JOY TEST

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/ M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) Package Insert

CE IVD

REF IRT-555

English

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B, Respiratory Syncytial Virus(RSV), Adenovirus and M.pneumoniae antigens present in human nasopharynx.

For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B, Respiratory Syncytial Virus(RSV), Adenovirus and M.pneumoniae antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2/Influenza/RSV/Adenovirus/M.pneumoniae infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2, Influenza A+B, RSV, Adenovirus and M.pneumoniae antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of correlative antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial/viral infection. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2, Influenza A+B, RSV, Adenovirus and M.pneumoniae.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza (commonly known as "flu") is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Laboratory identification of human influenza virus infections is commonly performed using direct antigen detection, virus isolation in cell culture, or detection of influenza-specific RNA by reverse transcriptase-polymerase chain reaction (RT-PCR). Rapid tests for influenza A and B virus infections, which can provide results within 30 minutes. [2]

Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill. Most children with RSV infection, both those who were hospitalized and those who were treated as outpatients, had no coexisting medical conditions or characteristics that significantly identified them as being at greater risk for severe RSV disease, except for being under 2 years of age. [3]

Human Adenoviruses comprise an important group of etiologic agents that are responsible for various diseases in adults and children, such as respiratory, ocular, gastroenteric, and urinary infections. In immunocompromised and organ-transplanted individuals, these agents can cause generalized infections. [4]

M. pneumoniae is infection has a worldwide distribution. It occurs through-out the year, most frequently in the colder months. Clinical diagnosis of M.pneumoniae infection is frequently hindered by a lack of specific signs and symptoms, although in the majority of cases increasing cough, malaise, low-grade fever and headache are reported. Timely laboratory diagnosis is also complicated. Culture of the organism is difficult and often only of retrospective value, as is the classic serologic assay, the complement fixation test. [5]

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Nucleocapsid protein, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The Influenza A+B Rapid Test (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in human nasopharyngeal swab specimen. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The RSV Rapid Test (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab specimens. In this test, antibody specific to the Respiratory Syncytial Virus nucleoproteins is coated on the test line region of the test. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored line in the test region. The presence of this colored line in the test region indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The Adenovirus Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in nasopharyngeal swab specimen. In this test, antibody specific to the adenovirus is separately coated on the test line region of the test. During testing, the extracted specimen reacts with the antibody to adenovirus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to adenovirus on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The Mycoplasma pneumoniae Antigen Rapid Test (Nasopharyngeal Swab) a qualitative, lateral flow immunoassay for the detection of M. pneumoniae antigen in nasopharyngeal swab specimen. In this test, antibody specific to M. pneumoniae antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to M.pneumoniae that is coated onto particles. The mixture migrates up the membrane to react with the antibody to M. pneumoniae on the membrane and generate a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-SARS-CoV-2, anti-Influenza A, anti-Influenza B, anti-RSV, anti-Adenovirus and anti-M.pneumoniae as the capture reagent, anti-SARS-CoV-2, anti-Influenza A, anti-Influenza B, anti-RSV, anti-Adenovirus and anti-M.pneumoniae as the detection reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient specimens and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Viral Transport Media (VTM) may affect the test result, do not store specimens in viral transport media; extracted specimens for PCR tests cannot be used for the test.
8. Wash hands thoroughly after handling.
9. Please ensure that an appropriate amount of specimens are used for testing. Too much or too little specimen size may lead to deviation of results.
10. The used test should be discarded according to local regulations.
11. Humidity and temperature can adversely affect results.

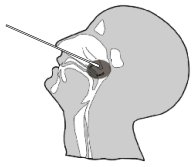
STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Nasopharyngeal Swab Specimen Collection

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx 5-10 times.
3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.



Specimen Transport and Storage

Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab specimen is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8 °C.

SPECIMEN PREPARATION

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.
Please refer to the Procedure Card for detailed information of Specimen Extraction.

1. Place the swab specimen in the Extraction Tube with Extraction Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

***NOTE**: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8 °C.

MATERIALS

Materials Provided

•Test Cassettes	•Package Insert	•Sterile Swabs
•Extraction Buffer	•Extraction Tubes and Tips (Optional)	•Workstation
•Procedure Card		

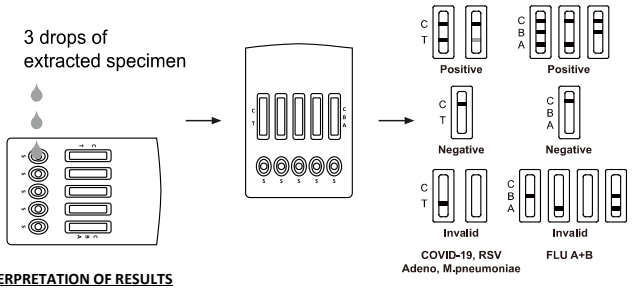
Materials Required But Not Provided

• Timer

DIRECTIONS FOR USE

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen collection tube and add **3 drops of the extracted specimen** to each of the specimen well(S) respectively and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

SARS-CoV-2/RSV/Adenovirus/M.pneumoniae POSITIVE:* Two colored lines appear in the SARS-CoV-2/RSV/Adenovirus/M.pneumoniae window. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the test region indicates detection of SARS-CoV-2/RSV/Adenovirus/M.pneumoniae antigens in the specimen.

Influenza A POSITIVE:* Two colored lines appear in the FLU window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). Positive result in the Influenza A region indicates that Influenza A antigen was detected in the specimen.

Influenza B POSITIVE:* Two colored lines appear in the FLU window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). Positive result in the Influenza B region indicates that Influenza B antigen was detected in the specimen.

Influenza A and Influenza B POSITIVE:* Three colored lines appear in the FLU window. One colored line should be in the control region (C) and two colored lines should be in the Influenza A region (A) and Influenza B region (B). Positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the specimen.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen, Influenza A and/or B antigen, RSV antigen, Adenovirus antigen, M.pneumoniae antigen present in the specimen. So any shade of color in the test region (T/B/A) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test line region (T/B/A).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Quality Control

Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended. [1]

LIMITATIONS

1. The test procedure and the interpretation of test result must be followed closely when testing for the presence of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus/ M.pneumoniae antigens in the human

nasopharyngeal swab specimens from suspected individuals. For optimal test performance, proper specimen collection is critical. Failure to follow the procedure may give inaccurate results.

2. The performance of the SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
3. The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus/M.pneumoniae antigens in human nasopharyngeal swab specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2, Influenza A, Influenza B, RSV, Adenovirus or M.pneumoniae infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus/M.pneumoniae antigens can be determined by this qualitative test.
4. The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus/ M.pneumoniae antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2/Influenza A/Influenza B/RSV/Adenovirus/M.pneumoniae infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-specimen the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions:
   a) The concentration of the novel coronavirus, influenza A virus, influenza B virus, RSV, Adenovirus or M.pneumoniae antigens in the specimen is lower than the minimum detection limit of the test.
   b) The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting specimens at different times for the same patient may avoid false negatives.
   c) Incorrect specimen collection and storage.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. A negative result for SARS-CoV-2, Influenza A, Influenza B or RSV, Adenovirus or M.pneumoniae obtained from this kit should be confirmed by RT-PCR/culture.
10. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. A positive result for Influenza A and/or B, RSV, Adenovirus and M.pneumoniae does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	80	2	82
	Negative	3	189	192
Total		83	191	274
Relative Sensitivity		96.4%（95%CI*: 89.8%~99.2%）		
Relative Specificity		99.0%（95%CI*: 96.3%~99.9%）		
Accuracy		98.2%（95%CI*: 95.8%~99.4%）		

Influenza A+B Test :

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	38	2	40	39	2	41
	Negative	2	215	217	3	213	216
Total		40	217	257	42	215	257
Relative Sensitivity		95%(95%CI*:82.6%-99.5%)			92.9%(95%CI*:80.3%-98.2%)		
Relative Specificity		99.1%(95%CI*:96.5%-99.9%)			99.1%(95%CI*:96.5%-99.9%)		
Accuracy		98.4%(95%CI*:95.9%-99.5%)			98.1%(95%CI*:95.4%-99.3%)		

RSV Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
RSV Antigen	Positive	33	9	42
	Negative	2	225	227
Total		35	234	269
Relative Sensitivity		94.3%(95%CI*:80.8%-99.3%)		
Relative Specificity		96.2%(95%CI*:92.8%-98.2%)		
Accuracy		95.9%(95%CI*:92.8%-97.9%)		

Adenovirus Test:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Adenovirus Antigen	Positive	31	3	34
	Negative	1	209	210
Total		32	212	244
Relative Sensitivity		96.9%(95%CI*:82.9%-99.9%)		
Relative Specificity		98.6%(95%CI*:95.7%-99.7%)		
Accuracy		98.4%(95%CI*:95.7%-99.5%)		

M.pneumoniaeTest:

SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
M.pneumoniae Antigen	Positive	45	5	50
	Negative	4	244	248
Total		49	249	298
Relative Sensitivity		91.8%(95%CI*:80.3%-97.3%)		
Relative Specificity		98.0%(95%CI*:95.3%-99.3%)		
Accuracy		97.0%(95%CI*:94.3%-98.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at the concentrations listed:

Description	Concentration
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/mL
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1 x 10^6 $TCID_{50}$/mL
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/mL
MERS COV Florida	1.17 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/mL
Measles	1.58 x 10^4 $TCID_{50}$/mL
Mumps	1.58 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/mL
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/mL

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using below standard controls : Negative, SARS-CoV-2 antigen weak, SARS-CoV-2 antigen strong, Influenza A weak, Influenza B weak, Influenza A strong, Influenza B strong, RSV weak, RSV strong, Adenovirus weak, Adenovirus strong, M.pneumoniae weak and M.pneumoniae strong. Three different lots of SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab) have been tested, ten replicates were tested with each standard control each day, and the test was conducted at 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10^8 org/mL and all found to be negative when tested with the SARS-CoV-2/Influenza A+B/ RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab):

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp group F*

Interfering Substances

The interfering substances below were spiked with negative, SARS-CoV-2 antigen weak positive, Influenza A weak positive, Influenza B weak positive, RSV weak positive, Adenovirus weak positive and M.pneumoniae weak positive. No substances showed any interference with the SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab).

Substance	Concentration
Whole Blood	20 µl/mL
Mucin	50 µg/mL
Budesonide Nasal Spray	200 µl/mL
Dexamethasone	0.8 mg/mL
Flunisolide	6.8 ng/mL
Mupirocin	12 mg/mL
Oxymetazoline	0.6 mg/mL
Phenylephrine	12 mg/mL
Rebetol	4.5 µg/mL
Relenza	282 ng/mL
Tamiflu	1.1 µg/mL
Tobryamycin	2.43 mg/mL

BIBLIOGRAPHY

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	Caution
	*In vitro* diagnostic medical device
	Temperature limit
	Do not use if package is damaged and consult instructions for use
	Authorized representative in the European Community/European Union
	Catalogue number
	Contains sufficient for <n> tests
	Use-by date
	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor

Manufacturer

Hangzhou Alltest Biotech Co., Ltd.
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EC REP

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