BIO TECHNOLOGY boditech

Rheumatoid Arthritis

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.)

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 (13mL) 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™ II** REF FPRR021
  - **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.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
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): 160 IU/mL

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

- **Analytical sensitivity**

Limit of Blank (LoB)	5.86 IU/mL
Limit of Detection (LoD)	9.18 IU/mL
Limit of Quantification (LoQ)	25.0 IU/mL

- **Analytical Specificity**

- Cross-reactivity
  There was no significant cross-reactivity from these materials with the **ichroma™ ASO** test measurements.

Cross-reactivity material	Standard material conc. (IU/mL)		
	25.0	187.5	500
	Recovery (%)		
CRP (0.04 mg/mL)	115.7	104.9	99.3
RF IgM (25 IU/mL)	113.0	105.5	98.4
hCG (3,570 IU/mL)	113.3	102.3	95.7
PCT (6.55 ng/mL)	115.6	115.4	107.1
Troponin I (15 ng/mL)	111.4	103.2	97.2

- Interference
  There was no significant interference from these materials with the **ichroma™ ASO** test measurements.

Interference material	Standard material conc. (IU/mL)		
	25.0	187.5	500
	Recovery (%)		
Hemoglobin (2 mg/mL)	111.4	101.3	92.1
Bilirubin (0.2 mg/mL)	103.1	90.3	94.7
Intralipid (20 mg/mL)	111.1	108.6	100.0
Triglyceride (5 mg/mL)	112.2	108.5	104.4

- Anticoagulant
  Study of anticoagulant from table below with **ichroma™ ASO** showed following result. Heparin have effects on **ichroma™ ASO** test in the procedure.

Anticoagulant	Standard material conc. (IU/mL)		
	25.0	187.5	500
	Recovery (%)		
Sodium citrate (40 mg/mL)	108.3	100.8	94.7
Heparin (2.5 KU/mL)	74.6	79.6	73.1
Na-EDTA (10.8 mg/mL)	98.5	102.3	97.6
K-EDTA (10.8 mg/mL)	103.8	105.8	99.4

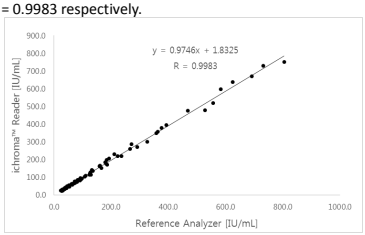
- **Precision**
  - Between lot
    One person tested three different lots of **ichroma™ ASO,** ten times at each concentration of the control standard.
  - Between person
    Three different persons tested **ichroma™ ASO,** five times at each concentration of the control standard.
  - Between day
    One person tested **ichroma™ ASO** during three days**,** five times at each concentration of the control standard.
  - Between site
    One person tested **ichroma™ ASO** at three different site, five times at each concentration of the control standard.

ASO	Between lot		Between person		Between day		Between site	
[IU/mL]	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)
25	28.5	2.2	27.0	4.4	27.7	5.7	27.0	7.0
187.5	184.1	6.5	168.4	4.8	179.6	5.4	174.6	7.7
500	546.6	1.8	516.0	5.5	537.4	4.7	485.0	10.0

- **Accuracy**
  The accuracy was confirmed by testing with 3 differents lots of **ichroma™ ASO.** The tests are repeated 10 times in each different concentration.

ASO [IU/mL]	Lot 1	Lot 2	Lot 3	AVG	SD	CV (%)	Bias (%)
25	27.4	27.2	27.7	27.4	0.2	0.9	9.6
187.5	185.2	161.5	171.9	172.8	11.9	6.9	-7.8
500	515.7	432.9	518.6	489.1	48.7	9.9	-2.2

- **Comparability**
  ASO concentrations of 100 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=0.9746X + 1.8325 and R = 0.9983 respectively.



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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

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