ichroma™ Strep A

INTENDED USE

ichroma™ Strep A is a fluorescence Immunoassay (FIA) for the qualitative determination of Streptococcus A in human throat specimen. It is useful as an aid in management and monitoring of Group A Streptococcal infection.

For *in vitro* diagnostic use only.

INTRODUCTION

Group A Streptococcus is one of the most common causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis.

Conventional procedures for identification of Group A Streptococcus from throat swabs involve the culture, isolation, and subsequent identification of viable pathogen at 24 to 48 hours or longer for results.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in the conjugate pad bind with antigen in the sample to form antigen-antibody complexes. These complexes then migrate through the through the nitrocellulose matrix and are captured by another sets of immobilized antibodies on the test line.

The more antigens in the sample, the more antigen-antibody complexes, which leads to a stronger fluorescence signal. This signal then is interpreted by the reader to display the "Positive"/"Negative" in the sample.

COMPONENTS

ichroma™ Strep A consists of 'Cartridges', 'Extraction Tubes', 'Extraction Buffer pack', 'Swabs', 'Control (Strep A Positive Control Swab, Strep A Negative Control Vial) and 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti Strep A, with streptavidin at the control line.
- The test strip contains anti strep A-fluorescence conjugate, biotin-BSA-fluorescence conjugate, BSA and sucrose as a stabilizer in drying condition.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges, 25 extraction tubes are packed in a box which also contains 25 extraction buffer packs, swabs, controls and ID chip.
- The extraction buffer contains sodium nitrite and citric acid.
- The extraction buffer is pre-dispensed in an extraction buffer pack.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- To store test samples in a freezer, refer to SAMPLE COLLECTION AND PROCESSING
- Do not reuse the cartridge, extraction Tube, extraction buffer pack, swab and control. A extraction buffer pack should be used for processing one sample only. So should a cartridge.
- Extraction buffer mixture (sample and extraction buffer) should be used immediately.
- Do not use the extract buffer 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 interchange test components between different lots or use test components after the expiration date, either of which might yield misleading of test result(s).
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge if is damaged or already opened.
- 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 contaminated extraction buffer, otherwise it might yield misleading result.
- Do not eat the extraction buffer. Any extraction buffer intake could cause diarrhea or vomiting.
- As extraction buffer is acidic solution. Please avoid contact with eyes, skin or clothing. If extraction buffer is contacted with eyes, skin or clothing, please wash them in the running water immediately.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with applicable local requirement.
- Just before use, allow the cartridge, the extraction buffer pack, control and the sample reach the room temperature by leaving them in the room for approximately 30 minutes at the least
- 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.
- **ichroma™ Strep A** as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used extraction buffer packs, extraction tubes, swabs, pipette tips and cartridges should be handled carefully and discarded by an appropriate measure in accordance with the relevant local regulations.
- **ichroma™ Strep A** 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 throat. 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 applicable local requirement.

STORAGE AND STABILITY

- The cartridge is stable for 18 months (while sealed in the original 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 (Strep A positive control, strep A 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-74

Components of **ichroma™ Strep A**

- Cartridge Box:
  - Cartridges 25
  - Extraction Tube 25
  - Extraction buffer pack 25
  - Swabs 25
  - Controls
    - Strep A Positive Control Swab 1
    - Strep A Negative Control Swab 1
  - Tube Holder 3
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

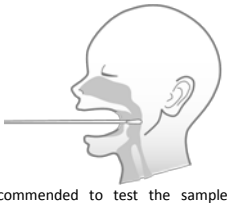
Following items can be purchased separately from **ichroma™ Strep A.** Please contact our sales division for more information.

- **ichroma™ II** REF FPRR021

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ Strep A** is human throat specimen.

- Sample Collection
  Take a sample collection tool (sterile swab) into the throat to collect sample. Do not touch tongue, oral cavity and teeth when collecting sample. Sample collection should be from the faucal or tonsil with inflammation. Swab and gently rotate a sterile swab to collect sufficient samples.



- 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 -20 °C.
- Samples stored at 2-8 °C for 2 days showed no performance difference.
- Samples stored frozen at -20 °C for a week showed no 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

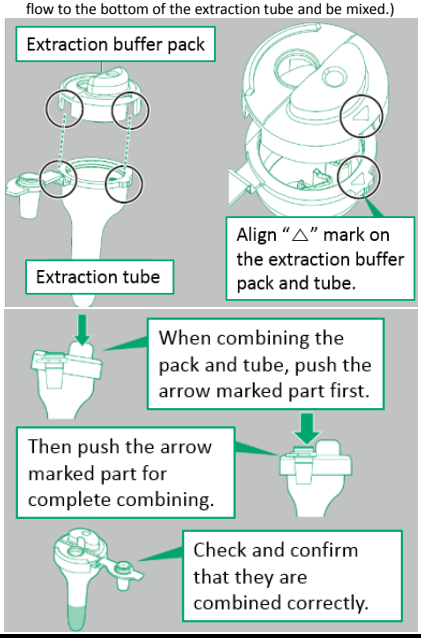
- Check the contents of **ichroma™ Strep A**: Sealed test cartridge, Extraction Tube, Extraction buffer pack, Swab, Controls and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID Chip.
- Keep the sealed cartridge and the detection buffer tube at room temperature for at least 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™ Strep A test at room temperature.
- If the color of extraction buffer is changed to yellow or orange, 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.

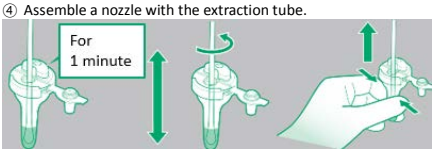
① Assemble an extraction tube and extraction buffer pack into one. (A structure in the extraction tube will puncture sealing of extraction buffer pack. Then solution A and solution B will flow to the bottom of the extraction tube and be mixed.)



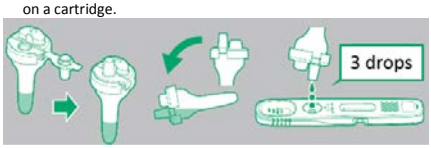
② Collect of sample with a swab and then put it into the extraction tube.
(Spin and squeeze the swab to extract the sample into the buffer.)

③ Leave the sample-mixed extraction buffer tube at room temperature for 1 minute.

④ Assemble a nozzle with the extraction tube.



⑤ Load only three drops of sample mixture 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 5 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 5 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
Strep A: Positive	Strep A positive (Contain strep A antigen)
Strep A: Negative	Strep A negative (Not contain strep A antigen)
Invalid	Result invalid. Need to retest.

QUALITY CONTROL

- The Quality control tests should be used to confirm the reliability and the validity of ichroma™ Strep A
- 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**
  - Limit of detection (LoD) 4 x 10^3 cfu/test
- **Analytical Specificity**
  - **Cross reactivity**
    There is no significant cross-reactivity on 34 various other viruses and 40 various bacteria.

	Virus		
#1	Adenovirus type1	#18	Respiratory Syncytial virus A
#2	Adenovirus type2	#19	Coxakie virus B1 - conn5
#3	Adenovirus type3	#20	Coxakie virus B3 - nancy(5A1)
#4	Adenovirus type4	#21	Polio virus - sabin(3A4)
#5	Adenovirus type6	#22	Corona virus - FCV(3A2)
#6	Adenovirus type7	#23	Corona virus - FIP(2A4)
#7	Coxaievirus A2	#24	HSV-1 F(3A20)
#8	Coxaievirus A4	#25	HSV-2 MS(4A6)
#9	Coxaievirus B2	#26	RSV - Strain B WV/14617/82 (VR-1400)
#10	Echovirus 3	#27	Adenovirus(type 5)
#11	Echovirus 6	#28	Rhinovirus-RV71
#12	Echovirus 9	#29	Rhinovirus-RV14
#13	Echovirus 25	#30	Influenza A - H3N2(HK)
#14	Enterovirus 71	#31	Influenza B-Lee
#15	Rubella virus	#32	Influenza A - H1N1(PR8)
#16	Mumps virus	#33	Rhinovirus - RV21
#17	Meales virus	#34	HCMV(AD-169)
	Bacteria		
#1	*S. Dysgalactiae subsp. dysgalactiae*	#21	*Escherichia coli*
#2	*S. mitis*	#22	*Hemophilus influenzae*
#3	*S. Mutans*	#23	*Hemophilus parainfluenzae*
#4	*S. Canis*	#24	*Klebsiella oxytoca*
#5	*S. Aglactiae*	#25	*Klebsiella pneumoniae*
#6	*S. Aglactiae*	#26	*Lactobacillus sp.*
#7	*S. Paraganguis*	#27	*Legionella spp*
#8	*S. Equisimilis subsp. equisimilis*	#28	*Listeria monocytogenes*
#9	*S. thermophilus*	#29	*Moraxella catarrhalis*
#10	*S. Anginosis*	#30	*Mycobacterium tuberculosis*
#11	*S. Pneumoniae*	#31	*Neisseria gonorrhoeae*
#12	*S. Porcinus*	#32	*Neisseria meningitidis*
#13	*Candida albicans*	#33	*Neisseirii sicca*
#14	*Candida glabrata*	#34	*Proteus mirabilis*
#15	*Candida tropicalis*	#35	*Proteus vulgaris*
#16	*Citrobacter freundii*	#36	*Pseudomonas aeruginosa*
#17	*Corynebacterium sp.*	#37	*Serratia marcescens*
#18	*Corynebacterium diphtheriae*	#38	*Staphylococcus aureus*
#19	*Enterococcus faecalis*	#39	*Staphylococcus epidermidis*
#20	*Enterococcus gallinarum*	#40	*Stenotrophomonas maltophilia*

- **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	Anti-viral drugs (TAMIFLU)	5 mg/ml
#6	Antibiotic (Bactroban, cream)	10 mg/ml
#7	Antibacterial, systemic (cefadroxil)	5 mg/ml
#8	Whole blood	10 %
#9	Acetaminophen	10 mg/ml
#10	Ibuprofen	10 mg/ml
#11	Povidone-iodine	3.50 %
#12	Acetylsalicylic acid (Aspirin)	30 mg/ml
#13	Mouth wash (LISTERIN)	20.00 %
#14	Throat candy (Cetylpyridinium chloride –candy, VICKS)	20 mg/ml
#15	Throat candy (Lysozyme chloride	20 mg/ml
#16	Throat candy (Lysozyme chloride	20 mg/ml

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

Between-Lot	Standard material		Judgment/Nr.	Detection rate(%)
Lot 1	Negative	Cal.2	20/20	100 %
	Positive-Low	Cal.3	20/20	100 %
	Positive-Middle	Cal.4	20/20	100 %
	Positive-High	Cal.5	20/20	100 %
	Total		80/80	100 % (95 % CI: 95%-100%)

Lot 2	Negative	Cal.2	20/20	100 %
	Positive-Low	Cal.3	20/20	100 %
	Positive-Middle	Cal.4	20/20	100 %
	Positive-High	Cal.5	20/20	100 %
	Total		80/80	100 % (95 % CI: 95%-100%)
Lot 3	Negative	Cal.2	20/20	100 %
	Positive-Low	Cal.3	20/20	100 %
	Positive-Middle	Cal.4	20/20	100 %
	Positive-High	Cal.5	20/20	100 %
	Total		80/80	100 % (95 % CI: 95%-100%)

- **Between-Person**

Between-Person	Standard material		Judgment/Nr.	Detection rate(%)
Lot 1	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 2	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 3	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)

- Between-days

Between-days	Standard material		Judgment/Nr.	Detection rate(%)
Lot 1	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 2	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 3	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)

- Between-site

Between-days	Standard material		Judgment/Nr.	Detection rate(%)
Lot 1	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 2	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)
Lot 3	Negative	Cal.2	3/3	100 %
	Positive-Low	Cal.3	3/3	100 %
	Positive-Middle	Cal.4	3/3	100 %
	Positive-High	Cal.5	3/3	100 %
	Total		12/12	100 % (95 % CI: 95%-100%)

- **Comparative analysis on commercial products**

		Reference		Total
		Positive	Negative	
ichroma™ Strep A	Positive	78	2	80
	Negative	2	54	56
Total		80	56	136

- **Clinical performance evaluation**
  - Clinical sensitivity: 97.5 %
  - Clinical specificity: 94.4 %

REFERENCES

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7. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
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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
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

For technical assistance; please contact:
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