SARS-CoV-2/FluA/FluB/RSV Test

Instructions for Use

For Professional Use

For Use with FlashDx-1000-E System

For *In vitro* Diagnostic Use

Rev A. Apr 2022

Proprietary Name

SARS-CoV-2/FluA/FluB/RSV

Common or Usual Name

SARS-CoV-2/FluA/FluB/RSV

Packing Specification

10 tests/box

Intended Use

SARS-CoV-2/FluA/FluB/RSV test 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, and/or respiratory syncytial virus (RSV) 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, and/or RSV RNA; 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, and/or RSV 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

The SARS-CoV-2/FluA/FluB/RSV test is an *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2, influenza A, influenza B, and/or RSV. 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 sequences in the following genes: ORF1ab, N and E genes of SARS-CoV-2, matrix gene of influenza A, NEP/NS1 gene of influenza B, and L gene of RSV. 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 virus transport medium (VTM), 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 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 the SARS-CoV-2/FluA/FluB/RSV 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 VTM, 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 VTM, 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 VTM, 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. We recommend using Copan FLOQSwabs (cat. No. 503CS01) but similar validated products can also be used. Collected samples can be preserved in validated VTM or UTM. We recommend using Copan UTM (cat. No. 23-600-982), KangJian UTM (cat. No. 156-101B) and Yocon VTM (cat. No. MT0301). Other virus transport mediums have not been verified. If customers choose to use them, 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 SARS-CoV-2/FluA/FluB/RSV test 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.

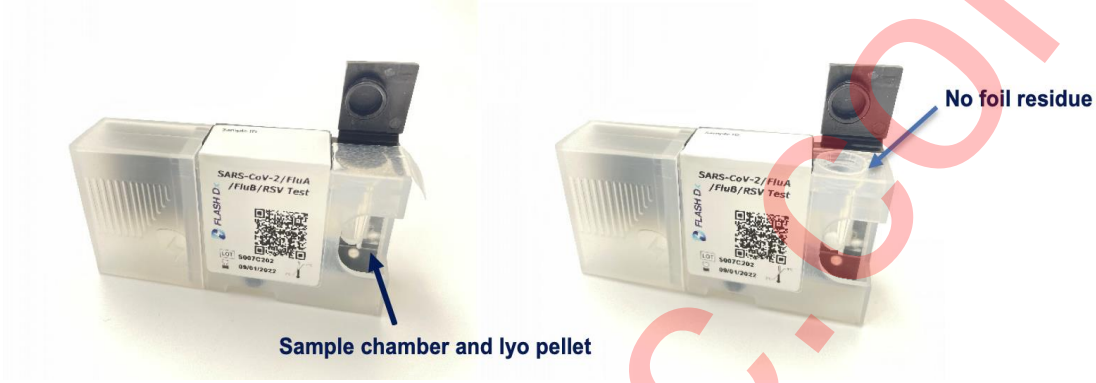

Figure 1. Left: Open cartridge showing the white lyo pellet at the bottom of sample chamber; Right: Make sure that there is no foil left on the top of sample chamber after peeling off the sample port foil.

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.

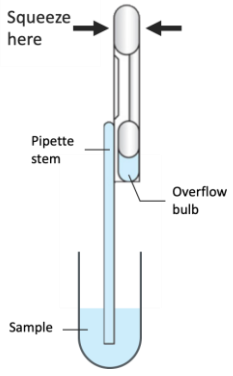

Figure 2. Transfer Pipette

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 waiting for the loading bay to move out. Put test cartridge into the loading bay, 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. SARS-CoV-2/FluA/FluB/RSV Possible Results

Result		Interpretation
SARS-CoV-2	SARS-CoV-2 ⊕ Detected	The 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	The 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	The Influenza A target RNA is detected. The signal of the FluA assay meets the target-specific positive criteria.
	FluA ⊖ Not Detected	The Influenza A target RNA is not detected. The signal of the 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	The Influenza B target RNA is detected. The signal of FluB assay meets the target-specific positive criteria.

	FluB ⊖ Not Detected	The Influenza B target RNA is not detected. The signal of the 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	The Influenza B target RNA is detected. The signal of at least one RSV assays meets the target-specific positive criteria.
	RSV ⊖ Not Detected	The Influenza B target RNA is not detected. None of the signal of the RSV assays meets the target-specific positive criteria.
	RSV UD Undetermined	Presence or absence of RSV target RNA 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 and RSV target RNA 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 and RSV target RNA 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

SARS-CoV-2/FluA/FluB/RSV test was evaluated with 169 frozen clinical specimens in viral transport media. Specimens were selected based on previously known result by two

independent third party CLIA labs. All samples handling and analysis were performed in a double-blinded manner. The thawed sample were then analyzed with SARS-CoV-2/FluA/FluB/RSV test by clinical lab's personnel independently in a blinded manner. The results were then unblinded and compared. Only valid samples were compared.

Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), Overall Percent Agreement (OPA) and Kappa coefficient were determined by comparing the results of SARS-CoV-2/FluA/FluB/RSV 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, and Sansure Biotech six respiratory pathogens test, a Chinese NMPA-approved RT-PCR test for the Flu A, Flu B, and RSV targets, respectively.

Table 3. Comparison Performance Results

SARS-CoV-2 Performance results								
SARS- CoV-2/FluA/FluB/RSV	PacificDx Covid-19		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	*39*	*0*	*39*	PPA	97.50%	87.12%	99.56%	
Negative	*1*	*40*	*41*	NPA	100.00%	91.24%	100.00%	
Total	*40*	*40*	*80*	OPA	98.75%	93.25%	99.78%	0.975
FluA Performance results								
SARS- CoV-2/FluA/FluB/RSV	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	*16*	*0*	*16*	PPA	100.00%	80.64%	100.00%	
Negative	*0*	*73*	*73*	NPA	100.00%	95.00%	100.00%	
Total	*16*	*73*	*89*	OPA	100.00%	95.86%	100.00%	1
FluB Performance results								
SARS- CoV-2/FluA/FluB/RSV	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	*29*	*0*	*29*	PPA	100.00%	88.30%	100.00%	
Negative	*0*	*60*	*60*	NPA	100.00%	93.98%	100.00%	
Total	*29*	*60*	*89*	OPA	100.00%	95.86%	100.00%	1
RSV Performance results								
SARS- CoV-2/FluA/FluB/RSV	Sansure six pathogen kit		Total			95% CI		Kappa
	Positive	Negative				Low	High	
Positive	*43*	*0*	*43*	PPA	97.73%	88.19%	99.60%	
Negative	*1*	*45*	*46*	NPA	100.00%	92.13%	100.00%	
Total	*44*	*45*	*89*	OPA	98.88%	93.91%	99.80%	0.978

For four pathogens, SARS-CoV-2/FluA/FluB/RSV demonstrated a PPA and NPA of 97.50% and 100% for SARS-CoV-2, respectively; 100.0% and 100.0% for Flu A, respectively; 100.0% and 100.0% for Flu B, respectively; 97.73% and 100.0% for RSV, respectively.

Analytical Performance

1. Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical LoD of SARS- CoV-2/FluA/FluB/RSV test. The LoD was established using one lot of reagent and limiting dilutions of SARS-CoV-2, FluA, FluB and RSV reference material 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.

Table 4. LoD Determination

Pathogens	Limit of detection (copies/mL)
SARS-CoV-2	500
Flu A	1200
Flu B	2000
RSV	1500

After verification process, LoD was determined as 500 copies/mL, 1200 copies/ml, 2000 copies/ml and 1500 copies/ml for SARS-CoV-2, Flu A, Flu B and RSV respectively.

2. Reproducibility

The reproducibility was established at two sites using two samples, one negative and one positive sample with concentration of 3xLOD. 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 SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus with various pathogens including endemic *human coronaviruses (HKU1, OC43, NL63 and 229E), SARS coronavirus, MERS coronavirus, parainfluenza virus 2, adenovirus 3 or 7,*

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 concentration. No cross reaction was observed.

Table 5. Cross reactivity test results

Strain	Tested Concentration	SARS-CoV-2	Flu A	Flu B	RSV
parainfluenza virus 2	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
adenovirus 3	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
adenovirus 7	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
measles virus	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
mumps virus	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
mycoplasma pneumoniae	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
legionella	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
bacillus pertussis	$1.0x10^6$ cp/mL	Negative	Negative	Negative	Negative
haemophilus influenzae	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
staphylococcus aureus	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
streptococcus pneumoniae	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
streptococcus pyogenes	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
klebsiella pneumoniae	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative
andida albicans	$1.0x10^6$ cfu/mL	Negative	Negative	Negative	Negative

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 SARS-CoV-2/Flu/RSV potentially caused by co-infections were evaluated by testing other strains with high concentration (50~100xLOD) and target strain at 1~3xLOD in a simulated matrix. The concentrations for competitive strains of SARS-CoV-2, Flu A, Flu B and RSV were set as 50,000 copies/mL, 120,000 copies/mL, 20,000 copies/mL and 150,000 copies/mL respectively. The concentrations for target strains of SARS-CoV-2, Flu A, Flu B and RSV were set as 1,500 copies/mL, 3,000 copies/mL, 6,000 copies/mL and 4,500 copies/mL respectively. 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	50,000	+	+	+	+	+
	Target strain	Flu A	3,000	+	+	+	+	+
2	Competitive strain	SARS-CoV-2	50,000	+	+	+	+	+
	Target strain	Flu B	6,000	+	+	+	+	+
3	Competitive strain	SARS-CoV-2	50,000	+	+	+	+	+
	Target strain	RSV-A	4,500	+	+	+	+	+
4	Competitive strain	SARS-CoV-2	50,000	+	+	+	+	+
	Target strain	RSV-B	4,500	+	+	+	+	+
5	Competitive strain	Flu A	120,000	+	+	+	+	+
	Target strain	SARS-CoV-2	1,500	+	+	+	+	+
6	Competitive strain	Flu A	120,000	+	+	+	+	+
	Target strain	Flu B	6,000	+	+	+	+	+
7	Competitive strain	Flu A	120,000	+	+	+	+	+
	Target strain	RSVA	4,500	+	+	+	+	+
8	Competitive strain	Flu B	200,000	+	+	+	+	+
	Target strain	SARS-CoV-2	1,500	+	+	+	+	+
9	Competitive strain	Flu B	200,000	+	+	+	+	+
	Target strain	Flu A	3,000	+	+	+	+	+
10	Competitive strain	Flu B	200,000	+	+	+	+	+
	Target strain	RSVA	4,500	+	+	+	+	+
11	Competitive strain	RSVA	150,000	+	+	+	+	+
	Target strain	SARS-CoV-2	1,500	+	+	+	+	+

12	Competitive strain	RSVA	150,000	+	+	+	+	+
	Target strain	Flu A	3,000	+	+	+	+	+
13	Competitive strain	RSVA	150,000	+	+	+	+	+
	Target strain	Flu B	6,000	+	+	+	+	+

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. There is a risk of false negatives if viral nucleic acid has sequence variations.
7. Unreasonable sample collection, transportation and handling, as well as improper experimental operation and environment may lead to false negative or false positive results.
8. When sample is collected after individual is vaccinated with live attenuated vaccine, test result may be false positive.
9. Positive and negative predicted values largely depend on prevalence rate. Test performance may vary with prevalence rate and sampled population.
10. 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.
11. 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. The positive control samples and negative control samples are not supplied with the kit.

If certain labs procedures require controls to show that SARS-CoV-2/FluA/FluB/RSV Test is working properly, they can be separately ordered and used in independent cartridges for quality control. We recommend the use of commercially available positive and negative controls from Zeptometrix (Negative control Cat# NATCV9-6C and Positive control Cat# NATFRC-6C). 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 amplification.

Mix the tube containing external controls vigorously for at least 5 seconds. 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.

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