BIO TECHNOLOGY boditech

Infection

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 the sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on a test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for ichroma™ tests to show the result as 'Positive'/'Negative'.

COMPONENTS

ichroma™ Influenza A+B consists of 'cartridges', 'extraction buffer tubes', Control (Influenza A Positive Control Swab, Influenza B Positive Control swab, Influenza Negative Control Swab)'.

- The cartridge contains the membrane called a test strip which has anti human influenza A/B at the test line, while chicken IgY at the control line.
- All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a cartridge box. The test strip contains anti influenza A/B-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate.
- The extraction buffer contains sodium chloride as a stabilizer, 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.
- Follow the instructions and procedures described in this 'Instructions for use.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, extraction buffer tube and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridges or extraction buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing of one sample only.
- If test components and/or sample are stored in refrigerator, then allow cartridge and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- The extraction buffer contains sodium azide (NaN3), and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- 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 cartridges, extraction buffers and swaps should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- **ichroma™ Influenza A+B** will provide accurate and reliable results, when it is used only in conjunction with the instrument for ichroma™ tests.

WARNINGS AND PRECAUTIONS FOR SAMPLE

- Follow the instructions and procedures described in this 'Instructions for use'.
- 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.

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(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result as it makes the 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 in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Storage condition			
Component		Storage Temperature	Shelf life
Cartridge		1 - 30 °C	18 months
Extraction Tube (Extraction buffer)		1 - 30 °C	18 months
Controls	Influenza A Positive	1 - 30 °C	18 months
	Influenza B Positive	1 - 30 °C	18 months
	Influenza Negative	1 - 30 °C	18 months

- After the cartridge pouch is opened, the test should be performed immediately.

MATERIALS SUPPLIED

REF CFPC-61

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

- Cartridge box:
  - Cartridge 25
  - Extraction buffer tube set
    - Extraction buffer tube 25
    - Nozzle 25
  - Swab 25
  - Controls
    - Influenza A Positive Control swab 1
    - Influenza B Positive Control swab 1
    - Influenza Negative Control swab1
  - ID chip 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

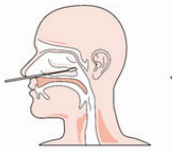
Following items can be purchased separately from **ichroma™ Influenza A+B.** Please contact our sales division for more information.

- **ichroma™ II** REF FPRR021
- **ichroma™ III** REF FPRR037
- **ichroma™ M2** REF FPRR031
- **ichroma™-50** REF FPRR022
- **ichroma™-50 PLUS** REF FPRR036

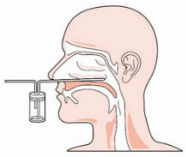
SAMPLE COLLECTION AND PROCESSING

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

- **Collection method for sample**
  - Nasopharyngeal swab specimens
    To collect samples, insert a sterile rayon swab in the nasal cavity and spin it smoothly 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 showed any performance difference.
- Once the sample was frozen, it should be thawed only one time and only for test, because repeated freezing and thawing can cause erroneous results.

TEST SETUP

- Check the contents of **ichroma™ Influenza A+B**: Sealed cartridges, extraction buffer tube set, swab, controls, ID chip and an instructions for use.
- Ensure that the lot number of the cartridges matches that of the extraction buffer as well as an ID chip.
- If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Insert the ID chip into the ID chip port of the instrument for ichroma™ tests.
- Turn on the instrument for ichroma™ tests.
- Insert the ID chip into the 'ID chip port'.

※ **Please refer to the instrument for ichroma™ tests operation manual for complete information and operating instructions.**

TEST PROCEDURE

▶ **ichroma™ II, ichroma™ M2**

1) Open the extraction buffer tube.
2) Sample collection

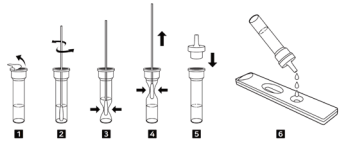
‣ With a sterile swab

Collect samples with a sterile swab and then put it into the extraction tube (Spin 5 times). Then go to the step 3).

‣ Sample in VTM or UTM

Collect 700 µL of samples with a pipette and put the collected samples into the extraction tube. Close the extraction buffer tube and gently invert it 10 times. Open the extraction buffer tube. Then go to the step 5).

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.)
   If the test performed with pipette, pipette out 70 ~ 80 µL of sample mixture onto the sample well on a cartridge.



7) For scanning, refer to following step.

Multi test mode / Read now mode

1) Leave the cartridge at room temperature for 10 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
2) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
3) Tap the 'Start' button on the instrument for ichroma™ tests to start the scanning process.
   (ichroma™ M2 is tested automatically after inserting.)
4) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
5) Read the test result on the display screen of the instrument for ichroma™ tests.

Single test mode/ Walk away mode

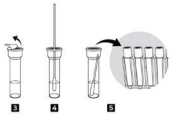
1) Insert the sample-loaded cartridge into the holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
2) Tap the 'Start' button on the instrument for ichroma™ tests.
   (ichroma™ M2 is tested automatically after inserting.)
3) The cartridge goes inside the instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 10 minutes.
4) Read the test result on the display screen of the instrument for ichroma™ tests.

▶ **ichroma™ III**

1) The test procedure is same with the 'Single test mode'

▶ **ichroma™-50, ichroma™-50 PLUS**

1) Insert the tip array in the tip station.
2) Insert the cartridges in the cartridge magazine individually.
3) Open the extraction buffer tube.
4) Put the sample collected swab into the extraction buffer tube and cut the swab (Please refer to the below instructions). The swab length should be shorter than tube height.
5) Insert the extraction buffer tube into the tube rack.



6) Tap the button located in the upper side of the No. of test cartridge region to select ID chip what you want to use.
7) When the selected cartridge slot is activated, set the number of test cartridge by tapping.
8) Tap the button located in the upper side of the No. of reagent region to select ID chip what you want to use.
9) When the selected slot is activated, set the number of Detector by tapping.
10) Set the number of pipette tips by tapping.
11) Tap the 'Start' button on the left upper of the main screen to start test.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests 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 B antigen)
Flu A: Negative	Influenza A negative
Flu B: Negative	Influenza B negative
Invalid	Result invalid. Need to retest.

QUALITY CONTROL

- Quality control tests are part of the good testing practice to confirm the expected result and validity of the assay and should be performed at regular intervals.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided with **ichroma™ Influenza A+B**. 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 mg/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(%)
3 days	Negative	Cal.1	9/9	100 %
	A-High	Cal.2	9/9	100 %
	A-Middle	Cal.3	9/9	100 %
	A-Low	Cal.4	9/9	100 %
	B-High	Cal.5	9/9	100 %
	B-Middle	Cal.6	9/9	100 %
	B-Low	Cal.7	9/9	100 %
	A-High	Cal.8	9/9	100 %
	A-Middle	Cal.9	9/9	100 %
	A-Low	Cal.10	9/9	100 %
	B-High	Cal.11	9/9	100 %
	B-Middle	Cal.12	9/9	100 %
	B-Low	Cal.13	9/9	100 %
Total			117/117	100 % (95 % CI:95 %-100 %)

- **Person to person (between person)**

Between-person	Standard material		Judgment/Nr.	Detection rate
6 Persons	Negative	Cal.1	18/18	100 %
	A-High	Cal.2	18/18	100 %
	A-Middle	Cal.3	18/18	100 %
	A-Low	Cal.4	18/18	100 %
	B-High	Cal.5	18/18	100 %
	B-Middle	Cal.6	18/18	100 %
	B-Low	Cal.7	18/18	100 %
	A-High	Cal.8	18/18	100 %
	A-Middle	Cal.9	18/18	100 %
	A-Low	Cal.10	18/18	100 %
	B-High	Cal.11	18/18	100 %
	B-Middle	Cal.12	18/18	100 %
	B-Low	Cal.13	18/18	100 %
Total			234/234	100 % (95 % CI: 95 %-100 %)

- **Lot to lot (between lot)**

Between-Lot	Standard material		Jugdment/Nr	Detection rate
3 Lots	Negative	Cal.1	30/30	100 %
	A-High	Cal.2	30/30	100 %
	A-Middle	Cal.3	30/30	100 %
	A-Low	Cal.4	30/30	100 %
	B-High	Cal.5	30/30	100 %
	B-Middle	Cal.6	30/30	100 %
	B-Low	Cal.7	30/30	100 %
	A-High	Cal.8	30/30	100 %
	A-Middle	Cal.9	30/30	100 %
	A-Low	Cal.10	30/30	100 %
	B-High	Cal.11	30/30	100 %
	B-Middle	Cal.12	30/30	100 %
	B-Low	Cal.13	30/30	100 %
Total			390/390	100 % (95 % CI: 95 %-100 %)

- **Site to site (between site)**

Between-site	Standard material		Judgment/Nr	Detection rate
3 Sites	Negative	Cal.1	9/9	100 %
	A-High	Cal.2	9/9	100 %
	A-Middle	Cal.3	9/9	100 %
	A-Low	Cal.4	9/9	100 %
	B-High	Cal.5	9/9	100 %
	B-Middle	Cal.6	9/9	100 %
	B-Low	Cal.7	9/9	100 %
	A-High	Cal.8	9/9	100 %
	A-Middle	Cal.9	9/9	100 %
	A-Low	Cal.10	9/9	100 %
	B-High	Cal.11	9/9	100 %
	B-Middle	Cal.12	9/9	100 %
	B-Low	Cal.13	9/9	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

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

For technical assistance, please contact:
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