ASO FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-ASO-001

A Fluorescence Immunoassay for the quantitative detection of Anti-streptolysin O (ASO) in human whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda ASO FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Anti-streptolysin O (ASO) in whole blood, serum, or plasma. Anti-streptolysin O (ASO) titre is mainly used to determine whether a previous group A streptococcal infection caused a post-streptococcal disease such as scarlet fever, rheumatic fever, or kidney disease called glomerulonephritis.

BACKGROUND

Anti-streptolysin O (ASO or ASLO) is the antibody made against streptolysin O, an immunogenic, oxygen-labile streptococcal haemolytic exotoxin produced by most strains of group A and many strains of groups C and G Streptococcus bacteria. The "O" in the name stands for oxygen-labile; the other related toxin being oxygen-stable streptolysin-S. The main function of streptolysin O is to cause haemolysis (the breaking open of red blood cells)- in particular, beta-haemolysis.
Increased levels of ASO in the blood could cause damage to the heart and joints. In most cases, penicillin is used to treat patients with increased levels of ASO.
When the body is infected with streptococci, it produces antibodies against the various antigens that the streptococci produce. ASO is one such antibody. A raised or rising levels can indicate past or present infection. Historically it was one of the first bacterial markers used for diagnosis and follow up of rheumatic fever or scarlet fever. Its importance in this regard has not diminished.
Since these antibodies are produced as a delayed antibody reaction to the above-mentioned bacteria, there is no normal value. The presence of these antibodies indicates an exposure to these bacteria. However, as many people are exposed to these bacteria and remain asymptomatic, the mere presence of ASO does not indicate disease.

TEST PRINCIPLE

The ASO FIA Rapid Test Device detects ASO based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains ASO, it attaches to the fluorescence microspheres-conjugated ASO antigen. Then the complex will be captured by the capture antigens coated on the nitrocellulose membrane (Test line). The concentration of ASO in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of ASO in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show ASO concentration in specimen.

REAGENTS

The test include ASO antigen coated fluorophore and ASO antigen coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Extremes in humidity and temperatures can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda ASO FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT CONTENTS

- 25 x Foil wrapped ASO test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (ASO)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

For Venipuncture Specimens

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage keep below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger-prick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Citrate sodium, and Oxalate potassium can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode.

Standard Test mode is a 'set and forget' method where the test will automatically be read after 15 minutes.

Quick Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then select the test mode and/or sample type according to testing needs.
2. Insert the ID card provided with the kit into the analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. Follow the appropriate steps below for the chosen specimen type:
   For venipuncture whole blood/serum/plasma specimens:
   i. Pipette **10 µl of whole blood/serum/plasma** into the buffer tube.
   ii. Close the tube cap and shake the tube for approximately **10 seconds**

to mix the specimen and dilution buffer well.

iii. Let the diluted specimen homogenise for approximately 1 minute. Diluted specimens should be used as soon as possible.

iv. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test cassette. Start the timer at the same time.

For finger-prick whole blood specimens:

i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.

ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.

iii. Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.

iv. Gently apply pressure from the palm to the pricked finger so a rounded drop of blood forms over the puncture site.

v. Using the provided capillary dropper and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 10 µl), *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then add to the specimen well (S) of the test cassette. Start the timer.

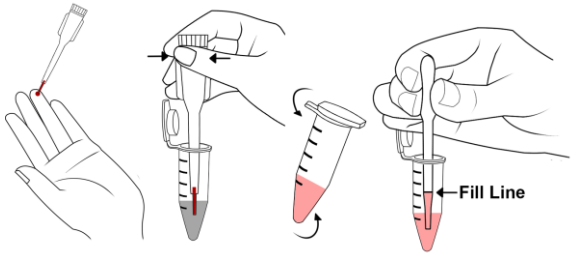

Figure 1

5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

Results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyser screen. For additional information, please refer to the analyser user manual.

Linearity range of the Biopanda ASO FIA Rapid Test is 25-800 IU/mL.

QUALITY CONTROL

Each FIA Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS OF THE TEST

1. The Biopanda ASO FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of ASO.
2. The test will only indicate the presence of ASO in the specimen and should not be used as the sole criterion for cancer diagnosis.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The test results are based on measuring the levels of ASO in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Detection Group	Reference Value	
	Normal	Elevated
Children under 5	<100 IU/mL	>100 IU/mL
Adults	<200 IU/mL	>200 IU/mL

Note: Due to differences in geography, race, environment, gender, etc., each laboratory should establish its own reference interval.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤±15%.
2. **Analytical sensitivity**
   The ASO FIA Rapid Test Device can detect levels of ASO as low as 25IU/mL in whole blood, serum or plasma.
3. **Linearity Range**
   25-800 IU/mL, R≥0.990.
4. **Precision**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 specimens of Anti-streptolysin O (ASO). C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens of Anti-streptolysin O (ASO). C.V. is ≤15%.
5. **Interfering substances**
   The following substances do not interfere with the test results at the indicated concentration: 300mg/L SAA, 200mg/L CRP, 100ng/mL PCT, 10ng/mL IL-6, 20mg/dL bilirubin, 1g/dL haemoglobin, 1000mg/dL triglycerides.
6. **Method comparison**
   The product was evaluated with 80 clinical specimens compared with Commercial ASO device, and the correlation coefficient (r) was 0.972.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's ASO FIA Rapid Test Device kit. Please read this manual carefully before operating to ensure proper use.

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