Infection

# ichroma™ Mycoplasma

## INTENDED USE

**ichroma™ Mycoplasma** is a fluorescence Immunoassay (FIA) for the qualitative determination of Mycoplasma pneumoniae antigen in human throat specimen. It is useful as an aid in management and monitoring of Mycoplasma pneumoniae infection.
For *in vitro* diagnostic use only.

## INTRODUCTION

Mycoplasma pneumoniae is a pathogen that causes severe respiratory infections such as pneumonia, including minor respiratory infections such as sore throat and bronchitis, with 1.0-32.4 percent of the community-acquired pneumonia-causing bacteria and 6.3-9.2 percent of the domestic atypical pneumonia-causing bacteria. Symptoms vary, such as sore throat, wheezing, fever, chills, coughing, runny nose, general weakness, wheezing, breathing difficulties, so clinical judgment alone does not distinguish it from viral or other bacterial pneumonia. Although β-lactamometer antibiotics are not valid for M. pneumoniae infection, macrolide, tetracline, and fluroquinolone are effective, early and accurate diagnosis is critical to treatment.
As a diagnostic method of M. pneumoniae infection, culture method using respiratory specimen, direct polymerase chain reaction method, and serum test method can be used. The culture method has a longer test time of 2 to 3 weeks, lower sensitivity, and polymerase chain reaction method is faster and more sensitive than culture method, but it cannot distinguish infection from Colony-forming. For this reason, M. pneumoniae infection is primarily diagnosed with serologic screening, and the particle agglutination assay and enzyme immunoanalysis are used.
This product is a medical in vitro diagnostic reagent that can be examined for mycoplasma pneumoniae infection within 10 minutes, and it can be checked much faster and easier than PCR or cell culture that takes 24 to 48 hours.

## PRINCIPLE

The test uses a sandwich immunodetection method.
The detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antibodies 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 result as 'Positive'/'Negative'.

## COMPONENTS

**ichroma™ Mycoplasma** consists of 'cartridges', 'extraction tube sets', and 'controls(mycoplasma positive & negative control swabs)'.

- The cartridge contains the membrane called a test strip which has anti-human mycoplasma at the test line, and chicken IgY at the control line.
- The cartridge contains the sample pad which has bovine serum albumin as a stabilizer and sodium azide as a preservative in carbonate buffer.
- The cartridge contains the conjugate pad which has anti-mycoplasma-fluorescence conjugate and anti-chicken IgY fluorescence conjugate.
- All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a box.
- The extraction buffer contains sodium chloride as a stabilizer, tween 20 as a surfactant, and sodium azide as a preservative in Tris-HCl buffer. The extraction buffer is pre-dispensed in a tube.
- The mycoplasma positive control swab contains recombinant Mycoplasma pneumoniae.
- The mycoplasma negative control swab is non-treated.

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'Instruction for use'.
- Do not reuse cartridge or extraction buffer.
- After mixing samples with the extraction buffer, use it immediately.
- Do not use the extract buffer of other products.
- 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).
- Lot numbers of all the test components (cartridges, extraction buffer tubes, controls and ID chip) must match each other.
- 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.
- Do not release the cartridge from pouch before completing the test setup.
- Do not eat the desiccant which is kept in a pouch.
- Do not use the contaminated extraction buffer, otherwise it might yield incorrect test result(s).
- Do not eat the extraction buffer. Any extraction buffer intake could cause diarrhea or vomiting.
- Please apply the exact drops for accurate test result. If not, it may cause incorrect results.
- If the test result is "Negative" even through the patient has significant infectious symptoms, it should be recommended to conduct additional test including PCR or culture test.
- The accurate determination of test results as "Positive" should be confirmed by additional clinical evaluation.

- "Negative" of test results should be considered with possibilities of other infections. Positive result should be considered with additional infections by other pathogenic bacterium.
- The instrument for ichroma™ tests may generate slight vibration during use.
- High or low temperature might yield incorrect test result(s).
- Allow cartridges, extraction buffer tubes, controls, and samples to be at room temperature for approximately 30 minutes before use.
- Carefully insert the cartridge into the reader to prevent the sample from splashing out.
- Do not touch the sample well or the testing window with your hand.
- Used cartridges, extraction buffer tubes, nozzles, and swabs should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- Waste material should be discarded after sterilizing with autoclave at 121 °C for more than 1 hour.
- The cartridge and the extraction buffer contain sodium azide ($NaN_3$), 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.
- **ichroma™ Mycoplasma** will provide accurate and reliable results subject to the below conditions.
- **ichroma™ Mycoplasma** should be used only in conjunction with the instrument for ichroma™ tests.

## WARNINGS AND PRECAUTIONS FOR SAMPLE

- It is recommended to test the sample immediately after sample collection.
- Refrain from smoking or eating, while sample is collected.
- Do not use samples taken outside the throat. This may result in a non-specific response that may result in inaccurate results. As a result, training procedures for sampling and handling are required.
- New clean sterile swab shall be used when using different samples to prevent cross-contamination between samples. Also, do not reuse sterile swab once used.
- If samples that are not suitable for testing are used due to blood mixing or certain drug use, incorrect test results may be generated.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the relevant local regulations.
- 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.
- Used cartridges, sampling tools and samples should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.

## STORAGE AND STABILITY

| Storage condition | | | |
|---|---|---|---|
| Component | Storage Temperature | Shelf life | Note |
| Cartridge | 1 - 30 °C | 18 months | Disposable |
| Extraction buffer tube | 1 - 30 °C | 18 months | Disposable |
| Mycoplasma positive control swab | 1 - 30 °C | 18 months | Disposable |
| Mycoplasma negative control swab | 1 - 30 °C | 18 months | Disposable |

## 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 antigens to the antibodies which is the 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 antigens with time and/or temperature may also cause false negative result as it makes antigens 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.

## MATERIALS SUPPLIED

REF CFPC-94

Components of **ichroma™ Mycoplasma**

- Cartridge box:
  - Cartridge 25
  - Extraction tube set
    - Extraction buffer tube 25
    - Nozzle 25
  - Swab 25
  - Control
    - Mycoplasma Positive control swab 1
    - Mycoplasma Negative control swab 1
  - ID chip 1
  - Instructions for use 1

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

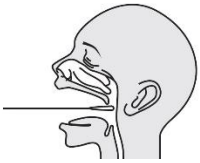
Following items can be purchased separately from **ichroma™ Mycoplasma.** Please contact our sales division for more information.

- **ichroma™ II** REF FPRR021
- **ichroma™-50** REF FPRR022
- **ichroma™-100** REF FPRR029
- **ichroma™ M2** REF FPRR031
- **ichroma™ III** REF FPRR037

## SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Mycoplasma is <u>human throat specimen.</u>**

- Sample Collection
  To collect samples, insert the sample collection tool (sterile swab) into the pharynx with excess secretion through the oral cavity, and spin it smoothly on the inner wall of the pharynx to collect as much sample as possible. Be careful not to mix with saliva when collecting.



<Throat Swab>

- It is recommended to test the sample immediately after collection. If do not use the sample immediately, it should be stored in a VTM (1-2 mL) at 2-8 °C or -70 °C.
- Samples stored for 2 days at 2-8 °C did not show any performance difference.
- Samples stored frozen at -70 °C up to a year did not show any performance difference.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

## TEST SETUP

- Check the contents of **ichroma™ Mycoplasma**: Sealed cartridges, extraction tube sets, swabs, controls, an ID chip and an instruction for use.
- Ensure that the lot number of the cartridge matches that of the extraction buffer tube, controls as well as the ID chip.
- If the sealed cartridges and the extraction buffer tubes have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Avoid placing the instrument directly under an air handling unit as the air flow can affect the flow of samples on the test strip.
- 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

*** Caution**

- Before performing the test, keep all clinical samples and components of **ichroma™ Mycoplasma** 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 Sample Collection

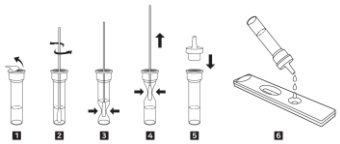
<With a sterile swab>
Collect samples with a sterile swab and then put it into the extraction tube (Spin 5 times). Squeeze the sterile swab to extract the sample into the buffer. Then go to the step ③.
<Sample in VTM >
Collect 450 µL of samples with a pipette and put the collected samples into the extraction buffer 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 buffer tube to pull it out of tube.

⑤ Assemble a nozzle to the top of extraction buffer 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 on the sample well of 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 steps:

▶ **ichroma™ II, ichroma™ M2, ichroma™ 100**

Multi test mode / Read now mode

1) Leave the sample-loaded cartridge at room temperature for 10 minutes.

⚠ *<u>Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.</u>*

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) Press the 'Select' or 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

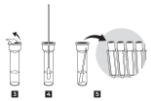
1) Insert the sample-loaded cartridge into the holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
2) Press the 'Select' or tap the 'Start' button 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**

1) Insert the tip array in the tip station.
2) Insert the cartridge magazine with the cartridges into the magazine station.
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 instruction). 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 the ID chip that you want to use.
7) When the selected cartridge slot is activated, set the number of the detector tube by tapping.
8) Set the number of pipette tips by tapping.
9) Tap the 'Start' button on the left upper of the main screen to start test.

## INTERPRETATION OF TEST RESULT

- 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 |
|---|---|
| Mycoplasma: Positive | Mycoplasma Positive (Contains Mycoplasma antigen) |
| Mycoplasma: Negative | Mycoplasma Negative |
| Invalid | Result Invalid, Need to retest. |

## QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results 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™ Mycoplasma**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

## PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity**

- **LoD**

6 samples of Mycoplasma pneumonia FH strain made from serial dilution were tested with three lots of **ichroma™ Mycoplasma.** Concentration of which the instrument performed with 95% positive agreement is as follows.

| Strain | LoD |
|---|---|
| Mycoplasma pneumonia FH strain (ATCC 15531) | 3.52 x $10^3$ CFU/mL |

- **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.

**<Mycoplasma Judgment standard (Positive/Negative)>**

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

- **Analytical Specificity**

- Cross reactivity

**ichroma™ Mycoplasma** test results did not show any significant cross-reactivity with 16 various other viruses and 15 various bacteria.

| | Virus | Concentration |
|---|---|---|
| 1 | HSV-1 F(3A20)strain | 2.4 x $10^6$ $TCID_{50}$/mL |
| 2 | HSV-2 MS(4A6)strain | 2.6 x $10^6$ $TCID_{50}$/mL |
| 3 | Corona FCV(4A1)strain | 1.5 x $10^6$ $TCID_{50}$/mL |
| 4 | Corona FIP(2A4)strain | 3.0 x $10^6$ $TCID_{50}$/mL |
| 5 | Coxakie B1 conn5 strain | 8.7 x $10^6$ $TCID_{50}$/mL |
| 6 | Coxakie B3 nancy(5A1)strain | 2.3 x $10^6$ $TCID_{50}$/mL |
| 7 | Polie virus sabin(3A4)strain | 4.0 x $10^7$ $TCID_{50}$/mL |
| 8 | Rhino virus RV14strain | 3.7 x $10^6$ $TCID_{50}$/mL |
| 9 | Rhino virus RV21strain | 1.1 x $10^4$ $TCID_{50}$/mL |
| 10 | Rhino virus RV71strain | 2.4 x $10^6$ $TCID_{50}$/mL |
| 11 | Adeno virus type 5 4A1 strain | 2.4 x $10^6$ $TCID_{50}$/mL |
| 12 | HCMV AD-169 | 1.0 x $10^4$ $TCID_{50}$/mL |
| 13 | Influenza A virus H1N1 PR8 | 1.5 x $10^7$ PFU/mL |
| 14 | Influenza A virus H3N2 Hongkong | 1.4 x $10^6$ PFU/mL |
| 15 | Influenza B virus B/Lee/40 | 7.6 x $10^6$ PFU/mL |
| 16 | Entero virus 71 strain H(5A2) | 2.4 x $10^6$ $TCID_{50}$/mL |

| | Bacteria | Concentration |
|---|---|---|
| 1 | *S. Canis* | 4.98 x $10^9$ CFU/mL |
| 2 | *S. Dysgalactiae subsp dysgalactiae* | 3.21 x $10^9$ CFU/mL |
| 3 | *S. Pneumoniae* | 1.53 x $10^9$ CFU/mL |
| 4 | *S. Anginosis* | 3.80 x $10^9$ CFU/mL |
| 5 | *S. Mutans* | 3.71 x $10^9$ CFU/mL |
| 6 | *S. Equisimilis subsp equisimilis* | 2.83 x $10^9$ CFU/mL |
| 7 | *S. mitis* | 2.83 x $10^9$ CFU/mL |
| 8 | *S. Aglactiae* | 2.72 x $10^9$ CFU/mL |
| 9 | *S. Dysgalacteae subsp. Equisimilis* | 1.90 x $10^9$ CFU/mL |
| 10 | *S. Paraganguis* | 1.47 x $10^9$ CFU/mL |
| 11 | *S. Porcinus* | 1.16 x $10^9$ CFU/mL |
| 12 | *S. thermophilus* | 1.93 x $10^9$ CFU/mL |
| 13 | *S. pyogenes* | 1.08 x $10^9$ CFU/mL |
| 14 | *Escherichia coli* | 1.08 x $10^9$ CFU/mL |
| 15 | *Mycoplasma genitalium* | 5.62 x $10^7$ CFU/mL |

**- Interference**

Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. **ichroma™ Mycoplasma** test results did not show any significant interference with these materials.

| Interference Materials | Conc. |
|---|---|
| Nasal sprays drop | 30% |
| Nasal corticosteroids | 30% |
| Antihistamine drug | 7.5 mg/mL |
| Nasal ointment | 7.5 mg/mL |
| Anti-viral drugs (Oseltamivir) | 7.5 mg/mL |
| Mucin | 1% |
| Antibacterial, systemic (Cefadroxil Cap) | 7.5 mg/mL |
| Whole blood | 1.0% |
| Acetaminophen | 20 mg/mL |
| Ibuprofen | 20 mg/mL |
| Povidone-iodine | 3.5% |
| Acetylsalicylic acid (Aspirin) | 30mg/mL |
| Mouth wash (LISTERIN) | 20% |
| Throat candy (Cetylpyridium chloride) | 30mg/mL |
| Throat candy (Dipotassium glycyrrhizinate) | 30mg/mL |
| Throat candy (South Tomorrow Extract) | 30mg/mL |

- **Precision**

- Single-site study

Repeatability (within-run precision)
within-laboratory precision (Total precision)
Lot to lot precision

3 Lots of **ichroma™ Mycoplasma** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

- Multi-site study

Reproducibility

1 Lot of **ichroma™ Mycoplasma** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

| Single-site study | | | | | | |
|---|---|---|---|---|---|---|
| | Repeatability | | Within-laboratory precision | | Lot to Lot precision | |
| | Positive/ Total | Positive rate (%) | Positive/ Total | Positive rate (%) | Positive/ Total | Positive rate (%) |
| Negative | 0/40 | 0 | 0/80 | 0 | 0/120 | 0 |
| Low Positive | 40/40 | 100 | 80/80 | 100 | 120/120 | 100 |
| High Positive | 40/40 | 100 | 80/80 | 100 | 120/120 | 100 |

| Multi-site study | | |
|---|---|---|
| | Reproducibility | |
| | Positive/ Total | Positive rate (%) |
| Negative | 0/75 | 0 |
| Low Positive | 75/75 | 100 |
| High Positive | 75/75 | 100 |

- **Clinical performance**

**ichroma™ Mycoplasma** have demonstrated the following clinical performance results. (vs. RT-PCR)

| | Result | 95%CI |
|---|---|---|
| Clinical Sensitivity | 81.9% (68/83) | 71.6% – 89.2% |
| Clinical Specificity | 98.8% (79/80) | 92.3% – 99.9% |

- **Comparability**

| | | Comparator A | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| ichroma™ Mycoplasma | Positive | 29 | 40 | 69 |
| | Negative | 1 | 93 | 94 |
| | Total | 30 | 133 | 163 |
| Positive agreement (95%CI) | | 96.7% (29/30) (95%CI: 81.9% – 99.9%) | | |
| Negative agreement (95%CI) | | 69.9% (93/133) (95%CI: 61.6% – 77.1%) | | |
| Total agreement (95%CI) | | 74.9% (122/163) (95%CI: 67.6% – 80.9%) | | |

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10. **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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