Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Influenza virus kit

Quick Chaser Flu A, B

[Package]

70000: Quick Chaser Flu A, B - 10 tests/kit

[Contents]

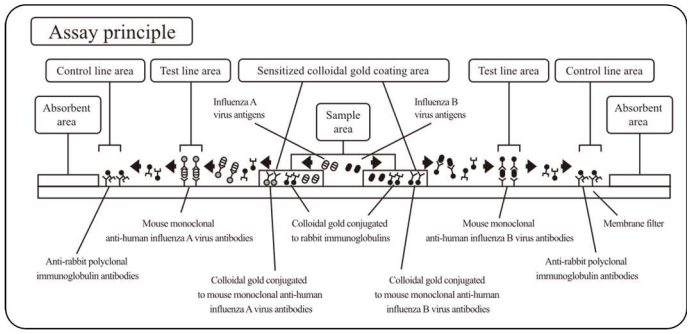
1) Test plate - 10 tests
   <Quick Chaser Flu A >
   • Mouse monoclonal anti-human influenza A virus antibodies
   • Colloidal gold conjugated to mouse monoclonal anti-human influenza A virus antibodies
   <Quick Chaser Flu B>
   • Mouse monoclonal anti-human influenza B virus antibodies
   • Colloidal gold conjugated to mouse monoclonal anti-human influenza B 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)
3) Swab (for nasopharyngeal swab specimen & for nasal aspirate specimen) - 10 pieces
4) Filter (for extraction reagent solution vial) - 10 piece
5) Filter cap - 10 pieces

[Intended use]

<Quick Chaser Flu A>
For qualitative detection of influenza A virus antigen in nasopharyngeal swab specimen, nasal swab specimen, nasal aspirate specimen, oropharyngeal swab specimen, or self-blown nasal discharge
(An aid in the diagnosis of influenza A virus infection)
<Quick Chaser Flu B>
For qualitative detection of influenza B virus antigen in nasopharyngeal swab specimen, nasal swab specimen, nasal aspirate specimen, oropharyngeal swab specimen, or self-blown nasal discharge
(An aid in the diagnosis of influenza B virus infection)

[Principle of the test]

"Quick Chaser Flu A, B" is the in vitro diagnostic reagent for qualitative detection of influenza virus antigen based on the immunochromatographic assay.
Colloidal gold conjugated to mouse monoclonal anti-human influenza A(B) virus 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 influenza A(B) virus antibodies are immobilized in the test line area, and anti-rabbit immunoglobulin antibodies are immobilized in the control line area.
If influenza A(B) virus antigens are present in the sample, according to the principle of immunochromatography, they react with colloidal gold conjugated to mouse monoclonal anti-human influenza A(B) virus antibodies as they migrate from the sample area. Moreover, they are captured in the test line area by reacting with mouse monoclonal anti-human influenza A(B) virus antibodies. As a result, a purple-red line with the colloidal gold appears in the 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 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 influenza A(B) virus 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 (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℃ prior to testing.
6) Sample (specimen) may contain infectious materials such as HIV, HBV, HCV, etc. Handle sample (specimen) with great care as there is a risk of infection during the test.
7) 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.
8) Do not collect the specimen with a swab soaked in the extraction reagent solution.
9) The filter cap does not provide an airtight seal. Do not use it for purposes of transportation or preservation.
10) Perform the specimen collection under the guidance of a qualified person.
11) The material of the membrane used for the test plate is nitrocellulose. Do not perform tests near a fire as nitrocellulose is extremely flammable.
12) When collecting the self-blown nasal discharge by swab, infectious splash may diffuse upon spreading the specimen collection sheet which the patient used. Please take sufficient measures to prevent infection. Also, be careful when a patient blows their nose as the virus may spatter around by the aerosol.
13) When collecting or handling the self-blown nasal discharge, use masks, gloves, etc. to prevent infection. If nasal discharge is spattered or spilled, wipe off thoroughly and clean with a disinfectant solution, etc.
14) Regarding the aspiration tube with a trap for collecting nasal aspirate specimen and specimen collection sheet for self-blown nasal discharge, 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) 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.
20) Do not touch sample area, test line area, and control line area by hand directly.
21) 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.

22) Do not use the reagents, accessories, etc. of this product for any purpose other than this test.
23) Test plate, swab, and extraction reagent solution vial (including filter and caps) are intended for single use only.
24) Use swabs included in this product, or use swabs for oropharyngeal specimens sold separately.
25) Avoid getting swabs wet and store them away from direct sunlight, high temperature, and humidity.
26) Do not touch the spherical tip of the swab before use.
27) Do not press the spherical tip (sponge) or the 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.
28) Use swab immediately after opening the packaging.
29) Do not use a swab if a break and/or hole are found on the packaging.
30) Do not use a swab if stained, broken, or bent.
31) Do not bend or curve the rod of the swab before collecting the specimen.
32) 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 the specimens with the swab.
33) 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.
34) After preparing the sample, be careful not to spatter the sample when removing the swab.
35) 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.
36) 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
37) 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]

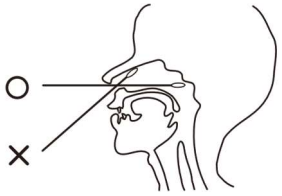
This product can be interpreted both visually and with a dedicated device. "Specimen collection" and "Sample preparation" are common to both visual and a dedicated device.

1. Swab :
• Use a swab included in this test kit when using a nasopharyngeal swab, nasal swab, nasal aspirate, or self-blown nasal discharge as a specimen.
• When using an oropharyngeal swab specimen, use a swab (for oropharyngeal specimen) sold separately.
2. Prepare the following item when using a self-blown nasal discharge as a specimen;
• Specimen collection sheet
(about 20 cm square, made of a material that does not infiltrate the nasal discharge such as vinyl or nylon)
3.Extraction reagent solution: Use without preparation.

[Specimen collection and handling]

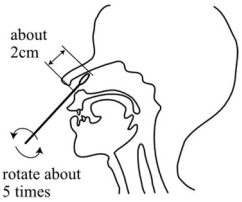
Proper specimen collection and handling are critical to the performance of this kit.

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.

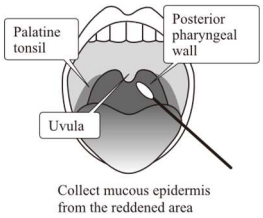


Note) An elastic plastic rod is employed in swabs to reduce the burden of patients. However, on the other hand, the tip of the swab may not be reached to the inflamed region on the wall of the nasal cavity or you may not be able to rub the tip on the wall of the nasal cavity adequately to collect enough 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.

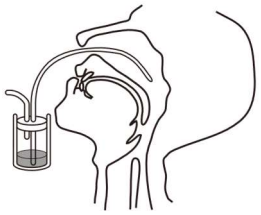
2. Nasal (anterior nares) swab specimen:
Insert the swab inside the nostril for about 2 cm and collect mucus epidermis by rotating the swab in a circular path against the nasal wall about 5 times.



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



4. 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.

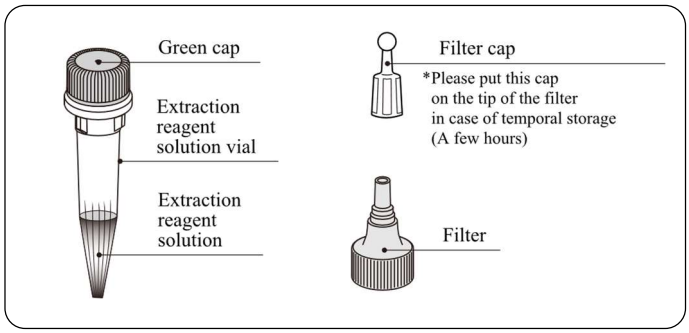


*Be reminded that sensitivity decreases by dilution of the specimen with saline.

5. Self-blown nasal discharge:
If it is determined that nasal discharge can be collected by consultation, hand out the specimen collection sheet to the patient then instruct the patient to blow their nose.
Note) Nasal discharge cannot be used for infants who are unable to blow their nose or for patients with dry nasal passages. Please check at the time of consultation. If the amount of nasal discharge from the nose is not enough to adhere to the entire surface of the sponge tip of the swab, the sample volume is considered to be insufficient, so do not use it for the test. Perform the test again using a sample collected by another method. When collecting and handling nasal discharge, pay close attention to the risk of secondary infection due to nasal discharge.

[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	Adeno	Flu A,B
Nasopharyngeal swab specimen	○ ⟷	○
Nasal aspirate specimen	○ ⟷	○
Self-blown nasal discharge	×	○
Oropharyngeal swab specimen	○ ⟷	○
Conjunctival swab specimen	○	×

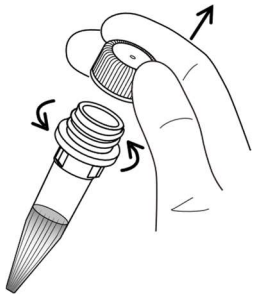
Applicable specimen : ○

Availability of mutual use of sample: ⟷

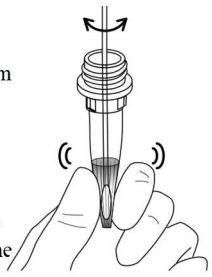
Note) Do not use sample mutually except the above combinations.

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℃ 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

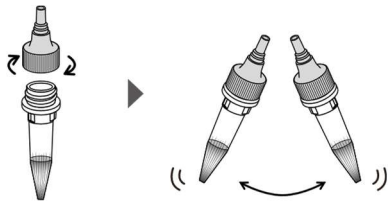
1. Loosen the green cap by turning it counterclockwise.



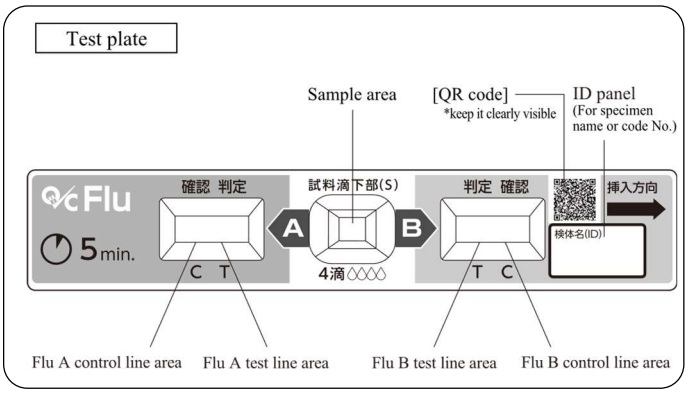
2. Insert the spherical tip with the specimen into the bottom of the extraction reagent solution vial and press the spherical tip from the outside of the vial for extracting the specimen. Turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and the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



· Details of test plate



· Test procedure

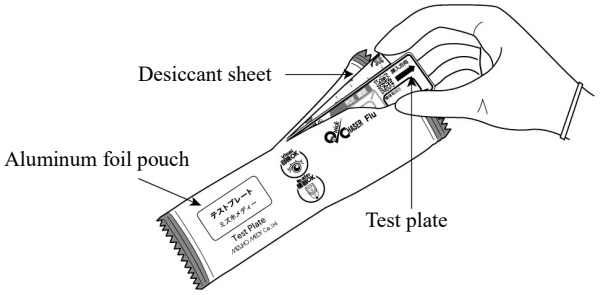
1) Preparation of reagent

Test plate: No prior preparation required.

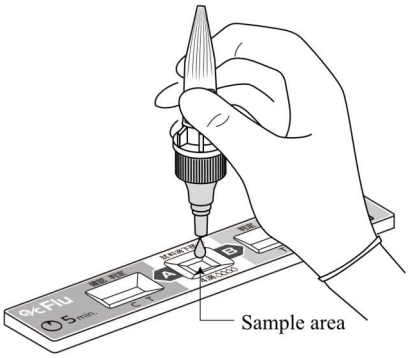
2) Test procedure

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

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



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.



<When interpreting visually>

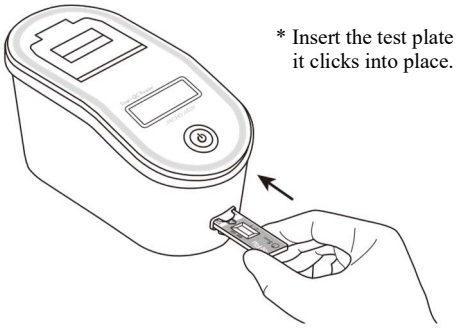
3.-1 Leave to react at 15 to 30°C.

Interpret test results visually by reading lines in the test line area and control line area after 1 to 5 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.

1) Mode 1 [Read Now]

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

1. Leave to react at 15 to 30°C.
2. After 5 minutes, insert the test plate into the test plate insertion slot of the dedicated device.
3. The lines appearing in the test line area and control line area are read inside the dedicated device.

2)Mode 2 [Walk Away]

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

1. Immediately after dropping the sample, insert the test plate into the test plate insertion slot of the dedicated device.
2. The measurement starts automatically, and the lines appearing in the test line area and control line area are read every minute 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. (function only in Mode 2)

[Interpretation]

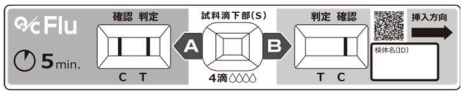
<When interpreting visually>

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

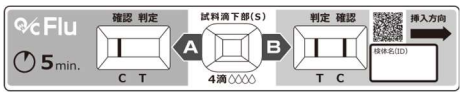
<Positive>

Both test line and control line appear.

Flu A Positive



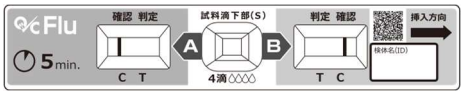
Flu B Positive



<Negative>

Only control lines appear.

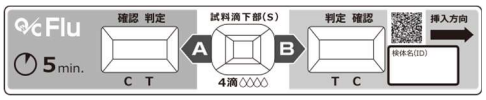
Negative



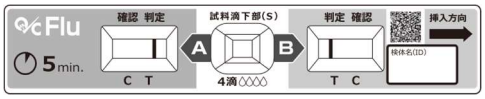
<Retest>

If both test line and control line do not appear or no control line appears for either or both of Flu A and B, 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



<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
Flu A Positive Flu B Negative	FLU A : + FLU B : −
Flu A Negative Flu B Positive	FLU A : − FLU B : +
Negative	FLU A : − FLU B : −
Retest	FLU A : *# 03 FLU B : *# 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 influenza virus infection should not be 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 an oropharyngeal swab as a specimen, the detection rate tends to be lower than that of a nasopharyngeal swab, nasal swab or nasal aspirate, so please pay attention to the specimen collection methods.
3) When using a self-blown nasal discharge as a specimen, correct test results may not be obtained unless proper specimen collection is performed. Please pay attention to the specimen collection methods.
4) In the case of Flu A test line or Flu B test line and control line appear at 1 to 5 minutes after dropping the sample, it can be interpreted as Flu A positive or Flu B positive. Negative should be interpreted at 5 minutes after dropping the sample. The streak line might appear before 5 minutes temporarily. After 5 minutes, colloidal gold can appear like a streak line as the appearance of the test line. After 5 minutes, colloidal gold can appear like a line due to the drying of the test plate with time. Therefore, please interpret test results within 5 minutes.
5) This product is used as an aid in the diagnosis of influenza virus infection. In case influenza virus antigens 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 the influenza 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.
6) If test lines appear in both Flu A and Flu B, there is a possibility of dual infections of Flu A and Flu B; 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 5 minutes after the sample is dropped. If measured within 5 minutes, correct results may not be obtained.

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) When using self-blown nasal discharge as a specimen, in some cases the amount of influenza virus antigen in nasal discharge is small, and the detection rate may be lower than that of nasopharyngeal swab and nasal swab specimens.

12) When using self-blown nasal discharge as a specimen, a sufficient amount of nasal discharge may not be collected if the nasal discharge has not been accumulated as a clinical symptom, or the required amount of nasal discharge was not collected on the specimen collection sheet because the nose has been blown immediately before the test for another purpose, etc. In these cases, an insufficient amount of nasal discharge may result in lower detection rate. When collecting the specimen from a specimen collection sheet, make sure that the sponge tip of the swab is completely wet after specimen collection and that a sufficient amount of nasal discharge has been collected on the specimen collection sheet.

[Performance characteristics]

1) Performance

<Quick Chaser Flu A>

1. Sensitivity
   When in-house positive control [note 1)] was tested, a positive result was obtained.
2. Accuracy
   • When in-house negative control [note 2)] was tested, a negative result was obtained.
   • When in-house positive control was tested, a positive result was obtained.
3. Reproducibility
   • When in-house negative control was tested three times simultaneously, negative result was shown in all cases.
   • When in-house positive control was tested three times simultaneously, positive result was shown in all cases.

   Note 1) Influenza A virus antigen solution diluted with in-house negative control sample to be equivalent to 3.5×10^4TCID$_{50}$/test of the calibration reference material.

   Note 2) Extraction reagent solution

   TCID$_{50}$/test: A 10^n serial dilution of the sample is prepared, and the dilution ratio when a 50% cytopathic effect (CPE) on MDCK (Madin Darby Canine Kidney) cells is observed is defined as the virus infectious titer of 10^nTCID$_{50}$/test.
4. Detection limit
   A/Texas/1/77 2.2×10^4TCID$_{50}$/test
5. Reactivity to influenza virus
   Following influenza A virus have been confirmed to be positive by this product.
   (1) Human-derived influenza A virus
   A/Puerto Rico/8/34(H1N1)
   A/New Jersey/8/76(H1N1)
   A/Taiwan/1/86(H1N1)
   A/New Caledonia/20/99(H1N1)
   A/Solomon Islands/03/06(H1N1)
   A/California/04/09(H1N1)
   A/California/07/09(H1N1)
   A/Osaka/68/09(H1N1)pdm
   A/Osaka/114/09(H1N1)pdm
   A/Adachi/1/57(H2N2)
   A/Port Chalmers/1/73(H3N2)
   A/Texas/1/77 (H3N2)
   A/Shangdong/9/93(H3N2)
   A/Panama/2007/99(H3N2)
   A/Hiroshima/52/2005(H3N2)
   A/Viet Nam/1203/2004(H5N1)
   A/Anhui/1/2013(H7N9)
   (2) Animal-derived influenza A virus
   A/Duck/Czech/56(H4N6)
   A/Duck/Hong Kong/820/80(H5N3)
   A/Shearwater/Australia/1/72(H6N5)
   A/Tufted duck/Shimane/124R/80(H7N7)
   A/duck/Mongolia/119/2008(H7N9)
   A/duck/Mongolia/128/2008(H7N9)
   A/duck/Mongolia/147/2008(H7N9)
   A/duck/Mongolia/129/2010(H7N9)
   A/Turkey/Ontario/6118/68(H8N4)
   A/Turkey/Wisconsin/66(H9N2)
   A/Chicken/Germany/N/49(H10N7)
   A/Duck/England/56(H11N6)
   A/Duck/Alberta/60/76(H12N5)
   A/Gull/Maryland/704/77(H13N6)
   A/Mallard/Astrakhan/263/82(H14N5)
   A/Duck/Australia/341/83(H15N8)
6. Cross reactivity
   • Viruses except for Influenza virus (Virus suspension : Approximately 1×10^6TCID$_{50}$/mL)
   Cross reactivity was not observed with Adenovirus, Coxsackie virus, Cytomegalovirus, Echovirus, HSV, Mumps virus, Parainfluenza virus, Respiratory syncytial virus, Rhinovirus.
   • Chlamydia ($11\times10^6-10^7$EB/mL) and Mycoplasma (1×10^5 organisms /mL)
   Cross reactivity was not observed with *Chlamydia pneumonia*, *Chlamydia trachomatis, Mycoplasma pneumoniae*.
   • Bacteria ($1\times10^6-10^7$CFU/mL)
   Cross reactivity was not observed with *Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Listeria monocytogenes, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus sp.* group B, C, G, F.
7. Interfering substances and medications
   Following substances and blood did not interfere with the performance of this product at the concentration listed below.
   ·Cold medicine 1 (Concentration of Acetaminophen: 5mg/mL)
   ·Cold medicine 2 (Concentration of Ibuprofen: 5mg/mL)
   ·Gargle 1 containing Chlorhexidine gluconate (0.25%)
   ·Gargle 2 containing Tincture of Myrrh (0.5%)
   ·Gargle 3 containing Povidone iodine (3.25%)
   ·Intraoral antiphlogistic containing water-soluble azulene (10%)
   ·Cough drop 1 containing Dipotassium Glycyrrhizinate (20mg/mL)
   ·Cough drop 2 containing Nandina Fruit Extract (Dry) (10mg/mL)
   ·Cough drop 3 containing Cetylpyridinium chloride (20mg/mL)
   ·Acetylsalicylic acid (20mg/mL)
   ·Diphenhydramine hydrochloride (5mg/mL)
   ·Dextromethorphan (10mg/mL)
   ·Blood (1%)
   Regarding the sample containing blood (1% or more), collect specimen again because such sample could give influence to the interpretation

<Quick Chaser Flu B>

1. Sensitivity
   When in-house positive control [note 3)] was tested, a positive result was obtained.
2. Accuracy
   • When in-house negative control was tested, a negative result was shown.
   • When in-house positive control was tested, a positive result was shown.
3. Reproducibility
   • When in-house negative control was tested three times simultaneously, negative result was shown in all cases.
   • When in-house positive control was tested three times simultaneously, positive result was shown in all cases.

   Note 3) Influenza B virus antigen solution diluted with in-house negative control sample to be equivalent to 1.7×10^5TCID$_{50}$/test of the calibration reference material.
4. Detection limit
   B/Hong Kong/5/72 1.1×10^5TCID$_{50}$/test
5. Reactivity to influenza virus
   Following influenza B virus have been confirmed to be positive by this product.
   Human-derived influenza B virus
   B/Hong Kong 5/72
   B/Malaysia/2506/2004

B/Brisbane/60/2008
B/Qingdao/102/91
B/Tokio/53/99
B/Victoria/504/00
B/Shandong/7/97
B/Shanghai/361/2002

6. Cross reactivity

• Viruses except for Influenza virus (Virus suspension : Approximately $1\times10^6 TCID_{50}$/mL)

Cross reactivity was not observed with Adenovirus, Coxsackie virus, Cytomegalovirus, Echovirus, HSV, Mumps virus, Parainfluenza virus, Respiratory syncytial virus, Rhinovirus.

• Chlamydia (1×10^6–10^7EB/mL) and Mycoplasma (1×10^5 organisms/mL)

Cross reactivity was not observed with *Chlamydia pneumonia, Chlamydia trachomatis, Mycoplasma pneumoniae*.

• Bacteria (1×10^6 –10^7CFU/mL)

Cross reactivity was not observed with *Escherichia coli, Haemophilus influenza, Klebsiella pneumonia, Listeria monocytogenes, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus pneumonia, Streptococcus pyogenes, Streptococcus sp.* group B, C, G, F.

7. Interfering substances and medications

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

·Cold medicine 1 (Concentration of Acetaminophen: 5mg/mL)
·Cold medicine 2 (Concentration of Ibuprofen: 5mg/mL)
·Gargle 1 containing Chlorhexidine gluconate (0.25%)
·Gargle 2 containing Tincture of Myrrh (0.5%)
·Gargle 3 containing Povidone iodine (3.25%)
·Intraoral antiphlogistic containing water-soluble azulene (10%)
·Cough drop 1 containing Dipotassium Glycyrrhizinate (20mg/mL)
·Cough drop 2 containing Nandina Fruit Extract (Dry) (10mg/mL)
·Cough drop 3 containing Cetylpyridinium chloride (20mg/mL)
·Acetylsalicylic acid (20mg/mL)
·Diphenhydramine hydrochloride (5mg/mL)
·Dextromethorphan (10mg/mL)
·Blood (1%)

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

2) Correlations

1. Comparison with virus culture method

*Comparative evaluation with the isolation and culture of virus conducted under the guidance of the Ministry of Health, Labor and Welfare of Japan during the influenza season from 2004 to 2006.

Specimen type		Sensitivity(%)	Specificity(%)	Accuracy(%)	Number of Specimen
Naso-pharyngeal swabs	Flu A	92.3 (36/39)	90.1 (200/222)	90.4 (236/261)	261
	Flu B	86.4 (70/81)	92.8 (167/180)	90.8 (237/261)	261
Nasal aspirates	Flu A	98.3 (58/59)	93.5 (87/93)	95.4 (145/152)	152
	Flu B	89.1 (49/55)	96.9 (94/97)	94.1 (143/152)	152
Oro-pharyngeal swabs	Flu A	64.3 (9/14)	97.0 (96/99)	92.9 (105/113)	113
	Flu B	71.4 (5/7)	98.1 (104/106)	96.5 (109/113)	113

The facility which performed viral isolation and culture:
Osaka Prefectural Institute of Public Health

2. Comparison with existing approved products
(Immunochromatographic assay)
<Quick Chaser Flu A>

• Nasopharyngeal swab specimen

Quick Chaser Flu A n＝99

Other product A	Positive	Negative	Total
Positive	21	0	21
Negative	0	78	78
Total	21	78	99

Positive agreement rate : 100%(21/21)
Negative agreement rate : 100%(78/78)
Total agreement rate : 100%(99/99)

• Oropharyngeal swab specimen

Quick Chaser Flu A n＝62

Other product A	Positive	Negative	Total
Positive	13	0	13
Negative	2*1	47	49
Total	15	47	62

Positive agreement rate : 100%(13/13)
Negative agreement rate : 95.9%(47/49)
Total agreement rate : 96.8%(60/62)

*1 Both discrepant cases were positive with other kits.

• Nasal aspirate specimen

Quick Chaser Flu A n＝139

Other product A	Positive	Negative	Total
Positive	50	4*1	54
Negative	1*2	84	85
Total	51	88	139

Positive agreement rate : 92.6% (50/54)
Negative agreement rate : 98.8% (84/85)
Total agreement rate : 96.4% (134/139)

*1 Regarding one of four cases where results were positive with other product but negative with Quick Chaser, it was negative with the PCR method and the method of "isolation and culture of virus". Another sample was negative with the method of "isolation and culture of virus", but positive with the PCR method. One of the other two cases was negative with the PCR method. The other case was positive with the PCR method.

*2 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was negative with the PCR method and the method of "isolation and culture of virus"

Quick Chaser Flu A n＝139

Other product B	Positive	Negative	Total
Positive	50	2*1	52
Negative	1*2	86	87
Total	51	88	139

Positive agreement rate : 96.2% (50/52)
Negative agreement rate : 98.9% (86/87)
Total agreement rate : 97.8% (136/139)

*1 Regarding one of two cases where results were positive with other product but negative with Quick Chaser showed, it was negative with the PCR method and the method of "isolation and culture of virus". The test result of the other sample was negative with the method of "isolation and culture of virus", but positive with the PCR method.

*2 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was negative with the PCR method and the method of "isolation and culture of virus"

• Self-blown nasal discharge

Quick Chaser Flu A n＝138

Other product A	Positive	Negative	Total
Positive	55	1*1	56
Negative	0	82	82
Total	55	83	138

Positive agreement rate : 98.2% (55/56)
Negative agreement rate : 100% (82/82)
Total agreement rate : 99.3% (137/138)

*1 Regarding one case where the result was positive with other product but negative with Quick Chaser, it was negative with the PCR method and the method of "isolation and culture of virus".

Quick Chaser Flu A n＝138

Other product C	Positive	Negative	Total
Positive	54	1*1	55
Negative	1*2	82	83
Total	55	83	138

Positive agreement rate : 98.2% (54/55)
Negative agreement rate : 98.8% (82/83)
Total agreement rate : 98.6% (136/138)

*1 Regarding one case where the result was positive with other product but negative with Quick Chaser, it was negative with the method of "isolation and culture of virus" and positive with the PCR method.

*2 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was positive with the PCR method and the method of "isolation and culture of virus".

<Quick Chaser Flu B>

• Nasopharyngeal swab specimen

Quick Chaser Flu B n＝94

Other product A	Positive	Negative	Total
Positive	16	0	16
Negative	0	78	78
Total	16	78	94

Positive agreement rate : 100% (16/16)
Negative agreement rate : 100% (78/78)
Total agreement rate : 100% (94/94)

• Oropharyngeal swab specimen

Quick Chaser Flu B n＝57

Other product A	Positive	Negative	Total
Positive	16	0	16
Negative	0	41	41
Total	16	41	57

Positive agreement rate : 100% (16/16)
Negative agreement rate : 100% (41/41)
Total agreement rate : 100% (57/57)

• Nasal aspirate specimen

Quick Chaser Flu B n＝139

Other product A	Positive	Negative	Total
Positive	51	3*1	54
Negative	0	85	85
Total	51	88	139

Positive agreement rate : 94.4% (51/54)
Negative agreement rate : 100% (85/85)
Total agreement rate : 97.8% (136/139)

*1 Regarding one of three cases where results were positive with other product but negative with Quick Chaser, it was positive with the PCR method and the method of "isolation and culture of virus". Another case was negative with the method of "isolation and culture of virus", but positive with the PCR method. The other case was positive with the PCR method.

Quick Chaser Flu B n＝139

Other product B	Positive	Negative	Total
Positive	50	2*1	52
Negative	1*2	86	87
Total	51	88	139

Positive agreement rate : 96.2% (50/52)
Negative agreement rate : 98.9% (86/87)
Total agreement rate : 97.8% (136/139)

*1 Regarding one of two cases where results were positive with other product but negative with Quick Chaser, it was positive with the PCR method and the method of "isolation and culture of virus". The other case was negative with the method of "isolation and culture of virus", but positive with the PCR method.

*2 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was positive with the PCR method.

• Self-blown nasal Discharge

Quick Chaser Flu B n＝138

Other product A	Positive	Negative	Total
Positive	53	0	53
Negative	1*1	84	85
Total	54	84	138

Positive agreement rate : 100% (53/53)
Negative agreement rate : 98.8% (84/85)
Total agreement rate : 99.3% (137/138)

*1 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was positive with the PCR method and negative with the method of "isolation and culture of virus".

Quick Chaser Flu B n＝138

Other product C	Positive	Negative	Total
Positive	53	0	53
Negative	1*1	84	85
Total	54	84	138

Positive agreement rate : 100% (53/53)
Negative agreement rate : 98.8% (84/85)
Total agreement rate : 99.3% (137/138)

*1 Regarding one case where the result was negative with other product but positive with Quick Chaser, it was positive with the PCR method and negative with the method of "isolation and culture of virus".

3. Clinical results of self-blown nasal discharge

*Comparative evaluation with the isolation and culture of virus conducted in 2008

Specimen type		Sensitivity(%)	Specificity(%)	Accuracy(%)	Number of Specimen
Self-blown Nasal discharge	Flu A	87.9 (29/33)	100 (144/144)	97.7 (173/177)	177
	Flu B	81.6 (31/38)	100 (148/148)	96.2 (179/186)	186

3) Test results for nasal swab solution added with cultured virus strains
Two concentrations of cultured strains A/Wyoming/03/2003 and B/Shanghai/36/2002 near the detection limit were added to the nasal swab solution and measured with Quick Chaser Flu A, B.

Influenza A virus (A/Wyoming/03/2003)

		6.4×10^1 $TCID_{50}$/mL	3.2×10^2 $TCID_{50}$/mL	Negative	Total
QC Flu A, B	Positive	25	25	0	50
	Negative	0	0	25	25
Total		25	25	25	75

Influenza B virus (B/Shanghai/36/2002)

		3.2×10^1 $TCID_{50}$/mL	1.6×10^2 $TCID_{50}$/mL	Negative	Total
QC Flu A, B	Positive	25	25	0	50
	Negative	0	0	25	25
Total		25	25	25	75

4) Calibration reference material (Standard material)
Influenza A virus: A/Texas 1/77(H3N2)
Influenza B virus: B/Hong Kong 5/72

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

Technical information
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