

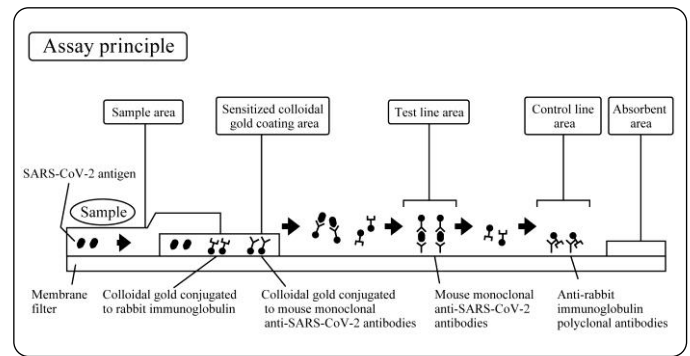
Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

SARS coronavirus antigen kit

Quick Chaser SARS-CoV-2



[Warnings and Precautions]

- 1) Take necessary biosafety measures for specimen collection and handling.
- 2) For in vitro diagnostic use only.
- 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 (3 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 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.

[Package]

68700: Quick Chaser SARS-CoV-2 - 10 tests/kit

[Contents]

- 1) Test plate - 10 tests
 - Mouse monoclonal anti-SARS-CoV-2 antibodies
 - Colloidal gold conjugated to mouse monoclonal anti-SARS-CoV-2 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)
- 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 qualitative detection of SARS-CoV-2 antigen in nasopharyngeal swab specimen or nasal swab specimen.

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

[Principle of the test]

“Quick Chaser SARS-CoV-2” is the in vitro diagnostic reagent for qualitative detection of SARS-CoV-2 antigen based on the immunochromatographic assay. Colloidal gold conjugated to mouse monoclonal anti-SARS-CoV-2 antibodies and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in 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 test line area and anti-rabbit immunoglobulin antibodies are immobilized in control line area.

If SARS-CoV-2 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 as they migrate from the sample area. Moreover, they will be captured in test line area by reacting with mouse monoclonal anti-SARS-CoV-2 antibodies. As a result, a purple-red line with the colloidal gold appears in 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 control line area, resulting in the appearance of a purple-red line in control line area regardless of the presence or absence of SARS-CoV-2 antigens.

- 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 such as HIV, HBV, and HCV, etc.
- Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or longer
 - Immerse in 2% glutaraldehyde solution for 1 hour or longer
 - 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]

This product can only be interpreted visually.

- Swab: Use swab included in this test kit.
- 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:

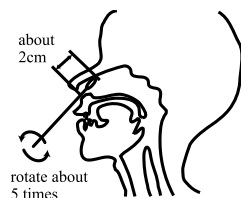
Along inferior nasal conchae (imaging a horizontal plane connecting nostril with external acoustic meatus), insert a swab in the nasal cavity and rub it on the mucosal surface several times to collect mucous epidermis.



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.

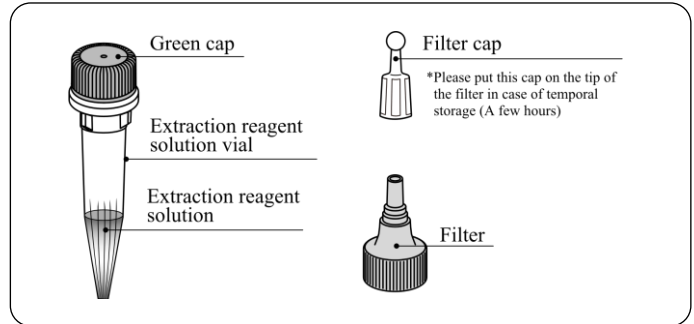
2. Nasal (anterior nares) swab specimen:

Insert the swab inside the nostril for about 2 cm 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:

Specimen	SARS-CoV-2	Flu A,B	Adeno
Nasopharyngeal swab specimen	○ ↔ ○	○ ↔ ○	○
Nasal swab*1 specimen	○ ↔ ○	○	×

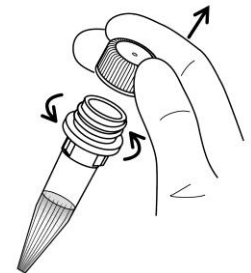
Applicable specimen : ○

Availability of mutual use of sample: ↔

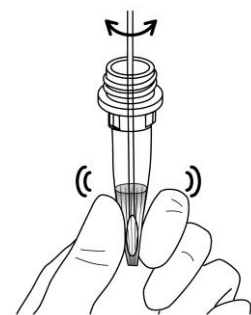
*1 It is collected by inserting swab inside nostril about 2 cm.

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

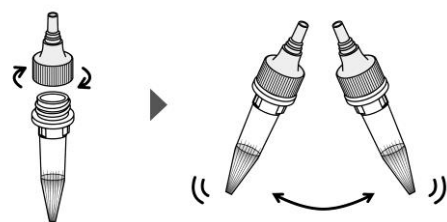
- Loosen the green cap by turning it counterclockwise.



- Insert the spherical tip with the specimen into the bottom of the extraction reagent solution vial and press the spherical tip from the outside of the vial for extracting the specimen. Turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and the bottom of the vial. Squeeze out liquid from the spherical tip and take the swab out of the vial.

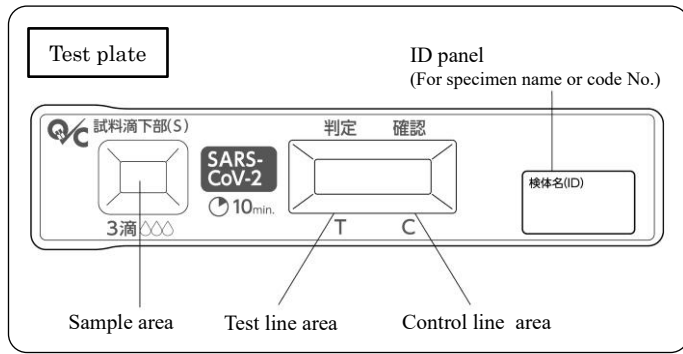


- Install filter and shake the vial gently to mix specimen thoroughly. The sample is ready for use.



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



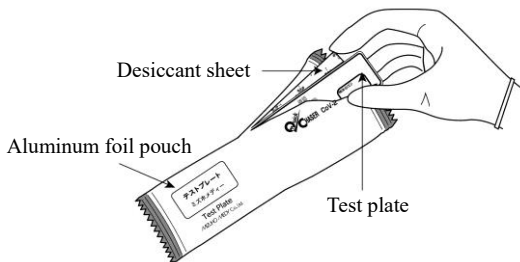
• Test procedure

1) Preparation of reagent

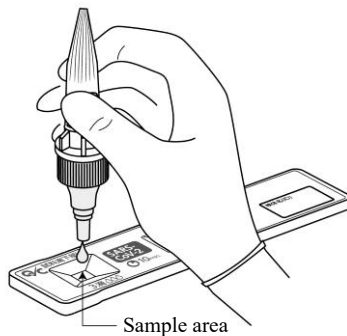
Test plate: No prior preparation required.

2) Test procedure

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

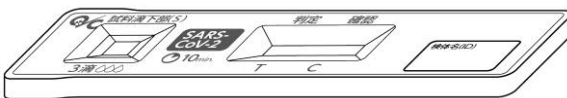


2. Add 3 drops (about 110 μL) of sample to the sample area of the test plate from the extraction reagent solution vial containing the prepared sample. Hold the vial vertically so that the tip of the extraction filter does not come into contact with the sample area of the test plate.



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.



<Negative>

Only a control line appears.



<Retest>

If both test line and control line do not appear or no control line appears, 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.



[Limitations]

- 1) Negative results should be treated as presumptive and do not rule out SARS-CoV-2 infection.
- 2) As for the diagnosis of coronavirus infection, refer to the latest information for medical institutions and testing laboratories issued from government authority, and should not be solely on the test results of this product but should be comprehensively made in consideration of other results and clinical symptoms.
- 3) Regarding the specimen for the test, refer to the local guidelines for SARS-CoV-2 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 and control line appear even before 10 minutes after dropping the sample, it can be interpreted as SARS-CoV-2 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. In case SARS-CoV-2 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. 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.

[Performance characteristics]

1) Performance

1. Sensitivity

- When In-house positive control ^{note 1)} was tested, positive result was obtained.

2. Accuracy

- When In-house positive control was tested, positive result was obtained.
- When In-house negative control ^{note 2)} was tested, negative results were obtained.

3. Reproducibility

- When In-house positive control was tested three times simultaneously, 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 400 pg/mL of the calibration reference material.

Note 2) Extraction reagent solution

4. Detection limit

Recombinant SARS-CoV-2 antigen 100 pg/mL

2) Calibration reference material (Standard material)

Recombinant SARS-CoV-2 antigen

3) 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 Ketotifen fumarate (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.

4) Cross reactivity*

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

<Viruses>

Influenza virus A	Influenza virus B
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
Respiratory syncytial virus	

<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 (1.0×10⁶ TCID₅₀/mL)
- 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.

[Clinical significance]*

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

(Summary of clinical performance)

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

Quick Chaser SARS-CoV-2

	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 this product /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

	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 this product /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.

[Shelf life]*

12 months from the date of manufacture

(As indicated on the product box and packaging)

[Reference]

NATIONAL INSTITUTE OF INFECTIOUS DISEASES (JAPAN):

Manual for the Detection of Pathogen 2019-nCoV Ver.2.9.1

[Approval conditions]

1) Stability tests under the actual storage condition should be conducted after manufacturing and marketing.

Technical information
Telephone **+81-942-85-3845**

*Regarding "Interfering substances and medications", "Cross reactivity", "Clinical significance" and "Shelf life", they are based on the SARS-CoV-2 detection data obtained from the previously approved product, Quick Chaser SARS-CoV-2/Flu A, B.