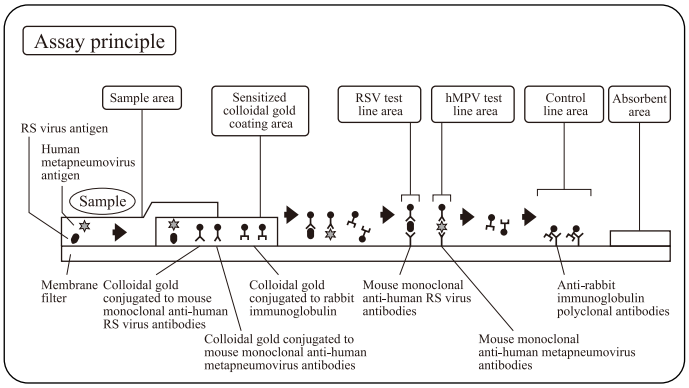
Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

RS virus kit, Human metapneumovirus kit

Quick Chaser RSV/hMPV



[Package]

70040: Quick Chaser RSV/hMPV - 10 tests/kit

[Contents]

1) Test plate - 10 tests
   - Mouse monoclonal anti-human RS virus antibodies
   - Mouse monoclonal anti-human metapneumovirus antibodies
   - Colloidal gold conjugated to mouse monoclonal anti-human RS virus antibodies
   - Colloidal gold conjugated to mouse monoclonal anti-human metapneumovirus antibodies
2) Extraction reagent solution vial - 0.6mL×10 vials
   Extraction reagent solution is buffer containing detergent.
3) Swab (for nasopharyngeal swab specimen & for nasal aspirate specimen) - 10 pieces
4) Filter (for extraction reagent solution vial) - 10 pieces
5) Filter cap - 10 pieces

[Intended Use]

For qualitative detection of RS virus antigen in nasopharyngeal swab specimen or nasal aspirate specimen (An aid in the diagnosis of RS virus infection)
For qualitative detection of human metapneumovirus in nasopharyngeal swab specimen, oropharyngeal swab specimen, or nasal aspirate specimen (An aid in the diagnosis of human metapneumovirus infection)

[Principle of the test]

"Quick Chaser RSV/hMPV" is the in vitro diagnostic reagent for qualitative detection of RS virus antigen and human metapneumovirus antigen based on the immunochromatographic assay.
Colloidal gold conjugated to mouse monoclonal anti-human RS virus antibodies, colloidal gold conjugated to mouse monoclonal anti-human metapneumovirus antibodies, and colloidal gold conjugated to rabbit immunoglobulins 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-human RS virus antibodies and mouse monoclonal anti-human metapneumovirus antibodies are immobilized in each test line area and anti-rabbit immunoglobulin polyclonal antibodies are immobilized in the control line area.
If RS virus antigens and/or human metapneumovirus antigens are present in the sample, according to the principle of immunochromatography, they react respectively with colloidal gold conjugated to mouse monoclonal anti-human RS virus antibodies and colloidal gold conjugated to mouse monoclonal anti-human metapneumovirus antibodies as they migrate from the sample area. Moreover, they are captured in the test line area by reacting respectively with mouse monoclonal anti-human RS virus antibodies and mouse monoclonal anti-human metapneumovirus antibodies. 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 migrate and will be captured by the anti-rabbit immunoglobulin polyclonal antibodies on the control line area, resulting in the appearance of a purple-red line in the control line area regardless of the presence or absence of RS virus antigens and human metapneumovirus antigens.

[Warnings and Precautions]

1) For in vitro diagnostic use only
2) Procedures not described in the Instructions for Use are not guaranteed.
3) This product can be interpreted both visually and with the dedicated device "Smart QC Reader". When interpreting with the dedicated device, use it according to the Instructions for Use and User Manual of the dedicated device.
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℃ prior to testing.
6) Strictly follow interpretation time to avoid false-negative and false-positive.
7) Sample (specimen) may contain infectious materials such as HIV, HBV, and HCV, etc. Handle sample (specimen) with great care as there is a risk of infection during the test.
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) Regarding the aspiration tube with a trap for collecting nasal aspirate specimen, use an unused, uncontaminated one for each test to prevent the spread of infection, to maintain the accuracy of the test, and to prevent contamination.
15) If the sample (specimen) spatters, wipe it off with alcohol for disinfection, etc.
16) 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.
17) Do not use this product beyond the expiration date.
18) Do not store extraction reagent solution vial sideways or upside down.
19) Do not use extraction reagent solution included in other kits.
20) 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.
21) Do not touch sample area, test line area, and control line area by hand directly.
22) 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.
23) Do not use the reagents, accessories, etc. of this product for any purpose other than this test.
24) Test plate, swab, and extraction reagent solution vial (including filter and caps) are intended for single use only.
25) Use swabs included in this product, or use oropharyngeal swab (oropharyngeal /conjunctival / saliva) sold separately.

26) Avoid getting swabs wet and store them away from direct sunlight, high temperature, and humidity.
27) Do not touch the spherical tip of the swab before use.
28) Do not press the spherical tip (sponge) or rod (handle) of the swab from the outside of the pouch at the time of taking out the swab from the packaging bag because the spherical tip could come off by the pressing load.
29) Use swab immediately after opening the pouch.
30) Do not use a swab if a break and/or hole are found on the packaging.
31) Do not use a swab if stained, broken, or bent.
32) Do not bend or curve the rod of the swab before collecting the specimen.
33) 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.
34) 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.
35) After preparing the sample, be careful not to spatter the sample when removing the swab.
36) 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.
37) 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.
   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℃ for 20 minutes or longer
38) 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 be interpreted both visually and with a dedicated device. "Specimen collection" and "Sample preparation" are common to both visual and a dedicated device.

1)Swab: Use a swab included in this test kit when using a nasopharyngeal swab or nasal aspirate as a specimen.
When testing with oropharyngeal specimen, use an oropharyngeal swab (oropharyngeal /conjunctival / saliva: product number 67330) which is sold separately.
2) Extraction reagent solution: Use without preparation.

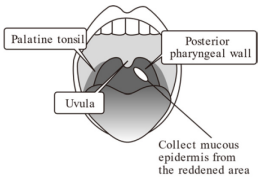
[Specimen collection and handling]

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

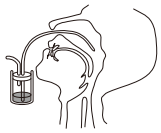
1. Nasopharyngeal swab specimen:
Along inferior nasal conchae (imaging a horizontal plane connecting nostril with external acoustic meatus), insert a swab in the nasal cavity and rub it on the mucosal surface several times to collect mucous epidermis.

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. Oropharyngeal swab specimen:
Collect mucous epidermis by rubbing the reddened area of the posterior pharyngeal wall, uvula, or palatine tonsil several times by swab.

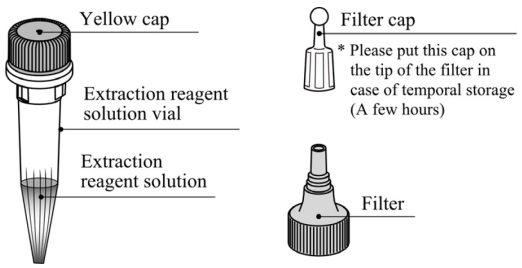


3. Nasal aspirate specimen：
Dip the spherical tip into the low-viscosity liquid part of the nasal aspirate specimen in a trap.
If it is difficult to collect specimen due to high viscosity or low volume of specimen, add 0.5 to 1mL of saline, and use suspension for the test.
*Be reminded that sensitivity decreases by dilution of the specimen with saline.



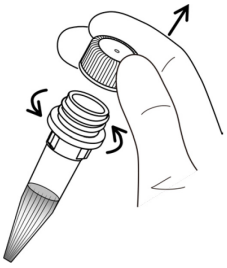
[Sample preparation and Test procedure]

●Details of extraction reagent solution vial

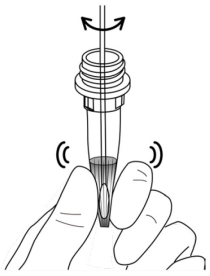


●Sample preparation

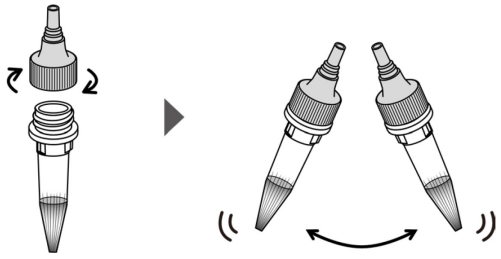
1. Loosen the yellow cap by turning it counterclockwise.



2. 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.

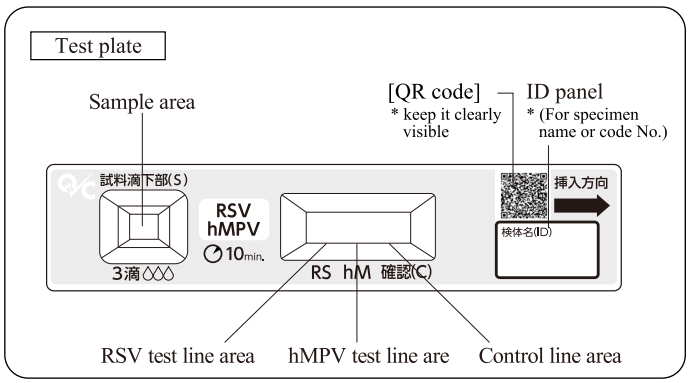


3. Install filter and shake the vial gently to mix specimen thoroughly. The sample is ready for use.



Samples should be tested as soon as possible. However, if specimens cannot be tested immediately, specimen 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 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

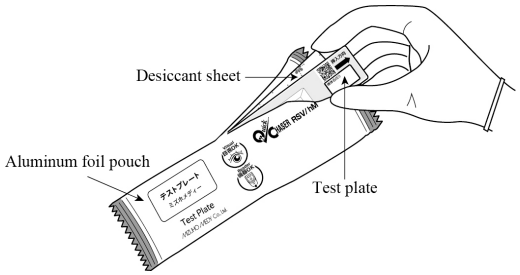
1) Preparation of reagent

Test plate: No prior preparation required.

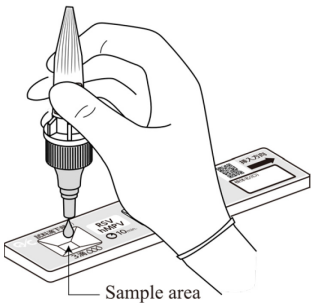
2) Test procedure

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

(Note) Please be careful not to stain the QR code when writing the sample name in the ID panel.



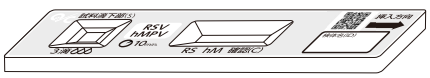
2. Add 3 drops (about 110 µL) of sample to the sample area of the test plate from the extraction reagent solution vial containing the prepared sample. Hold the vial vertically so that the tip of the extraction filter does not come into contact with the sample area of the test plate.



<When interpreting visually>

3.-1 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 5 to 10 minutes.



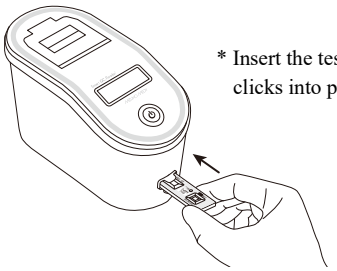
<When interpreting with the dedicated device>

3.-2 A method of reading and interpreting the lines that appear in the test line area and control line area with the dedicated device.

After checking the insertion direction of the test plate, measure according to the operation method of "Mode 1" or "Mode 2".

(Note)

- Do not attach labels etc. on the test plate.
- Be careful not to touch the sample area when inserting the test plate.
- Insert the test plate by keeping it horizontal to prevent the sample from spilling or splashing into the instrument.
- Insert the test plate all the way.



* Insert the test plate until it clicks into place.

●Mode 1 [Read Now]

This mode interprets the test plate after the reaction time has elapsed.

i) Leave to react at 15 to 30°C.

ii) After 10 minutes, insert the test plate into the test plate insertion slot of the dedicated device.

iii)The lines appearing in the test line area and control line area are read inside the dedicated device.

●Mode 2 [Walk Away]

This mode automatically interprets the test plate after dropping the sample inside the dedicated device.

i) Immediately after dropping the sample, insert the test plate into the test plate insertion slot of the dedicated device.

ii) The measurement starts automatically, and the lines appearing in the test line area and control line area are read every minute after 5 minutes inside the dedicated device.

* When the environmental temperature is lower than 15 °C, the temperature of the test plate is controlled to be 15 to 30 °C. (The function is only in Mode 2)

[Interpretation]

<When interpreting visually>

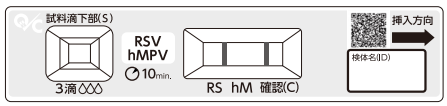
Interpret by existence of red-purple lines in test line area for RSV (RS), test line area for hMPV (hM) and control line area.

<Positive>

[Positive for RSV]

Both test line for RSV and control line appear.

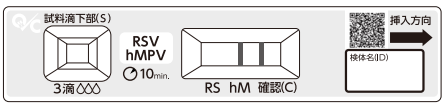
RSV Positive



[Positive for hMPV]

Both test line for hMPV and control line appear.

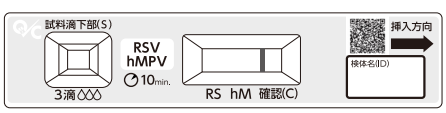
hMPV Positive



<Negative>

Only control line appears.

Negative

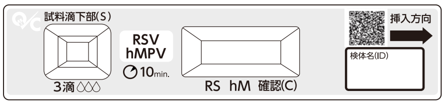


<Retest>

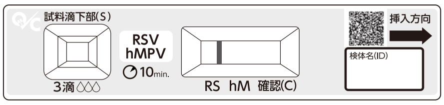
If both test line and control line do not appear or no control line appears, an operational error such as insufficient sample volume may be considered.

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.

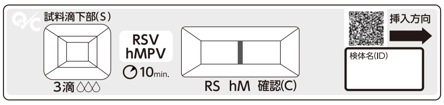
Retest



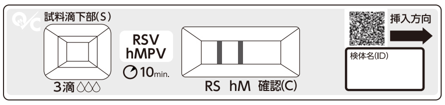
Retest



Retest



Retest



<When interpreting with the dedicated device>

Both Mode 1 [Read Now] and Mode 2 [Walk Away] are automatically interpreted according to the interpretation method of <When interpreting visually> based on the result of reading the lines with the dedicated device. Interpretation and display on the device screen are the same in Mode 1 [Read Now] and Mode 2 [Walk Away].

Interpretation	Display on the device screen
RSV Positive hMPV Negative	RSV : ＋ H.MPV : －
RSV Negative hMPV Positive	RSV : － H.MPV : ＋
Negative	RSV : － H.MPV : －
Retest	RSV : ＊ ＃03 H.MPV : ＊ ＃03

*Error code #03: Error when the control line is not detected.

*For error codes other than error code #03, refer to the User Manual of the dedicated device.

[Limitations]

1) Diagnosis of RS virus infection and Human metapneumovirus infection 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.
2) When using oropharyngeal swab specimen for the test, interpret solely for hMPV with the result and do not interpret for RS virus. Not intended to use oropharyngeal swab specimen for RS virus test.
3) Do not use saliva and sputum as a specimen.
4) In the case of RSV test line or hMPV test line and control line appear at 5 to 10 minutes after dropping the sample, it can be interpreted as RSV positive or hMPV 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.
5) This product is used as an aid in the diagnosis of RS virus and human metapneumovirus infection. In case RS virus antigen and human metapneumovirus antigen amount in the specimen is below the detection limit of the test or inadequate specimen collection, test result could be interpreted as negative, even though the patient is infected by RS virus or human metapneumovirus. 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.
6) If test lines appear in both RSV and hMPV, there is a possibility of dual infections of RSV and hMPV; 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.
7) The results of the visual interpretation and the interpretation with the dedicated device may not match. In such a case, make a comprehensive judgment based on both results, clinical symptoms, and other test results.
8) When interpreting with the dedicated device, if the control line area or test line area of the test plate is scratched or foreign matter (dust) is attached, it may be mistakenly detected as a line.
9) When using Mode 1 [Read Now] in the interpretation with the dedicated device, be sure to perform the measurement 10 minutes after the sample is dropped. If measured within 10 minutes, correct results may not be obtained.
10) As for specimen, use nasopharyngeal swab specimen and nasal aspirate specimen for RS virus test, use nasopharyngeal swab specimen, nasal aspirate specimen and oropharyngeal swab specimen for hMPV test.

[Performance characteristics]

1) Performance

1. Sensitivity
   - When in-house RS virus positive control [Note 1)] was tested, RS virus positive result was obtained.
   - When in-house human metapneumovirus positive control [Note2)] was tested, human metapneumovirus positive result was obtained.
2. Accuracy
   - When in-house RS virus positive control was tested, RS virus positive result was obtained.
   - When in-house human metapneumovirus positive control was tested, human metapneumovirus positive result was obtained.
   - When in-house negative control [Note 3)] was tested, negative result was obtained.
3. Reproducibility
   - When in-house RS virus positive control was tested three times simultaneously, RS virus positive result was obtained in all cases.
   - When in-house human metapneumovirus positive control was tested three times simultaneously, human metapneumovirus positive result was obtained in all cases.
   - When in-house negative control was tested three times simultaneously, negative result was obtained in all cases.

   Note 1) RS virus purified antigen diluted with extraction reagent solution to be equivalent to 3.64×10^{9}copies/mL of the calibration reference standard.

   Note 2) human metapneumovirus purified antigen diluted with extraction reagent solution to be equivalent to 9.57×10^{6}copies/mL of the calibration reference standard.

   Note 3) Extraction reagent solution
4. Detection limit

   RS virus

   Subtype A/A2 strain 9.10×10^{8}copies/mL

   Subtype A/Long strain 2.84×10^{7}copies/mL

   Subtype B/18537 strain 4.55×10^{8}copies/mL

   Subtype B/9320 strain 1.82×10^{9}copies/mL

   Human metapneumovirus

   Subtype A1 2.39×10^{6}copies/mL

   Subtype B1 2.99×10^{5}copies/mL
5. Reactivity

   It is confirmed that this product reacts with RS virus type A/A2, A/Long, B/18537 and B/9320 and human metapneumovirus A1, A2, B1 and B2.

2) Correlations

Comparison with existing approved products

(Immunochromatographic assay)

●Nasopharyngeal swab specimen

<RS virus>

		Quick Chaser RSV/hMPV		
		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] Regarding one case where the result was negative with other product (1) but

positive with Quick Chaser, it was positive with the RT-PCR method.

Quick Chaser RSV/hMPV

Other Product (2)	Positive	Negative	Total
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)

<Human metapneumovirus>

Quick Chaser RSV/hMPV

Other Product (3)	Positive	Negative	Total
Positive	51	0	51
Negative	3*[2]	61	64
Total	54	61	115

Positive agreement rate : 100% (51/51)
Negative agreement rate : 95.3% (61/64)
Total agreement rate : 97.4% (112/115)

*[2] Regarding three cases where the results were negative with other product (3) but positive with Quick Chaser, they were positive with the RT-PCR method.

Quick Chaser RSV/hMPV

Other Product (4)	Positive	Negative	Total
Positive	51	0	51
Negative	3*[3]	61	64
Total	54	61	115

Positive agreement rate : 100% (51/51)
Negative agreement rate : 95.3% (61/64)
Total agreement rate : 97.4% (112/115)

*[3] Regarding three cases where the results were negative with other product (4) but positive with Quick Chaser, they were positive with the RT-PCR method.

●Nasal aspirate specimen
＜RS virus＞

Quick Chaser RSV/hMPV

Other Product (1)	Positive	Negative	Total
Positive	65	0	65
Negative	0	53	53
Total	65	53	118

Positive agreement rate : 100% (65/65)
Negative agreement rate : 100% (53/53)
Total agreement rate : 100% (118/118)

Quick Chaser RSV/hMPV

Other Product (2)	Positive	Negative	Total
Positive	65	0	65
Negative	0	53	53
Total	65	53	118

Positive agreement rate : 100% (65/65)
Negative agreement rate : 100% (53/53)
Total agreement rate : 100% (118/118)

<Human metapneumovirus>

Quick Chaser RSV/hMPV

Other Product (3)	Positive	Negative	Total
Positive	52	0	52
Negative	2*[4]	52	54
Total	54	52	106

Positive agreement rate : 100% (52/52)
Negative agreement rate : 96.3% (52/54)
Total agreement rate : 98.1% (104/106)

*[4] Regarding two cases where the results were negative with other product (3) but positive with Quick Chaser, they were positive with the RT-PCR method.

3) The difference in performance depending on the specimen type for hMPV
For hMPV antigen detection, there is no existing in-vitro diagnostic using oropharyngeal swab specimen, hence observed with this product, QC hMPV, the difference in performance between oropharyngeal swab specimen and nasopharyngeal swab specimen collected from the identical person.

Oropharyngeal swab specimen

Nasopharyngeal swab specimen	Positive	Negative	Total
Positive	26	2	28
Negative	3	45	48
Total	29	47	76

Positive agreement rate : 92.9% (26/28)
Negative agreement rate : 93.8% (45/48)
Total agreement rate : 93.4% (71/76)

Showed good correlation between oropharyngeal swab specimen and nasopharyngeal swab specimen, and considered that there is no difference depends on the specimen type.

4) Calibration reference material (Standard material)
RS virus antigen solution (in-house standard)
Human metapneumovirus antigen solution (in-house standard)

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

Acetyl salicylate (10 mg/ml)
Ibuprofen (20 mg/ml)
Diphenhydramine hydrochloride (5 mg/ml)
Oxymetazoline hydrochloride (10 mg/ml)
Dextromethorphan hydrogen bromide (5 mg/ml)
Phenylephrine hydrochloride (50 mg/ml)
Cold medicine (concentration of Acetaminophen: 10 mg/ml)
Nasal drop 1, containing Sodium cromoglicate, Chlorpheniramine maleate, Naphazoline hydrochloride (20%)
Nasal drop 2, containing Ketotifen fumarate (10%)
Inhalation 1, containing Salbutamol sulfate (20%)
Inhalation 2, containing Bromhexine hydrochloride (20%)
Gargle 1, containing Tincture of Myrrh (0.5 %)
Gargle 2, containing Povidone-iodine (2.0 %)
Intraoral antiphlogistic, containing Sodium Azulene Sulfonate (10 %)
Cough drop 1, containing Di-potassium Glycyrrhizinate (20 mg/ml)
Cough drop 2, containing Nandina Fruit Extract (Dry) (10 mg/ml)
Cough drop 3, containing Cetylpyridinium chloride (20 mg/ml)
Blood (1%)

6) Cross reactivity
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, Human Coronavirus, Coxsackie virus A9, Coxsackie virus B5, Human Echovirus 9, Herpes simplex virus type1, Mumps virus, Parainfluenza virus 1, Rhinovirus 8
• Bacteria
Bordetella pertussis, Candida albicans, Haemophilus influenzae, Klebsiella pneumoniae, Listeria monocytogenes, Moraxella catarrhalis, Mycoplasma pneumoniae, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus agalactiae (Group B)*, Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes* (Group A)

[Shelf life]

24 months from the date of manufacture
(As indicated on the product box and packaging)

[Reference]

1)Susanne Abels et al.: Journal of Clinical Microbiology, 39(9), 3135-3139(2001)
2)Gulden Yilmaz et al.: Journal of Clinical Microbiology, 37(7), 2390(1999)
3)Gurmukh Ahluwalia et al.: Journal of Clinical Microbiology, 25(5), 763-767(1987)

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