Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Series for immunodiagnostic test
Influenza virus kit

Quick Chaser Flu A,B

[Important and fundamental caution]

1) Diagnosis of influenza virus infection must be evaluated in conjunction with results of other tests and clinical symptoms.
2) When using a pharyngeal swab as specimen, the detection rate tends to be lower than that of a nasopharyngeal swab or nasal aspirate, so please pay attention to the specimen collection methods.
3) If the self-blown nasal discharge is used as specimen, correct test results may not be obtained unless proper specimen collection is performed. Please pay attention to the specimen collection methods.

[General precautions]

1) For in vitro diagnostic use only.
2) Procedures which are not described in instructions for use, are not guaranteed.

[Package]

67530: Quick Chaser Flu A,B - 10 tests/kit
67535: Quick Chaser Flu A,B - 50 tests/kit

[Contents]

1) Test plate - 10 tests (50 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 (50 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 (50 pieces)
4) Rack (for extraction reagent solution vial) - 1 piece (5 pieces)
5) Filter (for extraction reagent solution vial) - 10 pieces (50 pieces)
6) Blue cap (for temporary storage of extraction reagent solution vial) - 10 pieces (50 pieces)
7) Name label for extraction reagent solution vial - 1 sheet (5 sheets)

[Intended use]

<Quick Chaser Flu A>
For detection of influenza A virus antigen in nasopharyngeal swab specimen, nasal aspirate specimen, pharyngeal swab specimen or self-blown nasal discharge
<Quick Chaser Flu B>
For detection of influenza B virus antigen in nasopharyngeal swab specimen, nasal aspirate specimen, pharyngeal swab specimen or self-blown nasal discharge

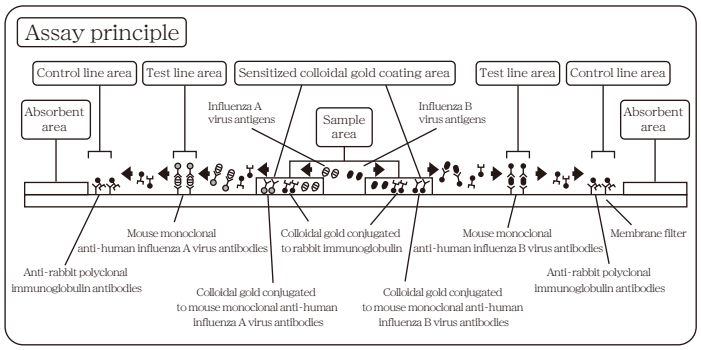
[Principle of the test]

"Quick Chaser Flu A,B" is the in vitro reagent for detection of influenza virus antigen based on Immunochromatographic Assay.

Colloidal gold conjugated to monoclonal anti-human influenza A(B) virus antibodies and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in sensitized colloidal gold coating area in test plate. And mouse monoclonal anti-human influenza A(B) virus antibodies are immobilized in test line area. Anti-rabbit polyclonal immunoglobulin antibodies are immobilized in control line area.

According to immunochromatographic principle, when sample is added to the sample area, in the presence of influenza A(B) virus antigen, they migrate to the area between sample area and test line area, where reacting with colloidal gold conjugated to mouse monoclonal anti-human influenza A(B) virus antibodies and moreover, react with mouse monoclonal anti-human influenza A(B) virus antibodies and they are caught in test line area.

As the result, purple-red lines are visible. Moreover, purple-red lines are also simultaneously visible for catching colloidal gold conjugated to rabbit immunoglobulin by anti-rabbit immunoglobulin in control line area, regardless of presence of influenza A(B) virus antigen.



[Procedural precautions]

1) Collected specimen should be prepared as sample in accordance with after-mentioned **"Preparation of sample in Test procedure"** and tested as soon as possible.
2) Add fixed volume (4 drops) to the center of sample area from tip of filter about 10mm away from the sample area so as to make droplets. In case of adding other than fixed volume, an accurate reaction may not be performed.
3) Bring test plate and extraction reagent solution to 15~30℃ prior to testing.
4) Interferring substances and medications
   Following substances and blood did not interfere the performace 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 Povidoneiodine (3.25%)
   ・Intraoral antiphlogistics 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 including blood (1% or more), collect specimen again because such sample could give influence to the interpretation.

[Test procedure]

●Specimen collection

1) Preparation of specimen collection

① Swab :

・Use swab, included in this test kit when using nasopharyngeal swab, nasal aspirate or self-blown nasal discharge as a specimen.

・When using pharyngeal swab specimen, use swab (for pharyngeal specimen) sold separately.

② Prepare following item when using 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)

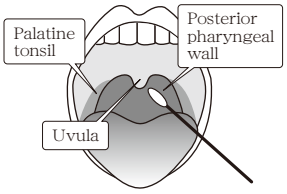
③ Extraction reagent solution: Use it without preparation.

2) Specimen collection

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

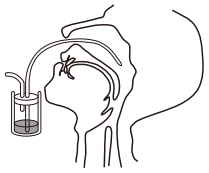
Note) Elastic plastic rod is employed in swab to reduce the burden of patients. However, on the other hand, the tip of swab may not be reached to inflamed region on the wall of nasal cavity or you may not be able to rub the tip on the wall of nasal cavity adequately to collect enough volume of virus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

② Pharyngeal swab specimen:
Collect mucous epidermis by rubbing several times reddened area of the posterior pharyngeal wall, uvula or palatine tonsil by swab.



Collect mucous epidermis from reddened area

③ Nasal aspirate specimen :
Dip spherical tip into low-viscosity liquid part of nasal aspirate specimen in trap.
If it is difficult to collect specimen due to high viscosity or low volume of specimen, add 0.5～1mL of saline, and use suspension for the test.

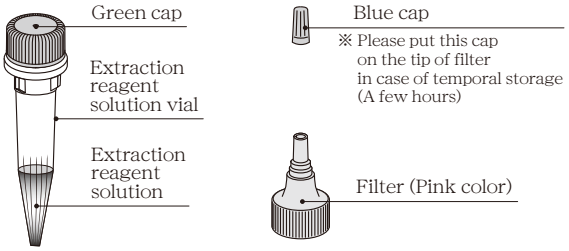


※Be reminded that sensitivity are decreased by dilution of specimen with saline.

④ 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 own 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 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.

●Details of Extraction reagent solution vial



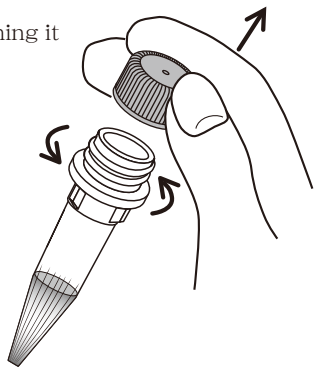
●Reagent preparation

Relationships of applicable specimen and mutual use of sample with another Quick Chaser product are as follows:

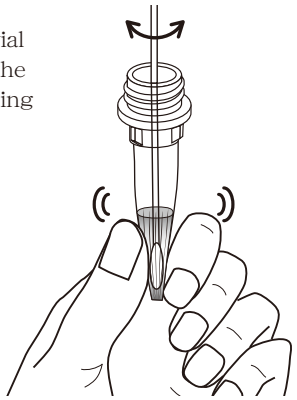
Specimen	Adeno	Flu A,B
Nasopharyngeal swab specimen	○ ⟷	○
Nasal aspirate specimen	○ ⟷	○
Self-blown nasal discharge	×	○
Pharyngeal swab specimen	○ ⟷	○

Applicable specimen : ○
Availability of mutual use of sample : ⟷
Note) Do not use sample mutually except the above combination.

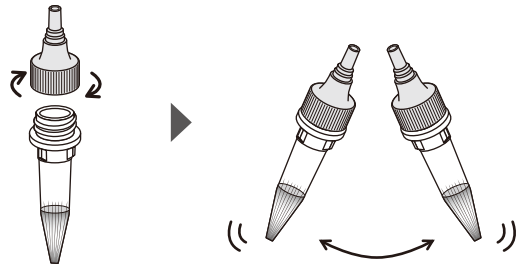
① Loosen green cap with turning it counterclockwise.



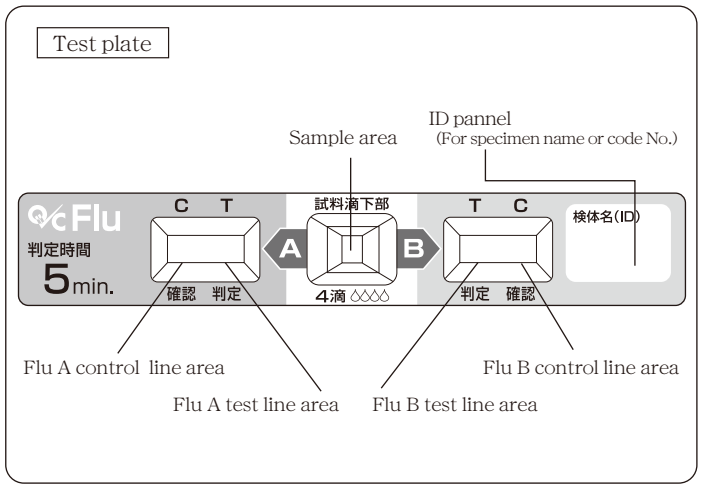
② Insert the spherical tip with specimen into the bottom of extraction reagent solution vial and press spherical tip from the outside of the vial for extracting specimen and turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and bottom of the vial.
Take swab out of the vial with squeezing out liquid from the spherical tip, pressing spherical tip.



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



●Details of test plate



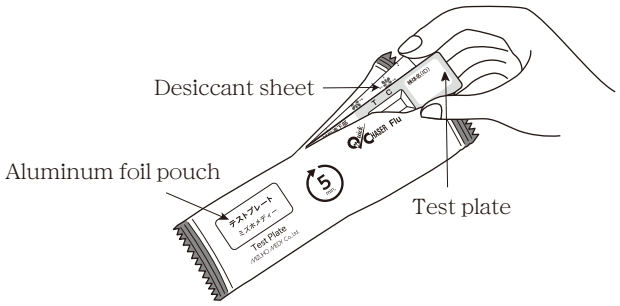
●Test procedure

1) Preparation of reagent

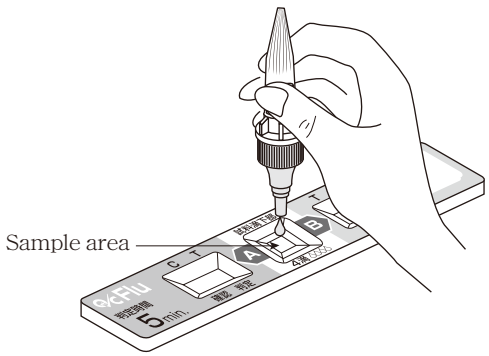
Test plate: No prior preparation required

2) Test procedure

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

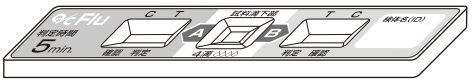


② Add 4 drops (about 150 μL) of sample vertically to the sample area of test plate from extraction reagent solution vial including prepared sample with avoiding contact of tip of extraction filter with sample area.



③ Leave to react at 15℃～ 30℃.

Interpret test results visually by lines in test line area and control line area after 1 ～ 5 minutes.



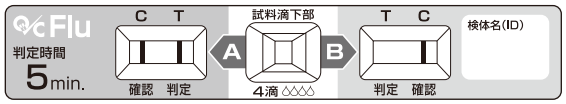
[Interpretation]

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

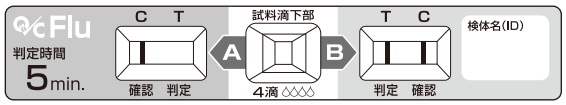
《Positive》

Both test line and control line appear.

Flu A Positive



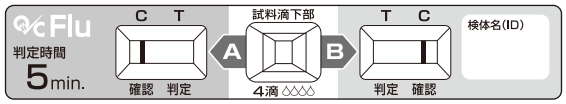
Flu B Positive



《Negative》

Only control line appear.

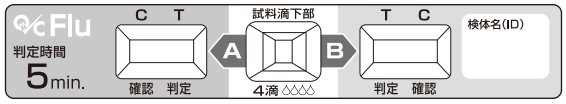
Negative



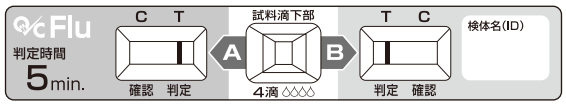
《Retest》

If both test line and control line do not appear or no control line appear for either or both of Flu A and B, sample volume may not be enough. Recheck test procedure and retest with new test plate. If the same result come out in the retest again, confirm it with other method.

Retest



Retest



●Interpretational precautions

1) In case Flu A test line or Flu B test line and control line appear at 1 ～ 5 minutes after dropping sample, it can be interpreted as Flu A positive or Flu B positive. Negative should be interpreted at 5 minutes after dropping sample. Streak line might appear before 5 minutes temporarily. Do not interpret the temporal streak line as appearance of test line. After 5 minutes, colloidal gold can appear like line due to drying of test plate with time. Therefore, please interpret test results within 5 minutes.

2) This product is used as aid in the diagnosis for infection of influenza virus. In case influenza virus antigens load in specimen are below the detection sensitivity of the test or specimen collection are not enough, test result could be interpreted as negative, even though patients are infected by influenza virus. Moreover, factors in specimen could cause non-specific reaction and negative specimen could be interpreted as positive. It is recommended that the diagnosis of influenza virus be made properly by qualified personnel in conjunction with the assessment of clinical progress and results of other tests for confirmation.

3) In case both test lines (A type and B type) appear, it could be a possibility of dual infection. Collect specimen again and retest it with new test plate just in case. It is recommended that the diagnosis should be made in conjunction with the assessment of clinical progress and results of other tests etc.

[Performance characteristics]

1) Performance

＜Quick Chaser Flu A＞

① Sensitivity

When In-house positive control (3.5×10^4TCID$_{50}$/test) was tested, a positive result was obtained.

TCID$_{50}$ / test: Ten fold serial dilutions of virus culture (10^n) were added to MDCK cell and incubated at 34 ℃ for 5 days. The quantity of influenza virus that produced a cytopathic effect (CPE) in 50% of the cultures inoculated is expressed as 10^nTCID$_{50}$/mL. TCID$_{50}$ value was calculated by the method of Reed and Muench. The calculation result was converted to 0.1ml per test as 3.5×10^8TCID$_{50}$/test.

② Accuracy

・When In-house negative control 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 controls were tested three times simultaneously, negative results were obtained in all cases.

・When In-house positive controls were tested three times simultaneously, positive results were obtained in all cases.

④ Detectability

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 Influenza virus (Virus suspension : Approximately 1×10^6TCID$_{50}$/mL)
Cross reactivity were 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 were not observed with *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*.

・Bacteria (1×10^6～10^7CFU/mL)
Cross reactivity were 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*.

＜Quick Chaser Flu B＞

① Sensitivity

When In-house positive control (1.7×10^5TCID$_{50}$/test) was tested, a positive result was shown.

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 controls were tested three times simultaneously, negative results were shown in all cases.

・When In-house positive controls were tested three times simultaneously, positive results were shown in all cases.

④ Detectability

1.1 x 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 Influenza virus(Virus suspension : Approximately 1×10^6TCID$_{50}$/mL)
Cross reactivity were 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 (1×10^5organisms/mL)
Cross reactivity were not observed with *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*.

・Bacteria (1×10^6～10^7CFU/mL)
Cross reactivity were 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*.

2) Correlations

① Comparison with virus culture

※Evaluation compared to virus culture combined 2004-2006 Influenza seasons.

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

Facility which performed viral isolation and cuture:
Osaka Prefectual Institute of Public Health

② Comparison with existing approved products (Immunochromatographic Assay)

＜Quick Chaser Flu A＞

●Nasopharyngeal swab specimen n=99

Quick Chaser Flu A

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

Sensitivity : 100%(21/21)
Specificity : 100%(78/78)
Accuracy : 100%(99/99)

●Pharyngeal swab specimen n=62

Quick Chaser Flu A

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

Sensitivity : 100%(13/13)
Specificity : 95.9%(47/49)
Accuracy : 96.8%(60/62)

※1 All two discrepant cases were positive with other kits.

●Nasal aspirate specimen n=139

Quick Chaser Flu A

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

Sensitivity : 92.6%(50/54)
Specificity : 98.8%(84/85)
Accuracy : 96.4%(134/139)

※1 Regarding one sample out of four samples other product showed positive and Quick Chaser showed negative, the test result was negative by PCR method, and the method of " isolation and culture of virus". Another one sample was negative by the method of " isolation and culture of virus, but positive by PCR method. One of the other two samples was negative by PCR method. The other sample was positive by PCR method.

※2 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was negative by PCR method and by the method of " isolation and culture of virus"

Quick Chaser Flu A

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

Sensitivity : 96.2%(50/52)
Specificity : 98.9%(86/87)
Accuracy : 97.8%(136/139)

※1 Regarding one sample out of two samples other product showed positive and Quick Chaser showed negative, the test result was negative by PCR method and by the method of " isolation and culture of virus ". The test result of the other sample was negative by the method of " isolation and culture of virus ", but positive by PCR method.

※2 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was negative by PCR method and by the method of " isolation and culture of virus"

●Self-blown nasal discharge n=138

Quick Chaser Flu A

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

Sensitivity : 98.2%(55/56)
Specificity : 100%(82/82)
Accuracy : 99.3%(137/138)

※1 Regarding one sample which was interpreted as positive by other product, but negative by Quick Chaser, the test result was negative by PCR method and by the method of "isolation and culture of virus".

Quick Chaser Flu A

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

Sensitivity : 98.2%(54/55)
Specificity : 98.8%(82/83)
Accuracy : 98.6%(136/138)

※1 Regarding one sample which was interpreted as positive by other product, but negative by Quick Chaser, the test result was negative by the method of "isolation and culture of virus" and positive by PCR method.

※2 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was positive by PCR method and by the method of "isolation and culture of virus".

＜Quick Chaser Flu B＞

●Nasopharyngeal swab specimen n=94

Quick Chaser Flu B

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

Sensitivity : 100%(16/16)
Specificity : 100%(78/78)
Accuracy : 100%(94/94)

●Pharyngeal swab specimen n=57

Quick Chaser Flu B

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

Sensitivity : 100%(16/16)
Specificity : 100%(41/41)
Accuracy : 100%(57/57)

●Nasal aspirate specimen n=139

Quick Chaser Flu B

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

Sensitivity : 94.4%(51/54)
Specificity : 100%(85/85)
Accuracy : 97.8%(136/139)

※1 Regarding one sample out of three samples other product showed positive and Quick Chaser showed negative, the test result was positive by PCR method and the method of " isolation and culture of virus ". The test result of another sample was negative by the method of " isolation and culture of virus ", but positive by PCR method. The test result of the other sample was positive by PCR method.

Quick Chaser Flu B

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

Sensitivity : 96.2%(50/52)
Specificity : 98.9%(86/87)
Accuracy : 97.8%(136/139)

※1 Regarding one sample out of two samples other product showed positive and Quick Chaser showed negative, the test result was positive by PCR method and the method of " isolation and culture of virus ". The test result of the other sample was negative by the method of " isolation and culture of virus ", but positive by PCR method.

※2 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was positive by PCR method.

●Self-blown nasal discharge n=138

Quick Chaser Flu B

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

Sensitivity : 100%(53/53)
Specificity : 98.8%(84/85)
Accuracy : 99.3%(137/138)

※1 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was positive by PCR method and negative by the method of "isolation and culture of virus".

Quick Chaser Flu B

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

Sensitivity : 100%(53/53)
Specificity : 98.8%(84/85)
Accuracy : 99.3%(137/138)

※1 Regarding one sample which was interpreted as negative by other product, but positive by Quick Chaser, the test result was positive by PCR method and negative by 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	A type	87.9(29/33)	100(144/144)	97.7(173/177)	177
	B type	81.6(31/38)	100(148/148)	96.2(179/186)	186

3) Calibration reference material (Standard material)

Influenza A virus : A/Texas 1/77(H3N2)

Influenza B virus : B/Hong Kong 5/72

[Precautions for use and handling]

1) Precautions for handling (Prevention of danger)

① HIV, HBV, and HCV could be included in specimen. Be careful of handling specimen as potentially infectious material.

② Be careful not to touch sample (specimen) or extraction reagent solution directly to skin or not to get them into eyes, wearing glasses, disposable glove or mask at the time of use.

③ Do not use swab to collect specimen, if it is already put into extraction reagent solution.

④ If specimen and / or extraction reagent solution are got into eyes or mouth, flush with a plenty of water as emergency treatment and see a doctor, if necessary.

⑤ Do not use blue cap which belong to kit for transporation or preservation because it does not have seal stregnth.

⑥ Perform the collection of specimen under the guidance of the qualified person.

⑦ Raw material of membrane which is used for test plate, is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.

⑧ When collecting the self-blown nasal discharge by swab, infectious splash may diffuse upon spreading the specimen collection sheet which patient used. Please take sufficient measures to prevent infection. Also, be careful when a patient blows their nose as the virus may be scatter around by the aerosol.

⑨ When collecting or handling the self-blown nasal discharge, use masks or gloves to prevent infection. If nasal discharge is scattered or spilled, wipe off thoroughly and clean with disinfectant solution etc.

⑩ Regarding aspiration tube with trap for nasal aspirate specimen and specimen collection sheet for self-blown nasal discharge, use unused and contamination-free one per test not to cause contamination for preventing infection spread and maintaining accuracy of test.

⑪ Wipe off with alcohol for disinfection in case of getting splattered with sample (specimen).

2) Precautions for use

① Do not freeze this product. Store it in accordance with description of instructions for use. Do not use frozen reagents because they could show false results by change of quality.

② Do not use this product beyond expiration date.

③ Do not store extraction reagent solution vial with laying down or inverting.

④ To prevent moisture, do not open the foil pouch until you are ready to perform test.

⑤ Do not touch sample area, test line area and control line area by hands directly.

⑥ Do not perform test in the place such as under air conditioner where the dry wind directly blows the surface of test plate, to prevent uneven migration.

⑦ Do not use reagent, accessaries etc. of the product except the purpose of this product.

⑧ Test plate, swab, and extraction reagent solution vial (Filter, green cap and blue cap are included) are intended for single use only.

⑨ Use swab included in this product, or use swabs for pharyngeal specimen sold separately.

⑩ Store swab avoiding direct sunlight, high temperature and humidity with being careful about the water wets.

⑪ Do not touch spherical tip before use.

⑫ Do not press the spherical tip (sponge) or rod (handle) of swab from the outside of the pouch at the time of taking out swab from the packaging bag because the spherical tip could come off by the pressing load.

⑬ Use swab immediately after opening the pouch.

⑭ If break and /or hole are found on the packaging bag of swab, do not use it.

⑮ If swab is stained, broken or bent, do not use it.

⑯ Do not bend the rod of swab before collecting specimen.

⑰ Be careful not to break the rod of swab and injure region to be collected (mucous epidermis) by pushing too hard at the time of collecting specimen.

⑱ Elastic plastic rod is employed in swab to reduce the burden of patients. However, on the other hand, the tip of swab may not be reached to inflamed region on the wall of nasal cavity or you may not be able to rub the tip on the wall of nasal cavity adequately to collect enough volume of virus antigens, even though the tip of swab is reached to inflamed region on the wall of nasal cavity. Therefore, make sure the tip of swab is reached to the wall of nasal cavity so as to rub the inflamed region at the time of collecting mucous epidermis.

⑲ Be careful not to splatter the sample at the time of taking the swab out of vial after preparing sample.

⑳ In case collection volume of specimen is excess, or high-viscosity, membrane filter could be clogged and adequate sample volume could not be dropped. In such cases, collect specimen again and retest it with new test plate.

㉑ 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 in nasopharyngeal swabs.

㉒ When using self-blown nasal discharge as a specimen, sufficient amount of nasal discharge my not be collected if nasal discharge was not accumulated as a clinical symptom, or the required amount of nasal discharge was not collected on the specimen collection sheet because the patient blew their nose immediately before the test for other purpose etc. In these cases, insufficient amount of nasal discharge may result in lower detection rate. When collecting specimen from a specimen collection sheet, make sure that the sponge tip of the swab after specimen collection is completely wet and that a sufficient amount of nasal discharge has been collected on the specimen collection sheet.

3) Precautions for waste disposal

① Treat liquid waste and used utensils by any one of following methods because sample (specimen) could contain infectious material such as HIV, HBV, and HCV etc.

a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1000ppm) for more than 1 hour.

b) Immerse in 2% glutaraldehyde solution for more than 1 hour.

c) Autoclave at 121℃ for more than 20 minutes.

② Regarding disposal of reagents and utensils etc. , dispose of them as medical waste, industrial waste or infectious waste in accordance with your waste disposal laws and regulations.

[Storage・Expiry]

・Storage: 1～30℃

・Expiry: 24 months (As indicated on package)

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

Manufacturer: **Mizuho Medy Co.,Ltd.**
5-4 Fujinoki-machi, Tosu City, Saga, 841-0048 Japan
https://www.mizuho-m.co.jp/en