole blood	0.1%(v/v)
beclomethasone	50 μg/mL
dexamethasone	50 μg/mL
triamcinolone acetonide	100 μg/mL
budesonide	320 μg/mL
mometasone	100 μg/mL
ribavirin	100 μg/mL
oxymetazoline	100 μg/mL
tobramycin	100 μg/mL
oseltamivir	100 μg/mL
azithromycin	100 μg/mL

4. Competitive Interference

Competitive interference of Respiratory Panel 1.0 potentially caused by co-infections were evaluated by testing other strains with high concentration (50~100 x LoD) and target strain at 1~3x LoD in a simulated matrix. The concentrations for competitive strains of Flu A, Flu B, RSV, ADV, PIV, HRV/HEV and MP were set as 100,000 copies/mL, 200,000 copies/mL, 10,000 copies/mL, 50,000 copies/mL, 50,000 copies/mL, 40,000 copies/mL and 150,000 copies/mL respectively. The concentration for target strain of SARS-CoV-2 was set as 1,500 copies/mL. The tests were conducted with five replicates for each target strain and each competitive strain combination.

Table 7. Competitive Interference

Combination	Strains	Test	Concentration (copies/mL)	Test 1	Test 2	Test 3	Test 4	Test 5
1	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	FluA-2009H1N1	100000	+	+	+	+	+
2	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	FluB	200000	+	+	+	+	+
3	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	RSV-A	100000	+	+	+	+	+
4	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	ADV-7	50000	+	+	+	+	+
5	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	PIV-1	50000	+	+	+	+	+
6	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	HRV	400000	+	+	+	+	+
7	Competitive strain	SARS-CoV-2	1500	+	+	+	+	+
	Target strain	MP	150000	+	+	+	+	+

Limitations

1. This test can be used for *in vitro* diagnosis only.
2. Test does not contain any infectious substances and will not infect humans or other animals. Testing sample should be handled as a potential source of infection, and its operation should be carried out in a microbiological and biomedical laboratory with biosafety protection facilities and protocols to protect operators from being affected during work.
3. Clinical laboratory shall strictly follow the *Administrative Measures for Clinical Gene Amplification Laboratories of Medical Institutions* (WBYZF [2010] No. 194 or effective

version) and other regulatory standards related to molecular biology laboratories and clinical gene amplification laboratories.

4. Sample types, sample collection and handling methods specified in the instructions for use should be strictly followed, otherwise test performance cannot be guaranteed.
5. Test result of this kit should be combined with the patient's clinical symptoms and other relevant medical examination results for comprehensive analysis, and should not be used as a sole basis for patient management.
6. This test doesn't include test of parainfluenza 4 (PIV4).
7. This test doesn't differentiate between Human Rhinovirus and Enterovirus. A follow-up test using an alternative method (e.g. cell culture or sequence analysis) if test reports positive on HRV/HEV and a differentiation between the viruses is required.
8. There is a risk of false negatives if viral nucleic acid has sequence variations.
9. Unreasonable sample collection, transportation and handling, as well as improper experimental operation and environment may lead to false negative or false positive results.
10. When sample is collected after individual is vaccinated with live attenuated vaccine, test result may be false positive.
11. Positive and negative predicted values largely depend on prevalence rate. Test performance may vary with prevalence rate and sampled population.
12. Nucleic acid fragments may appear in body for a long time, and has nothing to do with viral activity. Positive result does not necessarily mean active infection by corresponding virus or clinical symptoms was caused by corresponding virus.
13. Other interferences or PCR inhibitors that have not been verified may cause false negative results.

Interpretation of Symbol

The symbol IVD in the label indicates *in vitro* diagnostic medical device.

Quality Control (QC)

External QC controls (run controls) are not required to use this test kit. Positive control samples and negative control samples are not supplied with the kit.

If certain labs procedures require controls to show that Respiratory Panel 1.0 is working properly, they can be separately ordered and used in independent cartridges for quality control. We recommend the use of some commercially available controls and other heat-inactivated virus or pseudovirus may also serve the purpose, but verification should be performed in advance. Using

RNA reference material directly as positive control is not recommended since sample processing may affect RNA concentration before reverse transcription and cDNA amplification.

Mix the tube containing external controls thoroughly. Load 120μL of positive control or negative control into a cartridge and run test as a normal sample. The system should generate report of positive detection of included viruses or pseudoviruses, and negative report, respectively. Follow instruction of control samples for storage, expiration and freeze-thaw cycles.

References

1. Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/index.html).
2. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories (http://www.cdc.gov/biosafety/publications/).
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline.

Contact Information

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