BoatBIO

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IVD

SAA Rapid Test Kit (Colloidal Gold)

A rapid test for the diagnosis of inflammatory condition by detecting Serum Amyloid A (SAA) qualitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

PRODUCT NAME

SAA Rapid Test Kit(Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The SAA Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human SAA in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions. The cut-off of the test is 10μg/ml.

SUMMARY

Serum amyloid A (SAA) proteins are a family of apolipoproteins associated with high-density lipoprotein (HDL) in plasma. Different isoforms of SAA are expressed constitutively (constitutive SAAs) at different levels or in response to inflammatory stimuli (acute phase SAAs). These proteins are produced predominantly by the liver. The conservation of these proteins throughout invertebrates and vertebrates suggests that SAAs play a highly essential role in all animals. Acute-phase serum amyloid A proteins (A-SAAs) are secreted during the acute phase of inflammation. These proteins have several roles, including the transport of cholesterol to the liver for secretion into the bile, the recruitment of immune cells to inflammatory sites, and the induction of enzymes that degrade extracellular matrix. Serum amyloid A (SAA) is also an acute phase marker that responds rapidly. Similar to CRP, levels of acute-phase SAA increase within hours after inflammatory stimulus, and the magnitude of increase may be greater than that of CRP. Relatively trivial inflammatory stimuli can lead to SAA responses. It has been suggested that SAA levels correlate better with disease activity in early inflammatory joint disease than do ESR and CRP. Although largely produced by hepatocytes, more recent studies show that SAA is produced by adipocytes as well, and its serum concentration is associated with body mass index.

PRINCIPLE

The SAA Rapid Test is a qualitative, solid phase, two-site sandwich immunoassay for the detection of serum amyloid A protein in whole blood, serum or plasma. The membrane is pre-coated with anti-SAA antibodies on the test line region of the cassette. During testing, SAA, if present in the whole blood, serum or plasma specimen reacts with the colored particles coated with anti-SAA antibodies. The SAA-Conjugate complex migrates upward on the membrane chromatographically by capillary action to react with anti-SAA antibodies in the Test line region on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

- Test cassettes
- Package insert
- Plastic tubes with buffer
- Capillaries
- Droppers

Materials Required but Not Provided

- Timer
- Specimen collection containers
- Centrifuge
- Lancets

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

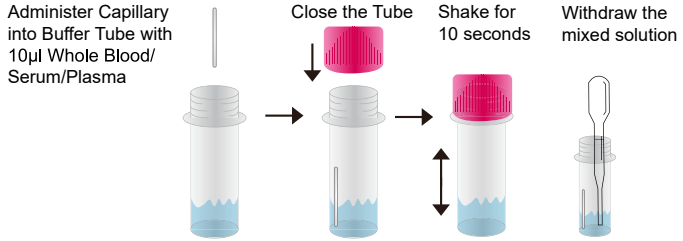
SPECIMEN COLLECTION AND PREPARATION

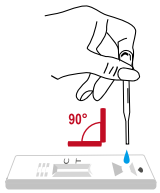
Preparation
Before performing the test, please make sure that all components are brought to room temperature (15-30°C).
1.Take a tube with buffer solution out of the kit. Document patient's name or ID on it. Unscrew the cap.
Sample Collection
2.Collect the specimen according to standard procedures.
- 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, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
- 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.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants. The specimens collected with these anti-coagulants also need to follow the same step of dilution with buffer..

Sample Dilution / Sample Stability
3.Administer the blood-filled end-to-end capillary into the plastic tube with dilution buffer. Alternatively, the 10μL of specimen can be added directly with the micro pipette into the buffer
4.Close the tube and shake the sample vigorously for approximately 10 seconds to mix specimen and dilution buffer well.
5.Allow the diluted sample to homogenize for 1 minute. Do not shake it during this time.
6.The sample can then be used immediately or stored for up to 8 hours.

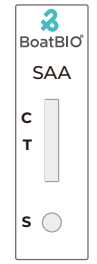
DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use
1.Remove the Test Cassette from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
2.Open the tube of the diluted sample .Transfer 3 drops of diluted sample (approximately 120 μL)to sample well. Start the timer.
3.Wait for the colored lines to appear. The result should be read at 5 minutes. Do not interpret the results after 10 minutes.





3 drops of Diluted Sample



Postive

Negative

Invalid

INTERPRETATION OF RESULTS

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of SAA antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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.

QUALITY CONTROL

Internal procedural controls are included in the test. Control line appearing in the control regions is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1.The SAA Rapid Test is for professional in vitro diagnostic use, and should only be used for the qualitative detection of serum amyloid A protein.
2.The SAA Rapid Test will only indicate the presence of serum amyloid A protein in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3.As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4.A faint line may appear, when the concentration of Serum Amyloid A protein in the specimen is close to 10μg/ml.
This SAA Test is deigned to work with hematocrit level between 25% and 65%.

Performance of this test kit at a different hematocrit level can lead to erroneous results.

EXPECT VALUE

The normal level of SAA in human blood specimens is less than 10μg/ml.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Overall Accuracy

The SAA Rapid Test was compared with leading commercial immunoturbidimetry (ITM) tests; the results show that SAA Rapid Test has a high sensitivity and specificity.

Method		EIA Test		Total Results
SAA Rapid Test	Results	Positive	Negative	
	Positive	97	4	101
	Negative	2	233	235
Total Results		99	237	336

Relative Sensitivity: 98.0% (97.5%CI*: 92.9%-99.8%) *Confidence Intervals
Relative Specificity: 98.3% (95%CI*: 95.7%-99.5%)
Accuracy: 98.2% (95%CI*: 96.2%-99.3%)

Analytical Sensitivity (Detection Limitation)

The SAA Rapid Test can detect out Serum Amyloid A protein as low as 10μg/ml.

Intra-Assay

Within-run precision has been determined by using 3 replicates of the specimens containing negative, 10μg/ml SAA, 40μg/ml SAA and 100μg/ml SAA standard sample. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same specimens of negative, 10μg/ml SAA, 40μg/ml SAA and 100μg/ml SAA standard sample in 3 independent assays. Three different lots of the SAA Rapid Test has been tested over a 3-days period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The SAA Rapid Test has been tested by C-reactive protein, HBsAg, anti-HIV, anti-HCV, anti-Syphilis, Rheumatoid factor (RF), anti-H. Pylori, anti-CMV IgG, anti-Rubella IgG and anti-TOXO IgG positive specimens. The results showed no cross-reactivity

Interfering Substances

The following potentially interfering substances were added to SAA negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200 mg/dL
Bilirubin: 1g/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL
Hemoglobin 1000mg/dL
Oxalic Acid: 60mg/dL

None of the substances at the concentration tested interfered in the assay.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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