

**Serum amyloid A1 (SAA1)** is a protein that in humans is encoded by the SAA1 gene. SAA1 is a major acute-phase protein mainly produced by hepatocytes in response to infection, tissue injury and malignancy. When released into blood circulation, SAA1 is present as an apolipoprotein associated with high-density lipoprotein (HDL). SAA1 is a major precursor of amyloid A (AA), the deposit of which leads to inflammatory amyloidosis.

Serum amyloid A (SAA) and C reactive protein (CRP) are the most sensitive acute phase proteins in plasma. Plasma concentrations of these proteins increase up to 1000-fold of their physiological levels in response to inflammation. In plasma both SAA and CRP are believed to be derived mostly from the liver. Hepatocytes secrete these proteins by the induction of inflammation related cytokines such as tumour necrosis factor  $\alpha$ , interleukin 1, and interleukin 6. Although some differences in cytokine regulation by hepatocytes has been noted between SAA and CRP, clinical observations suggest that plasma concentrations of these two proteins are highly correlated with each other in most inflammatory diseases.

## Anti-Human SAA1 Monoclonal Antibodies

Anti-SAA1 monoclonal antibody has been developed for five years, which could be used in development of immunoassays for human serum amyloid A1. All the antibodies were evaluated in CUSAg in-house colloidal gold immunochromatographic assay and latex enhanced immunoturbidimetric assay, respectively.

PROPERTIES	SPECIFICATION
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human serum amyloid A1
Purification method	Protein G affinity chromatography
Purity	>90% (SDS-PAGE)
Presentation	MAb solution in NaCl with 15 mM NaN <sub>3</sub> (pH 7.2)
Application	LFIA, LETIA
Catalog Number	CSB-DA118BmN② CSB-DA118BmN⑤

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## 1 Calibration Curve

### I. LFIA platform

A set of SAA1 calibrators with the concentration of 0, 0.5, 2, 10, 20, 50, 100 and 200 mg/L was detected on CUSAg LFIA platform using two anti-SAA1 monoclonal antibodies. The capture antibody was stripped on the nitrocellulose membrane, and the detection antibody was conjugated to colloidal gold. The best selected MAb combination for the development of semi-quantitative human SAA1 immunoassays is (capture-detection):

CSB-DA118BmN② - CSB-DA118BmN⑤

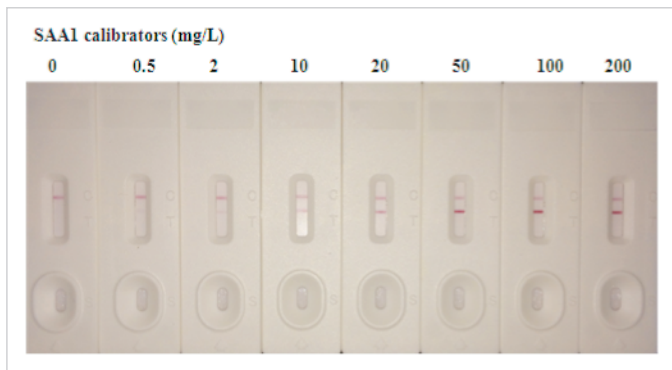


Fig.1 Semi-quantitative detection of SAA1 protein in colloidal gold immunochromatographic assay

### II. LETIA platform

SAA1 antigens specifically react with anti-human SAA1 monoclonal antibodies which were precoated on latex beads, resulting in agglutination and increase in turbidity. The calibration curve was fitted according to the relationship between absorbance values and SAA1 concentrations.

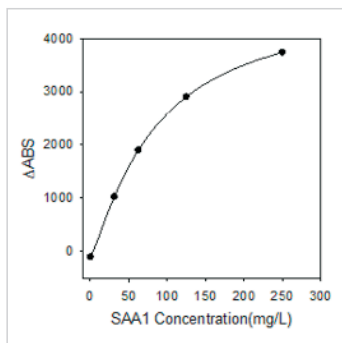


Fig.2 Calibration curve of SAA1 in particle-enhanced turbidimetric immunoassay

## 2 Clinical Comparison

### I. LFIA platform

28 samples from apparently healthy donors and patients with acute or chronic inflammation were detected with the CUSAg LFIA SAA1 assay. As shown in Fig.3, the detection signals of T line were proportional to the concentration of the SAA1 in the sample tested by commercial kit.

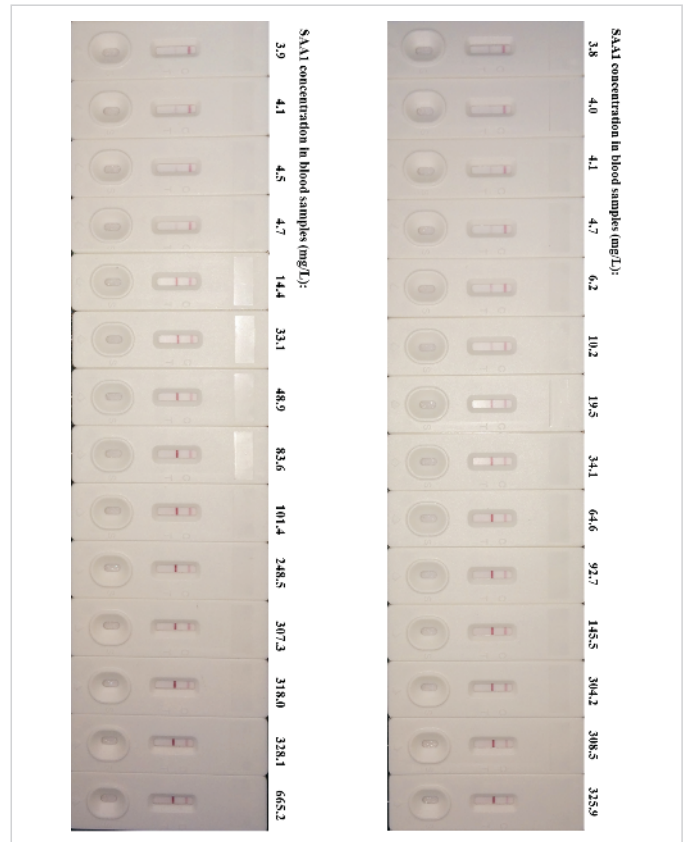


Fig.3 Semi-quantitative detection of the concentration of the SAA1 in the blood samples

### II. LETIA platform

Anti-SAA1 monoclonal antibodies were also evaluated in medium-scale clinical trials with 22 blood samples from donors. Fig.4 showed that the correlation coefficient (r) is as high as 0.93 between in-house latex reagents and commercial SAA1 immunoassay. These results show good agreement between the two systems.

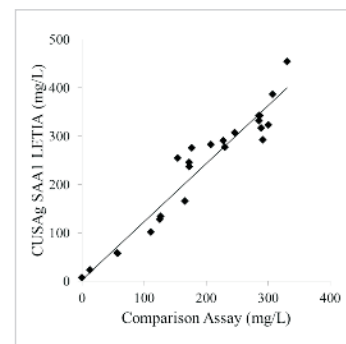


Fig.4 Clinical comparison of CUSAg LETIA immunoassay and commercial immunoassays

## 3 SAA1 protein

A certain amount of excellent SAA1 protein (Catalog Number CSB-DP118B) is also offered, it could be used as calibrator in immunoassay.