



# ichroma™ ASO

## INTENDED USE

**ichroma™ ASO** is a fluorescence Immunoassay (FIA) for the quantitative determination of Anti Streptolysin O (ASO) in human serum / plasma. It is useful as an aid in management and monitoring of scarlet fever, rheumatic fever and post infectious glomerulonephritis along with several other conditions.

For *in vitro* diagnostic use only.

## INTRODUCTION

ASO is an antibody produced in human blood against streptolysin O made from an infection of Streptococcus bacteria. An elevated or rising ASO titer may demonstrate recent streptococcal infections. Some autoimmune responses, glomerulonephritis, acute tonsillitis, scarlet fever and rheumatic fever may be associated with streptococcal infections. Even if ASO titers may vary due to a number of factors including population and age.

## PRINCIPLE

The test uses a sandwich immunodetection method; the detector recombinant protein in buffer binds to ASO in sample, forming recombinant protein-ASO complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-recombinant protein on test strip.

The more ASO in sample forms the more recombinant protein-ASO complex and leads to stronger intensity of fluorescence signal on detector recombinant protein, which is processed by instrument for ichroma™ tests to show ASO concentration in sample.

## COMPONENTS

**ichroma™ ASO** consists of 'Cartridges', 'Dried Detection Buffer Tubes', 'Diluent Vial' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has recombinant protein against human ASO at the test line, while chicken IgY at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains recombinant protein against human ASO-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, sucrose, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in each detection buffer tube. Dispensed detection buffer tube is dried by vacuum drying method. 25 dried detection buffer tubes are packed in an aluminum foil pouch.
- The diluent contains a detergent and bovine serum albumin (BSA) as a stabilizer and sodium azide in PBS as a preservative. The diluent is dispensed in a vial.

## 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.
- Lot numbers of all the test components (cartridge, ID chip and

detection buffer, diluent) 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 misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the test cartridge, detection buffer, diluent and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ ASO** 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 detection buffer tubes, pipette tips and test cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ ASO** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ ASO** should be used only in conjunction with Instrument for ichroma™ tests.
  - Any anticoagulants other than EDTA, sodium citrate should be avoided.(**ichroma™ ASO** should not be used heparin sodium.)

## STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4 - 30°C.
- The dried detection buffer pre-dispensed in a tube is stable for 20 months if stored at 4 - 30°C.
- The diluent dispensed in a vial is stable for 20 months if stored at 4-30 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

## 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-46

#### Components of **ichroma™ ASO**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Aluminum Pouch containing Detection Buffer tubes
  - Detection Buffer Tubes 25
- Diluent Vial
  - Diluent Vial (13 mL) 1

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- Instrument for **ichroma™** tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ D** REF 13303
- **ichroma™ Printer** REF FPRR007
- **Capillary Tube (5 µL)** REF CFPO-19

## SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ ASO** is human serum / plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20°C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change test values.

## TEST SETUP

- Check the contents of **ichroma™ ASO**: Sealed Cartridge, Detection Buffer Tubes, Diluent Vial and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip, diluent as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube, diluent at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for **ichroma™** tests.
- Insert the ID Chip into the ID chip port of the instrument for **ichroma™** tests.
- Press the 'Select' button on the instrument for **ichroma™** tests. (Please refer to the 'Instrument for **ichroma™** tests Operation Manual' for complete information and operating instructions.)

## TEST PROCEDURE

- 1) Open the diluent vial and transfer 500 µL diluent buffer to the detection buffer tube by using a pipette.
- 2) Transfer 5 µL (Human serum / plasma / control) of sample using a transfer pipette or capillary tube to the detection buffer tube.
- 3) Close the lid of the detection buffer Tube and mix the sample thoroughly by shaking 10 times up and down (Ensure that the sample mixture must be used immediately)..
- 4) Pipette out 75 µL of the sample mixture and load it into a sample well in the Test Cartridge.
- 5) Leave the sample-loaded cartridge at room temperature for 12 minutes.
- 6) 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 has been marked on the cartridge especially for this purpose.
- 7) Press 'Select' button on the instrument for **ichroma™** tests to start the scanning process.
- 8) Instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- 9) Read the test result on the display screen of the instrument for **ichroma™** tests.

## INTERPRETATION OF TEST RESULT

- Instrument for **ichroma™** tests calculates the test result automatically and displays ASO concentration of the test sample in terms of IU/mL.
- The cut-off (reference range)

Upper Limit of Normal ASO	
Age	Concentration of ASO
Adult	<166 IU/mL
Preschool age	<100 IU/mL
School age	<250 IU/mL
- Working range : 25~800 IU/mL.

## 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.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ ASO**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

## PERFORMANCE CHARACTERISTICS

- **Specificity**: There, in test samples, are biomolecules such as hemoglobin, bilirubin, intralipid, triglyceride, EDTA, sodium citrate, CRP, RF IgM, hCG, PCT, Troponin I in higher concentration than their normal physiological levels. But this doesn't interfere with the **ichroma™ ASO** test measurements, nor occurs any significant cross-reactivity.

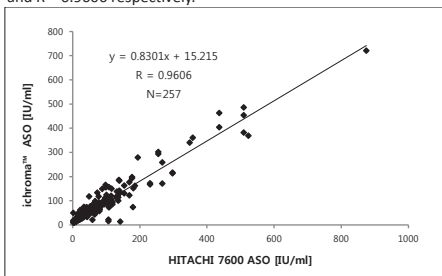
Interference	Concentration
Hemoglobin	10 mg/mL
Bilirubin	0.25 mg/mL
Intralipid	10 mg/mL
Triglyceride	10 mg/mL
EDTA	27.5 mg/mL
Sodium citrate	5.5 mg/mL

Cross-reactivity	Concentration
CRP	20 mg/mL
RF IgM	25 IU/mL
hCG	3,570 IU/mL
PCT	15.4 ng/mL
Troponin I	15 ng/mL

- **Prozone/Hook Effect:** No prozone/hook effect has been observed up to the ASO concentrations of 800 IU/mL.
- **Precision:** The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **ichroma™ ASO**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentration.

ASO (IU/mL)	Intra-assay		Inter-assay	
	Mean(IU/mL)	CV (%)	Mean(IU/mL)	CV (%)
25	26.20	3.53	25.3	5.5
187.5	183.89	4.74	182.2	4.5
500	500.35	4.89	498.7	2.7












- **Comparability:** ASO concentrations of 257 clinical samples were quantified independently with **ichroma™ ASO** and HITACHI 7600 as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were  $Y=0.8301X + 15.215$  and  $R = 0.9606$  respectively.



## REFERENCES

1. George C. K., Carolyn N. B., Wallis L. K., "Upper limits of normal" Antistreptolysin O and antideoxyribonuclease B titers. APPL. Microbiol. 1971; 21: 999-1001
2. Seckler M. D., Hoke T. R., The world wide epidemiology of acute rheumatic fever and rheumatic heart disease. Clinical Epidemiology, 2011; 3: 67-84
3. Kumar R. K., Tandon R., Rheumatic fever & rheumatic heart disease: The last 50 years. Indian J Med Res. 2013; 137: 643-658
4. Claudia S. M. M., Katya O., Alessandra L. B. M., Roberto S. M., Nilton C. M. Antistreptolysin O titer profile in acute rheumatic fever diagnosis, Journal de Pediatr(Rio J) 2001; 77: 105 -111

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

	Read instructions for use
	Use by
	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

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