ichroma™ Influenza A+B

INTENDED USE

ichroma™ Influenza A+B is the in vitro diagnostic device for the qualitative determination on influenza infection to detect influenza A and influenza B viral antigen in nasopharyngeal swab and nasal aspirate specimens taken from symptomatic patients.

For *in vitro* diagnostic use only.

INTRODUCTION

The Influenza virus, a single-stranded RNA virus, belongs to the family orthomyxoviridae and is known as 'seasonal influenza', due to the fact that in temperate climate it tends to occur in the winter months.

Influenza, or flu, known as 'febrile respiratory illness' can cause mild to severe symptoms, such as a high fever, chills, headache, muscle pains coughing and even death. These illness typically begins after exposure to the influenza virus in the respiratory epithelial cell from person-to- person through sneezing, coughing, or touching contaminated surfaces.

Within 48 hours after the onset of symptoms, the patient is strongly recommended to visit the nearest medical facility for the diagnosis of Influenza A or B and to take the antiviral medication.

The preventive measure is highly required for those at increased risk for severe illness, so that early and differential diagnosis between influenza types A or B is very essential.

This product is for in vitro diagnostic medical devices with which the infection of influenza A or B viruses can be determined within 10 minutes, much quicker and easier than the conventional diagnostic methods like PCR or viral culture which takes more than 24 to 48 hours for diagnosis.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in conjugate pad binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by ichroma™ II to show result as 'Positive'/'Negative'.

COMPONENTS

ichroma™ Influenza A+B consists of 'Cartridges', 'Extraction Tubes', 'Tube Caps', 'Swabs', 'Control (Influenza A Positive Control Swab, Influenza B Positive Control swab, Influenza Negative Control Swab)', 'Tube Holders' and 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human influenza A/B, while chicken IgY at the control line.
- The test strip contains anti influenza A/B-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges and 25 extraction tubes are packed in a box which also contains sealed tube caps, controls and ID chip.
- The extraction buffer contains sodium chloride, sodium azide in Tris-HCl buffer as a preservative.
- The extraction buffer is pre-dispensed in a tube.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Do not reuse cartridge or extraction buffer.
- After mixing samples with extracts, use it immediately.
- Do not use the extract buffer of other products.
- Avoid the mixed use of other products.
- In the case of different lot numbers (cartridge, extract buffer, controls or ID chip), it may get a different result. The lot number should be checked prior to test.
- Do not use the test kit if the pouch is damaged or not sealed
- Do not release the cartridge from pouch, too early before test.
- Do not eat the desiccant which is kept in a pouch.
- Do not use the test components after the expiration date. The use after expiration date may yield misleading test result.
- Do not use the contaminated extraction buffer, otherwise it might yield misleading result.
- Do not eat the extraction buffer. Any extraction buffer intake could cause diarrhea or vomiting.
- The extraction buffer contains NaN_3 as preservatives, of which the contact to eyes, skin or clothing should be avoided. If it happens, please wash with running water immediately.
- Please apply the exact drops for accurate test result. Or it may cause erroneous results.
- If the test result is "Negative" even though the patient has significant infectious symptoms, it should be recommended to conduct additional test including PCR or culture test.
- The accurate determination of test result as "Positive" should be confirmed by additional clinical evaluation.
- "Negative" result should be considered with possibilities of other infections. Positive result should be considered with additional infections by other pathogenic bacterium.
- The test should be used away from magnetic fields and vibrations. The intensive and instantaneous electromagnetic waves may interfere with the normal operation.
- Used extraction buffer tubes, tube caps, tube holders, swabs and cartridges should be handled carefully and discarded by an appropriate measure in accordance with the relevant local regulations.
- An exposure to larger quantities of sodium azide may cause specific health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ Influenza A+B** will provide accurate and reliable results, when it is used only in conjunction with ichroma™ II.

WARNINGS AND PRECAUTIONS FOR SAMPLE

- Carefully follow the instructions and procedures described in this Instruction for use.
- Use the fresh samples.
- It is possible to use frozen samples, only on the condition described in "SAMPLE COLLECTION AND PROCESSING".
- It is recommended to test the sample immediately after sample collection.
- Refrain from smoking or eating, while sample is collected.
- Do not collect samples outside of the nasopharynx. In any cases, pre-education for user is required for the proper sample collection.
- Please use fresh swab to avoid the cross-reactivity between samples. Never reuse the sterile swab.
- The improper samples such as those from an individual who has recently taken any interfering medicine or samples mistakenly mixed up with different patients shall cause inaccurate test results.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the relevant local regulations.

STORAGE AND STABILITY

- The cartridge is stable for 18 months (while sealed in an aluminum foil pouch) if stored at 1-30 °C.
- The extraction buffer dispensed in a tube is stable for 18 months if stored at 1-30 °C.
- The controls (influenza A/B positive control, influenza negative control) dispensed in a swab are stable for 18 months if stored at 1-30 °C.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF CFPC-61

Components of **ichroma™ Influenza A+B**

- Cartridge Box:
  - Cartridges 25
  - Extraction Tube Set 25
  - Swabs 25
  - Controls
    - Influenza A Positive Control Swab 1
    - Influenza B Positive Control Swab 1
    - Influenza Negative Control Swab 1
  - Tube Holder 3
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

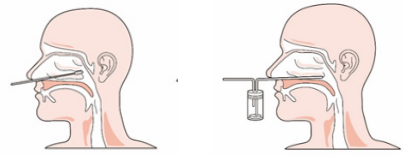
Following items can be purchased separately from **ichroma™ Influenza A+B.** Please contact our sales division for more information.

- **ichroma™ II** REF FPRR021

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Influenza A+B** is human nasopharyngeal swab and nasal aspirate specimens

- Sample Collection
  - Nasopharyngeal swab specimens
    To collect samples, insert a sterile rayon swab in the nasal cavity and smoothly spin it in the nasopharynx.
  - Nasal aspirate specimens
    To use suction catheter, insert pipe in the nasopharynx. Operate suction machine and collect sample. Collected samples should be used with a sterile rayon swab for this test.



< Nasopharyngeal swab> <Nasal aspirate>

- It is recommended to test the sample immediately after collection. If not using the sample immediately, it should be stored at 2-8 °C or -70 °C.
- Samples can be stored for 3 days at 2-8 °C and may not show any performance difference.
- Samples stored frozen at -70 °C up to a year might not show any performance difference.
- Once the sample was frozen, it should be thawed only once and only for test, because repeated freezing-and-thawing can cause erroneous results.

TEST SETUP

- Check the contents of **ichroma™ Influenza A+B**: Sealed test cartridge, Extraction Tube set, Swab, Controls and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID Chip.
- Keep the sealed cartridge and the detection buffer tube at room temperature for at least 30 minutes prior to the test (if it was stored in refrigerator). Place the test cartridge on a clean, dust-free and flat surface.
- Avoid directly windy place. The air flow can affect the flow of samples along the test strips.
- Insert the ID Chip into the ID chip port of the ichroma™ II**.**
- Turn on the ichroma™ II.
  (Please refer to the ichroma™ II operation manual for the concrete information and instructions).

TEST PROCEDURE

*** Caution**

- Before performing the test, keep all clinical samples and components of ichroma™ Influenza A+B test at room temperature.
- If the color of extraction buffer is changed, do not use it.
- Be careful not to spatter with sample, when inserting cartridge.
- The sample-loaded cartridge must be used immediately or within reaction time.
- Do not touch sample well and test window of the cartridge.
- Please load sample mixture in a sample well on the cartridge. Do not load sample mixture in a test window.
- Before use, verify the expiration date.

① Open the extraction buffer tube.

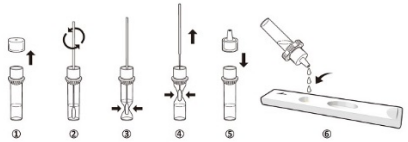
② Collect samples with a sterile swab and then put it into the extraction tube (Spin 5 times) squeeze the sterile swab to extract the sample into the buffer).

③ Squeeze the bottom to extract the sample into the buffer and start pushing the swab to the top

④ Continue squeezing and pushing the swab to the top of extraction tube to pull it out of tube

⑤ Assemble a nozzle to the top of extraction tube.

⑥ Load three drops of sample mixture onto the sample well on a cartridge.
(When using swab sample by transport media, mix extracted samples in transport media with extraction buffer in the same volume. Then load only three drops onto the sample well on a cartridge.)



- For scanning, refer to following step. Please refer to the ichroma™ II operation manual for concrete information.

▶ Single mode

- Insert the sample-loaded cartridge into the ichroma™ II and tap “Start” button. After 10 -minutes of incubation, the ichroma™ II will scan the sample-loaded cartridge and display the test result in the LCD display.

▶ Multi mode

- This test mode is used when you test several tests at a time. Load several sample-loaded cartridges by turns at room temperature. After 10-minutes of incubations, then insert each cartridge in turn into the ichroma™ II, where the test result immediately get scanned and displayed on its LCD display.

INTERPRETATION OF TEST RESULT

- ichroma™ II calculates the test result automatically and displays Positive/Negative.
- If test result is Invalid, you need to perform a new test on a new test cartridge with a new test sample.

Display	Judgment
Flu A: Positive	Influenza A positive (Contain influenza A antigen)
Flu B: Positive	Influenza B positive (Contain influenza A antigen)
Flu A: Negative	Influenza A negative
Flu B: Negative	Influenza B negative
Invalid	Result invalid. Need to retest.

QUALITY CONTROL

- The Quality control tests should be used to confirm the reliability and the validity of ichroma™ Influenza A+B
- The positive/negative controls are provided with the product for quality control.
- Quality control tests should be performed both to verify proper operation of instrument and to exclude any possible performance change in storage.
- For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity**
- **Cut-off**

The cut-off value is 0.68 RFU (Relative Fluorescence Unit) as COI (Cut off index) that is obtained from algorithm of the instrument.

<Influenza A+B judgment standard (positive/negative)>

COI (Cut off index)	Judgment
< 0.68 RFU	Negative (-)
≥ 0.68 RFU	Positive (+)

- **Limit of detection (LoD)**

The Limit of detection (LoD) was evaluated regarding 30 differentiates human isolates viruses.

Virus type	Strain	LoD
Influenza A (H1N1) pdm	A/California/07/2009	1.6 X 10^3 pfu/ml
Influenza A (H1N1)	A/Puerto Rico/07/34	3.5 X 10^4 pfu/ml
Influenza A (H1N1)	A/Solomon island/03/06	4.55 X 10^5 pfu/ml
Influenza A (H1N1)	A/Brisbane/59/2007	1.75 X 10^4 pfu/ml
Influenza A (H1N1)	A/Korea/2785/2009	9.5 X 10^3 pfu/ml
Influenza A (H1N1)	A/Yamagata/32/89	3 $TCID_{50}$/ml
Influenza A (H1N1)	A/Beijing/262/95	3.75 $TCID_{50}$/ml
Influenza A (H1N1)	A/New Caledonia/20/99	3 $TCID_{50}$/ml
Influenza A (H1N1) pdm	A/Osaka/2/14	2.75 $TCID_{50}$/ml
Influenza A (H1N1) pdm	A/Osaka/12/14	1.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/Hong Kong/06/1968	5.7 X 10^3pfu/ml
Influenza A (H3N2)	A/Perth/16/2009	5.7 X 10^3pfu/ml
Influenza A (H3N2)	A/Brisbane/10/2007	3.7 X 10^3pfu/ml
Influenza A (H3N2)	A/Shang dong/09/1995	2.85 X 10^3pfu/ml
Influenza A (H3N2)	A/Beijing/352/89	0.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/Wuhan/359/95	1.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/Sydney/5/97	2.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/Panama/2007/99	2 $TCID_{50}$/ml
Influenza A (H3N2)	A/Wyoming/3/03	0.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/New York/55/04	0.5 $TCID_{50}$/ml
Influenza A (H3N2)	A/Osaka/56/04	1.25 $TCID_{50}$/ml
Influenza A (H3N2)	A/Kitayushu/159/93	1.75 $TCID_{50}$/ml
Influenza B	B/Shang dong/7/97	2.5 $TCID_{50}$/ml
Influenza B	B/Shanghai/361/02	4.5 $TCID_{50}$/ml
Influenza B	B/Osaka/8/15	2.5 $TCID_{50}$/ml
Influenza B	B/Osaka/9/15	2.75 $TCID_{50}$/ml
Influenza B	B/Osaka/10/15	0.5 $TCID_{50}$/ml
Influenza B	B/Brisbane/60/2008	2.8 X 10^5 pfu/ml
Influenza B	B/Wisconsin/01/2010	6.55 X 10^4 pfu/ml
Influenza B	B/Lee/40	2.52 X 10^4 pfu/ml

- **Analytical Specificity**
- **Cross reactivity**

There is no significant cross-reactivity on 13 various other viruses and 36 various bacteria.

Virus			
#1	Coxakie virus B1 - conn5	#8	RSV B - WV/14617/82(VR-1400)
#2	Coxakie virus B3 - nancy(5A1)	#9	Adenovirus-type 5
#3	Polio virus - sabin(3A4)	#10	Rhinovirus -RV71
#4	Corona virus - FCV(3A2)	#11	Rhinovirus -RV14
#5	Corona virus - FIP(2A4)	#12	Rhinovirus - RV21
#6	HSV-1 - F(3A20)	#13	HCMV-AD-169
#7	HSV-2 - MS(4A6)		
Bacteria			
#1	Candida albicans	#19	Neisseria gonorrhoeae
#2	Candida glabrata	#20	Neisseria meningitidis
#3	Candida tropicalis	#21	Neisseiria sicca
#4	Citrobacter freundii	#22	Proteus mirabilis
#5	Corynebacterium sp.	#23	Proteus vulgaris
#6	Corynebacterium diphtheriae	#24	Pseudomonas aeruginosa
#7	Enterococcus faecalis	#25	Serratia marcescens
#8	Enterococcus gallinarum	#26	Staphylococcus aureus
#9	Escherichia coli	#27	Staphylococcus epidermidis
#10	Hemophilus influenzae	#28	Stenotrophomonas maltophilia
#11	Hemophilus parainfluenzae	#29	Streptococcus sp.(Grourp D)
#12	Klebsiella oxytoca	#30	Streptococcus agalactiae (Group B)
#13	Klebsiella pneumoniae	#31	Streptococcus anginosus (Group F)
#14	Lactobacillus sp.	#32	Streptococcus dysgalactiae (Group C)
#15	Legionella spp	#33	Streptococcus dysgalactiae (Group G)
#16	Listeria monocytogenes	#34	Streptococcus mutans
#17	Moraxella catarrhalis	#35	Streptococcus pneumoniae
#18	Mycobacterium tuberculosis	#36	Streptococcus pyogenes

- **Interference**

There is no significant interference effect on from these substances.

Interference material		Concentration
#1	Nasal sprays drops	20 %
#2	Nasal corticosteroids	20 %
#3	Homeopathic allergy relief medicine	5 mg/ml
#4	Throat lozenges, oral anesthetic & analgesic	5 mg/ml
#5	Antiviral drugs Tamiflu	5 mg/ml
#6	Antibiotic, nasal ointment	5 mg/ml
#7	Whole blood	1 %
#8	Acetaminophen	10 mg/ml
#9	Ibuprofen	10 mg/ml
#10	Povidone-iodine	1 %
#11	Acetylsalicylic acid	20 mg/ml
#12	Antibacterial	5 mg/ml
#13	Mucin	0.50 %
#14	Throat lozenge (VICKS, cetylpyridinium chloride)	20 mg/ml
#15	Throat lozenge (dipotassium glycyrrhizinate)	20 mg/ml
#16	Throat lozenge (dipotassium glycyrrhizinate)	20 g/ml

- **Precision**
  The precision performance of **ichroma™ Influenza A+B** was examined regarding to lot, site, person and days.

- **Day to day (between days)**

Between -days	Standard material		Judgment/Nr.	Detection rate(%)
1 day	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
2 day	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
3 day	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)

- **Person to person**

Between-person	Standard material		Judgment/Nr.	Detection rate
Person 1	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Person 2	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Person 3	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Person 4	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Person 5	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Person 6	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)

- **Lot to lot**

Between-Lot	Standard material		Jugdment/Nr	Detection rate
Lot 1	Negative	Cal.1	10/10	100 %
	A-High	Cal.2	10/10	100 %
	A-Middle	Cal.3	10/10	100 %
	A-Low	Cal.4	10/10	100 %
	B-High	Cal.5	10/10	100 %
	B-Middle	Cal.6	10/10	100 %

	B-Low	Cal.7	10/10	100 %
	A-High	Cal.8	10/10	100 %
	A-Middle	Cal.9	10/10	100 %
	A-Low	Cal.10	10/10	100 %
	B-High	Cal.11	10/10	100 %
	B-Middle	Cal.12	10/10	100 %
	B-Low	Cal.13	10/10	100 %
	Total		130/130	100 % (95 % CI: 95 %-100 %)
Lot 2	Negative	Cal.1	10/10	100 %
	A-High	Cal.2	10/10	100 %
	A-Middle	Cal.3	10/10	100 %
	A-Low	Cal.4	10/10	100 %
	B-High	Cal.5	10/10	100 %
	B-Middle	Cal.6	10/10	100 %
	B-Low	Cal.7	10/10	100 %
	A-High	Cal.8	10/10	100 %
	A-Middle	Cal.9	10/10	100 %
	A-Low	Cal.10	10/10	100 %
	B-High	Cal.11	10/10	100 %
	B-Middle	Cal.12	10/10	100 %
	B-Low	Cal.13	10/10	100 %
	Total		130/130	100 % (95 % CI: 95 %-100 %)
Lot 3	Negative	Cal.1	10/10	100 %
	A-High	Cal.2	10/10	100 %
	A-Middle	Cal.3	10/10	100 %
	A-Low	Cal.4	10/10	100 %
	B-High	Cal.5	10/10	100 %
	B-Middle	Cal.6	10/10	100 %
	B-Low	Cal.7	10/10	100 %
	A-High	Cal.8	10/10	100 %
	A-Middle	Cal.9	10/10	100 %
	A-Low	Cal.10	10/10	100 %
	B-High	Cal.11	10/10	100 %
	B-Middle	Cal.12	10/10	100 %
	B-Low	Cal.13	10/10	100 %
	Total		130/130	100 % (95 % CI: 95 %-100 %)

- **Site to site**

Between-site	Standard material		Judgment/Nr	Detection rate
Site-1	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Site-2	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)
Site-3	Negative	Cal.1	3/3	100 %
	A-High	Cal.2	3/3	100 %
	A-Middle	Cal.3	3/3	100 %
	A-Low	Cal.4	3/3	100 %
	B-High	Cal.5	3/3	100 %
	B-Middle	Cal.6	3/3	100 %
	B-Low	Cal.7	3/3	100 %
	A-High	Cal.8	3/3	100 %
	A-Middle	Cal.9	3/3	100 %
	A-Low	Cal.10	3/3	100 %
	B-High	Cal.11	3/3	100 %
	B-Middle	Cal.12	3/3	100 %
	B-Low	Cal.13	3/3	100 %
Total			39/39	100 % (95 % CI: 95 %-100 %)

- **Comparative analysis on commercial products**

RDT		PCR		ichroma™ Influenza A+B		Commercial-1		Commercial-2	
		(+)	(-)	(+)	(-)	(+)	(-)	(+)	(-)
Flu A-Positive	75	75	0	74	1	60	15	60	15
Flu B-positive	75	75	0	72	3	50	25	51	24
Positive total = N	150	150		146		110		111	
Flu A+B negative	125	0	125	0	125	0	125	0	125
Negative total = N	125	125		125		125		125	
Sensitivity (%)		150/150 = 100 %		146/150 = 97.3 %		110/150 = 73.3 %		111/150 = 74 %	
Specificity (%)		125/125 = 100 %		125/125 = 100 %		125/125 = 100 %		125/125 = 100 %	
Accuracy (%)		275/275 = 100 %		271/275 = 98.5 %		235/275 = 85.4 %		236/275 = 85.8 %	

* (+) : positive, (-) : negative

- **Clinical performance evaluation**

ichroma™ Influenza A+B have demonstrated the following clinical performance results.

Classification	Influenza A	Influenza B
Clinical sensitivity	98.6 % (74/75)	96 % (72/75)
Clinical specificity	100 % (125/125)	100 % (125/125)

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Note: Please refer to the table below to identify various symbols

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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