

Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

SARS coronavirus antigen kit
RS virus kit

Quick Chaser SARS-CoV-2/RSV

[Package]

70080: Quick Chaser SARS-CoV-2/RSV - 10 tests/kit

[Contents]

1) Test plate - 10 tests

- Mouse monoclonal anti-SARS-CoV-2 antibodies
- Mouse monoclonal anti-RS virus antibodies
- Colloidal gold conjugated to mouse monoclonal anti-SARS-CoV-2 antibodies
- Colloidal gold conjugated to mouse monoclonal anti-RS virus antibodies

2) Extraction reagent solution vial - 0.5mL×10 vials

Extraction reagent solution is buffer containing detergent.

Note) Extraction reagent solution of the following Quick Chaser products can be shared.

- Influenza virus kit Quick Chaser Flu A, B (Abbreviated name : Flu A, B)
- Adenovirus kit Quick Chaser Adeno (Abbreviated name: Adeno)
- SARS coronavirus antigen kit, Influenza virus kit Quick Chaser SARS-CoV-2/Flu (Abbreviated name: SARS-CoV-2/Flu) Quick Chaser SARS-CoV-2/Flu A, B (Abbreviated name: SARS-CoV-2/Flu A, B)
- SARS coronavirus antigen kit Quick Chaser SARS-CoV-2 (Abbreviated name: SARS-CoV-2)
- SARS coronavirus antigen kit, RS virus kit Quick Chaser SARS-CoV-2/RSV (Abbreviated name: SARS-CoV-2/RSV)

3) Swab (for nasopharyngeal swab specimen & nasal swab specimen) - 10 pieces

4) Filter (for extraction reagent solution vial) - 10 pieces

5) Filter cap - 10 pieces

[Intended use]

For detection of SARS-CoV-2 antigen and RS virus antigen in nasopharyngeal swab specimen or nasal swab specimen.

(An aid in diagnosis of SARS-CoV-2 infection or RS virus infection)

It is for in vitro diagnostic use only and for professional use only.

[Principle of the test]

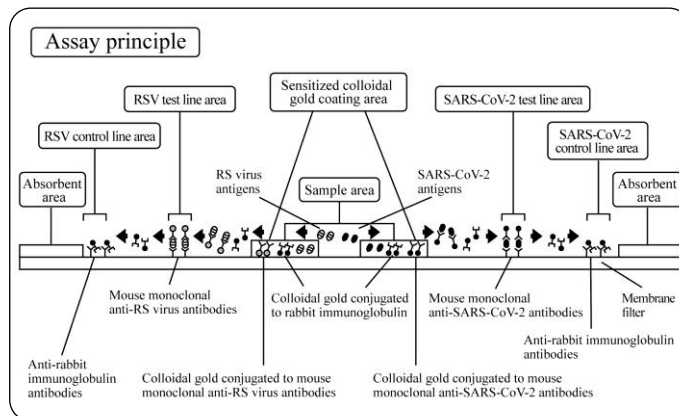
"Quick Chaser SARS-CoV-2/RSV" is the in vitro diagnostic reagent for detection of SARS-CoV-2 antigen and RS virus antigen based on the immunochromatographic assay.

Colloidal gold conjugated to mouse monoclonal anti-SARS-CoV-2 antibodies or colloidal gold conjugated to mouse monoclonal anti-RS virus antibodies, and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in each sensitized colloidal gold coating area on a membrane filter which is set in test plate. Also, mouse monoclonal anti-SARS-CoV-2 antibodies are immobilized in SARS-CoV-2 test line area, mouse monoclonal anti-RS virus antibodies are collectively immobilized in RS virus test line area, and anti-rabbit immunoglobulin antibodies are immobilized in each control line area.

If SARS-CoV-2 antigens or RS virus antigens are present in the sample, according to the principle of immunochromatography, SARS-CoV-2 antigens react with colloidal gold conjugated to mouse monoclonal anti-SARS-CoV-2

antibodies, RS virus antigens react with colloidal gold conjugated to mouse monoclonal anti-RS virus antibodies as they migrate from the sample area. Moreover, they will be captured in each test line area by reacting respectively with mouse monoclonal anti-SARS-CoV-2 antibodies, mouse monoclonal anti-RS virus. As a result, a purple-red line with the colloidal gold appears in each test line area.

At the same time, the colloidal gold conjugated to rabbit immunoglobulins also migrates and will be captured by the anti-rabbit immunoglobulin antibodies on each control line area, resulting in the appearance of a purple-red line in each control line area regardless of the presence or absence of SARS-CoV-2 antigens and RS virus antigens.



[Warnings and Precautions]

- 1) For in vitro diagnostic use only.
- 2) Take necessary biosafety measures for specimen collection and handling.
- 3) Procedures not described in the Instructions for Use are not guaranteed.
- 4) When adding a sample, keep the tip of the filter by about 10mm from the center of the sample area so that a drop can be formed, and add the specified volume (4 drops). If the sample volume is not as specified, the reaction may not be accurate.
- 5) Bring test plate and extraction reagent solution to 15 to 30°C prior to testing.
- 6) Strictly follow interpretation time to avoid false-negative and false-positive.
- 7) Handle sample (specimen) with great care as there is a risk of infection.
- 8) When using, wear protective equipment (glasses, disposable gloves, mask, etc.) and be careful not to let the sample (specimen) or extraction reagent solution directly adhere to the skin or get into your eyes.
- 9) Do not collect the specimen with a swab soaked in the extraction reagent solution.
- 10) If a sample (specimen) or extraction reagent solution accidentally gets into your eyes or mouth, take first-aid measures such as rinsing it thoroughly with water, and seek medical attention if necessary.
- 11) The filter cap does not provide an airtight seal. Do not use it for purposes of transportation or preservation.
- 12) Perform the specimen collection under the guidance of a qualified person.
- 13) The material of the membrane used for the test plate is nitrocellulose. Do not perform tests near a fire as nitrocellulose is extremely flammable.
- 14) If the sample (specimen) spatters, wipe it off with alcohol for disinfection, etc.
- 15) Do not freeze this product. Store it in accordance with the description of storage. Do not use frozen reagents as they may change the quality and may not give correct results.
- 16) Do not use this product beyond the expiration date.
- 17) Do not store extraction reagent solution vial sideways or upside down.
- 18) Use the test plate immediately after opening the aluminum foil pouch. If the test plate is left in a room for a long time, it could not react by exposure to moisture.
- 19) Do not touch sample area, test line area, and control line area by hand directly.
- 20) Do not perform the test in a place such as under an air conditioner where the dry wind directly blows the surface of the test plate, to prevent uneven migration.
- 21) Do not use the reagents, accessories, etc. of this product for any purpose other than this test.
- 22) Test plate, swab, and extraction reagent solution vial (including filter and caps) are intended for single use only.

- 23) Use swabs included in this product.
- 24) Avoid getting swabs wet and store them away from direct sunlight, high temperature, and humidity.
- 25) Do not touch the spherical tip of the swab before use.
- 26) Do not press the spherical tip (sponge) or rod (handle) of the swab from the outside of the packaging at the time of taking out the swab from the packaging bag because the spherical tip could come off by the pressing load.
- 27) Use swab immediately after opening the packaging.
- 28) Do not use a swab if a break and/or hole are found on the packaging.
- 29) Do not use a swab if stained, broken, or bent.
- 30) Do not bend or curve the rod of the swab before collecting the specimen.
- 31) Be careful not to break the rod of the swab or damage the collection site (mucosa) by applying too much force or pressing too hard when collecting specimen with a swab.
- 32) An elastic-plastic rod is employed in swabs to reduce the burden of patients. However, on the other hand, the tip of the swab may not be reached to the inflamed region on the wall of the nasal cavity or you may not be able to rub the tip on the wall of the nasal cavity adequately to collect enough volume of virus antigens, even though the tip of the swab is reached to the inflamed region on the wall of the nasal cavity. Therefore, make sure the tip of the swab is reached to the wall of the nasal cavity to rub the inflamed region at the time of collecting mucous epidermis.
- 33) After preparing the sample, be careful not to spatter the sample when removing the swab.
- 34) If the amount of specimen collected is excessive or the specimen is highly viscous, the filter may become clogged, and adequate sample volume may not be dropped. In that case, collect a new specimen and perform the retest.
- 35) Handle liquid waste and used utensils by any of the following disinfection and sterilization methods as sample (specimen) may contain infectious material.
 - a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or longer
 - b) Immerse in 2% glutaraldehyde solution for 1 hour or longer
 - c) Autoclave at 121°C for 20 minutes or longer
- 36) Regarding disposal of used reagents and utensils, dispose of them in accordance with the Local Regulation and Law of waste disposal.

[Storage and stability of the device]

Store kit at 1 to 30°C, out of direct sunlight or high humidity. Kit contents are stable until the expiration dates printed on the product box and packaging. Do not store upside down or sideways. Do not freeze.

[Preparation of specimen collection]

- 1) Swab : Use swab included in this test kit.
- 2) Extraction reagent solution: Use without preparation.

[Specimen collection and handling]

Proper specimen collection and handling are critical to the performance of this kit.

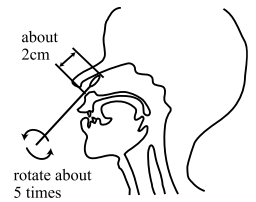
1. Nasopharyngeal swab specimen:

Along inferior nasal conchae (imaging a horizontal plane connecting nostril with external acoustic meatus), insert a swab in the nasal cavity and rub it on the mucosal surface several times to collect mucous epidermis.



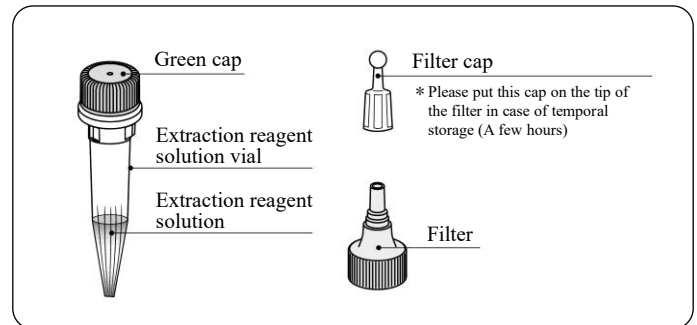
Note) An elastic-plastic rod is employed in swabs to reduce the burden of patients. However, on the other hand, the tip of the swab may not be reached to the inflamed region on the wall of the nasal cavity or you may not be able to rub the tip on the wall of the nasal cavity adequately to collect enough volume of virus antigens, even though the tip of the swab is reached to the inflamed region on the wall of the nasal cavity. Therefore, make sure the tip of the swab is reached to the wall of the nasal cavity to rub the inflamed region at the time of collecting mucous epidermis.

2. Nasal (anterior nares) swab specimen:
Insert the swab inside the nostril for about 2cm and collect mucus epidermis by rotating the swab in a circular path against the nasal wall about 5 times.



[Sample preparation and Test procedure]

• Details of Extraction reagent solution vial



• Sample preparation

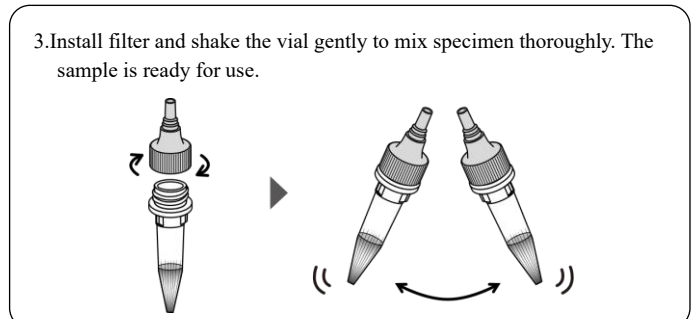
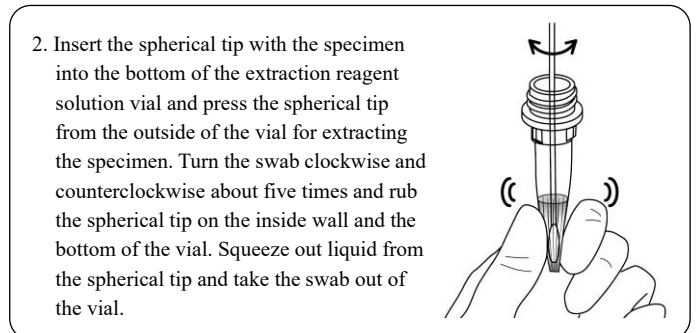
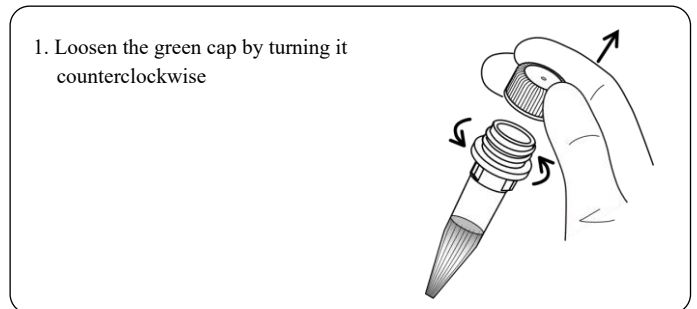
Relations of applicable specimens and mutual use of sample with another Quick Chaser product are as follows:

Product \ Specimen	Nasopharyngeal swab specimen	Nasal swab specimen*
SARS-CoV-2/RSV	○	○
Flu A, B	○	○
Adeno	○	×

Applicable specimen : ○

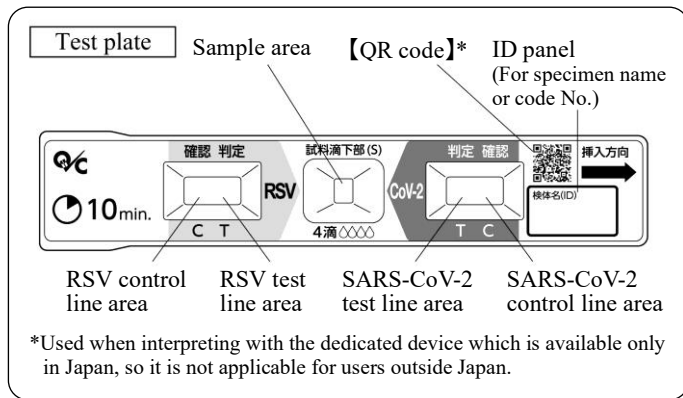
* It is collected by inserting swab inside nostril about 2cm.

Note) Do not use sample mutually except the above combination.



Samples should be tested as soon as possible. However, if specimens cannot be tested immediately, specimens extracted in the extraction reagent solution can be held at 2 to 8°C for up to 24 hours. Do not use the filter and filter cap for the purposes of transportation or preservation as they do not provide an airtight seal. Bring samples to room temperature before testing.

• Details of test plate



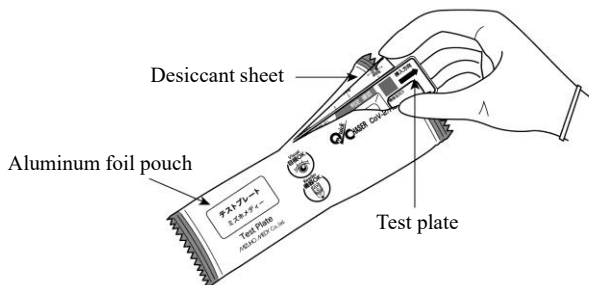
• Test procedure

1) Preparation of reagent

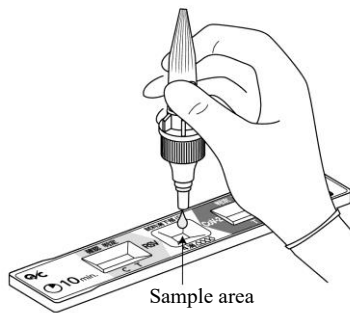
Test plate: No prior preparation required.

2) Test procedure

1. Remove test plate from the aluminum foil pouch. Discard the desiccant sheet included in the aluminum foil pouch.



2. Add 4 drops (about 150 µL) of sample to the sample area of the test plate from the extraction reagent solution vial containing the prepared sample. Hold the vial vertically so that the tip of the extraction filter does not come into contact with the sample area of the test plate.



3. Leave to react at 15 to 30°C.

Interpret test results visually by reading lines in the test line area and control line area after 10 minutes.



[Interpretation]

Interpretation by the existence of red-purple lines in test line area and control line area.

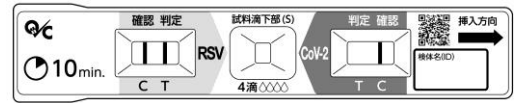
<Positive>

Both test line and control line appear.

SARS-CoV-2
Positive



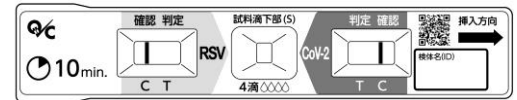
RS virus
Positive



<Negative>

Only control lines appear.

Negative



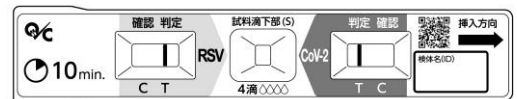
<Retest>

If both test line and control line do not appear or no control line appears for either or both of SARS-CoV-2 and RSV, an operational error such as insufficient sample volume may be considered. Recheck test procedure and retest with the new test plate. If the same result comes out in the retest again, confirm it with other methods.

Retest



Retest



[Limitations]

- 1) Negative results should be treated as presumptive and do not rule out SARS-CoV-2 and RS virus infection.
- 2) As for the diagnosis of coronavirus infection and influenza virus infection, refer to the latest information for medical institutions and testing laboratories issued from government authority, and should not be based solely on the test results of this product but should be comprehensively made in consideration of other test results and clinical symptoms.
- 3) Regarding the specimen for the test, refer to the local guidelines for COVID-19 testing and specimen collection.
- 4) When using a nasal (anterior nares) swab as a specimen, the detection rate tends to be lower than that of a nasopharyngeal swab, so please pay attention to the specimen collection methods.
- 5) In the case of SARS-CoV-2 test line or RS virus test line and control line appear even before 10 minutes after dropping the sample, it can be interpreted as SARS-CoV-2 positive or RS virus positive. Negative should be interpreted at 10 minutes after dropping the sample. The streak line might appear before 10 minutes temporarily. Do not interpret the temporal streak line as the appearance of the test line. After 10 minutes, colloidal gold can appear like a line due to the drying of the test plate with time. Therefore, please interpret test results at 10 minutes.
- 6) This product is used as an aid in the diagnosis of SARS-CoV-2 infection and RS virus infection. In case SARS-CoV-2 and RS virus antigens amount in the specimen are below the detection sensitivity of the test or inadequate specimen collection, test result could be interpreted as negative, even though the patient is infected by SARS-CoV-2 or RS virus. In addition, a non-specific reaction may occur depending on the factors in the sample, and a negative specimen may be interpreted as positive. The final definitive diagnosis should be made comprehensively from clinical symptoms and other test results.
- 7) If test lines appear in both SARS-CoV-2 and RSV, there is a possibility of dual infections of SARS-CoV-2 and RS virus; however, to be sure, collect a new specimen and perform the test again. In addition, please make a comprehensive judgment based on clinical symptoms and other test results.

[Clinical significance]

Quick Chaser SARS-CoV-2/RSV can rapidly detect SARS-CoV-2 and RS virus antigens with a simple operation and is considered to be useful as an aid in the diagnosis of SARS-CoV-2 and RS virus infection.

[Performance characteristics]

1) Performance

1. Sensitivity

- When SARS-CoV-2 In-house positive control ^{note 1)} was tested, SARS-CoV-2 positive result was obtained.
- When RS virus In-house positive control ^{note 2)} was tested, RS virus positive result was obtained.

2. Accuracy

- When SARS-CoV-2 In-house positive control was tested, SARS-CoV-2 positive result was obtained.
- When RS virus In-house positive control was tested, RS virus positive result was obtained.
- When In-house negative control ^{note 3)} was tested, negative results were obtained in both SARS-CoV-2 and RS virus.

3. Reproducibility

- When SARS-CoV-2 In-house positive control was tested three times simultaneously, SARS-CoV-2 positive result was shown in all cases.
- When RS virus In-house positive control was tested respectively three times simultaneously, RS virus positive result was shown in all cases.
- When In-house negative control was tested three times simultaneously, negative result was shown in all cases.

Note 1) SARS-CoV-2 control antigen solution diluted with an in-house negative control to be equivalent to 400pg/mL of the calibration reference material.

Note 2) RS virus control antigen solution diluted with an in-house negative control to be equivalent to 3.64×10⁹ copies/mL of the calibration reference material.

Note 3) Extraction reagent solution

4. Detection limit

SARS-CoV-2 detection

Recombinant SARS-CoV-2 antigen 100pg/mL

RS virus detection

A/Long strain 3.95 × 10³ TCID₅₀/mL

2) Correlations

<SARS-CoV-2>

1. Correlations with RT-PCR method using clinical specimens preserved in Japan (nasopharyngeal swab specimens suspended in transport medium)

		Quick Chaser SARS-CoV-2/RSV		
		Positive	Negative	Total
RT-PCR method	Positive	56	17	73
	Negative	0	102	102
	Total	56	119	175

Positive agreement rate : 76.7% (56/73)
 Negative agreement rate : 100% (102/102)
 Total agreement rate : 90.3% (158/175)

The following table shows the positive agreement rate stratified by the viral RNA load of RT-PCR positive specimens.

Viral RNA load (RNA copy/test)	The number of positive results by QC SARS-CoV-2/RSV /specimens (Positive agreement rate)
100,000 or more	26/26 (100%)
10,000 ~ 100,000	20/20 (100%)
1,600 ~ 10,000	10/12 (83.3%)
400 ~ 1,600	0/1 (0.0%)
under 400	0/14 (0.0%)

Positive agreement rate was 96.6% (56/58) when the viral load was 1,600 copies/test or more, and 94.9% (56/59) when the viral load was 400 copies/test or more.

2. Correlations with RT-PCR method using clinical specimens preserved in Japan (nasal swab specimens suspended in transport medium)

		Quick Chaser SARS-CoV-2/RSV		
		Positive	Negative	Total
RT-PCR method	Positive	22	25	47
	Negative	0	113	113
	Total	22	138	160

Positive agreement rate : 46.8% (22/47)
 Negative agreement rate : 100% (113/113)
 Total agreement rate : 84.4% (135/160)

The following table shows the positive agreement rate stratified according to the viral RNA load among RT-PCR positive specimens.

Viral RNA load (RNA copy/test)	The number of positive results by QC SARS-CoV-2/RSV /specimens (Positive agreement rate)
100,000 or more	0/0
10,000 ~ 100,000	16/18 (88.9%)
1,600 ~ 10,000	6/10 (60.0%)
400 ~ 1,600	0/4 (0.0%)
under 400	0/15 (0.0%)

Positive agreement rate was 78.6% (22/28) when the viral load was 1,600 copies/test or more, and 68.8% (22/32) when the viral load was 400 copies/test or more.

<RS virus>

1. Correlations with existing approved products (immunochromatographic assay) using nasopharyngeal swab specimens

		Quick Chaser SARS-CoV-2/RSV		
		Positive	Negative	Total
Other product (1)	Positive	55	0	55
	Negative	1*1	71	72
	Total	56	71	127

Positive agreement rate : 100% (55/55)
 Negative agreement rate : 98.6% (71/72)
 Total agreement rate : 99.2% (126/127)
 *1 The discrepant case was positive with RT-PCR method.

		Quick Chaser SARS-CoV-2/RSV		
		Positive	Negative	Total
Other product (2)	Positive	56	0	56
	Negative	0	71	71
	Total	56	71	127

Positive agreement rate : 100% (56/56)
 Negative agreement rate : 100% (71/71)
 Total agreement rate : 100% (127/127)

2. Two concentrations of RS virus cultured strain near the detection limit were added to the nasal swab solution and measured with Quick Chaser SARS-CoV-2/RSV.

Cultured strain of RS virus	Concentration		Quick Chaser SARS-CoV-2 /RSV		Total
			Positive	Negative	
A/Long	2 × LOD	7.90 × 10 ³ TCID ₅₀ /mL	25	0	25
	5 × LOD	1.98 × 10 ⁴ TCID ₅₀ /mL	25	0	25
Negative	No addition		0	25	25
Total			50	25	75

3) Calibration reference material (Standard material)
 SARS-CoV-2: Recombinant SARS-CoV-2 antigen
 RS virus: RS virus antigen solution (in-house standard)

4) Interfering substances and medications

Following substances and blood did not interfere with the performance of this product at the concentration listed below.

- Acetylsalicylic acid (5mg/ml)
- Ibuprofen (5mg/ml)
- Diphenhydramine hydrochloride (5mg/ml)
- Oxymetazoline hydrochloride (5mg/ml)
- Dextromethorphan hydrobromide (5mg/ml)
- Phenylephrine hydrochloride (5mg/ml)
- Cold medicine (concentration of Acetaminophen: 5mg/ml)
- Nasal drop 1, containing Sodium cromoglicate, Chlorpheniramine maleate, Naphazoline hydrochloride (10%)
- Nasal drop 2, containing Beclometasone Dipropionate (10%)
- Inhaled medication 1, containing Salbutamol sulfate (10%)
- Inhaled medication 2, containing Bromhexine hydrochloride (10%)
- Intraoral antiphlogistic, containing Sodium Azulene Sulfonate (10%)
- Blood (1%)

Regarding the sample containing 1% or more blood, collect specimen again because such sample could give influence to the interpretation.

5) Cross reactivity

Regarding SARS-CoV-2, cross reactivity at RS virus test line area was not observed.

Regarding RS virus, cross reactivity at the SARS-CoV-2 test line area was not observed.

Cross reactivity was not observed with the following viruses and bacteria.

<Viruses>

Influenza A virus	Influenza B virus
Adenovirus (Type 1)	Adenovirus (Type 2)
Adenovirus (Type 3)	Adenovirus (Type 4)
Adenovirus (Type 5)	Adenovirus (Type 6)
Adenovirus (Type 7)	Adenovirus (Type 11)
Coxsackievirus A9	Coxsackievirus B5
Human Echovirus 9	Herpes simplex virus type1
Mumps virus	Parainfluenza virus 1
Rhinovirus 8	Human Metapneumovirus

<Bacteria>

<i>Bordetella pertussis</i>	<i>Candida albicans</i>
<i>Hemophilus influenzae</i>	<i>Klebsiella pneumoniae</i>
<i>Listeria monocytogenes</i>	<i>Moraxella catarrhalis</i>
<i>Mycoplasma pneumoniae</i>	<i>Pseudomonas aeruginosa</i>
<i>Serratia marcescens</i>	<i>Staphylococcus aureus</i>
<i>Staphylococcus epidermidis</i>	<i>Streptococcus agalactiae</i> (Group B)
<i>Streptococcus mutans</i>	<i>Streptococcus pneumoniae</i>
<i>Streptococcus pyogenes</i> (Group A)	

Reactivity with other coronaviruses

- No reactivity was observed with the following coronaviruses.
Human coronavirus 229E
- No reactivity was observed with the following recombinant coronavirus antigens.
MERS-CoV (1µg/mL) HCoV-OC43 (1µg/mL)
HCoV-NL63 (1µg/mL) HCoV-HKU1 (1µg/mL)

Regarding SARS-CoV, cross reactivity was observed at the SARS-CoV-2 test line.

[Storage·Expiry]

- Storage: 1 to 30 °C
- Expiry: 12 months (As indicated on the package)

[Reference]

NATIONAL INSTITUTE OF INFECTIOUS DISEASES (JAPAN) :
Manual for the Detection of Pathogen 2019-nCoV Ver.2.9.1

Technical information
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<https://www.mizuho-m.co.jp/en>