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Neutrophil gelatinase-associated lipocalin (NGAL) is a novel early marker of acute kidney injury (AKI) for which it has been shown that it can also be released from the injured myocardium. It is a small protein expressed in neutrophils and in low levels in the kidney, prostate, and epithelia of the respiratory and alimentary tracts.

Under normal conditions NGAL levels are low in urine and plasma but rise sharply within 2 hours from basal levels in response to kidney injury to reach diagnostic levels within a very short time within 24 hours or more before any significant rise in serum creatinine.

Because NGAL is protease resistant and small, the protein is easily excreted and detected in the urine. NGAL levels in patients with AKI have been associated with the severity of their prognosis and can be used as a biomarker for AKI. NGAL can also be used as an early diagnosis for procedures such aschronic kidney disease, contrast induced nephropathy, and kidney transplant.

Anti-Human NGAL Monoclonal Antibodies

A new generation of anti-NGAL monoclonal antibodies, which was recently produced by CUSAg, makes possible the development of highly sensitive immunoassays. CUSAg antibodies are evaluated on different types of platforms e.g. LETIA,LF,MP.

Properties	Specification
Target species	Human
Host animal	Mice Balb/c
Immunogen	Human NGAL
Purification method	Protein G affinity chromatography
Presentation	Mab solution in PBS (pH 7.4)
Application	ELISA, CLIA, LETIA, LFIA and others
Catalog Number	CSB-DA001DmN①
	CSB-DA001AmN①
	CSB-DA001AmN②
	CSB-DA001AmN③

NGAL
NGAL
NGAL

1 Calibration Curve

• CLIA platform

All monoclonal antibodies were tested in pairs as capture and detection antibodies to select the best two-site MAb combinations for the development of a quantitative sandwich immunoassay. Calibration curves for several best two-site combinations are shown in Fig 1(R2 >0.99). The best selected MAb combinations for quantification of human NGAL are (capture-detection respectively):

Mab combination A: CSB-DA001DmN① - CSB-DA001AmN①
Mab combination B: CSB-DA001AmN① - CSB-DA001DmN①
Mab combination C: CSB-DA001AmN② - CSB-DA001DmN①
Mab combination D: CSB-DA001AmN③ - CSB-DA001DmN①

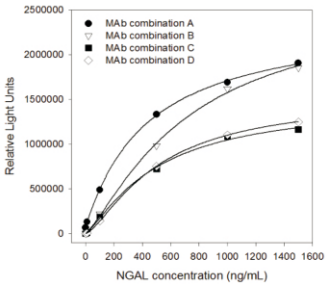


Fig.1 Calibration curves for NGAL in sandwich chemiluminescence immunoassay (CLIA)

• LETIA platform

Anti-human NGAL monoclonal antibodies were also evaluated via CUSAg latex-enhanced immunoturbidimetric assay. A set of NGAL calibrators reacts with specific antibodies coated onto microparticles to form an insoluble complex which can be measured turbidimetrically at a series of different wavelengths (Fig.2).

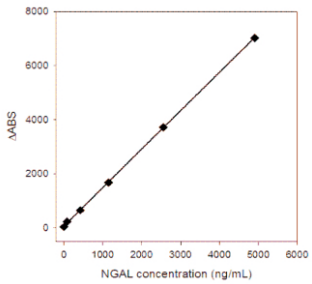
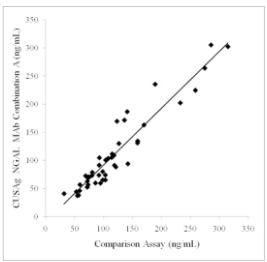
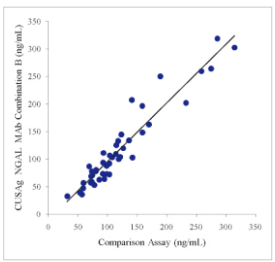


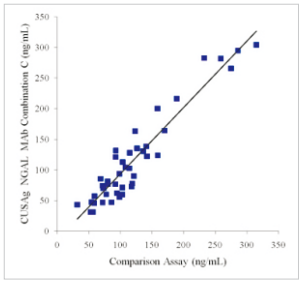
Fig.2 Calibration curve for human NGAL in latex-enhanced immunoturbidimetric assay

2 Clinical Comparison

•A study was performed where 50 specimens were tested using different antibody combinations (A, B, C and D) on the CUSAg CLIA platform and compared to a high-quality comparison assay. Data from this study were analyzed and summarized in the following figure (Fig.3). Results showed the four combinations have correlation coefficients (r) > 0.90.







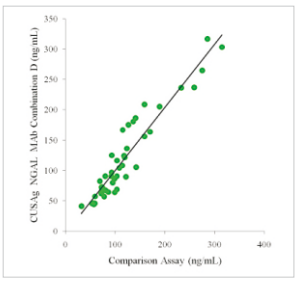


Fig.3 Determination of clinical samples using four MAb combinations on CLIA platform

• In order to meet the application of CUSAg anti-NGAL MAbs on LETIA platform, 40 clinical blood samples were separately tested using mixed MAbs on the CUSAg LETIA platform and compared to a commercial diagnostic kit. The correlation coefficient between the two systems was over 0.90.

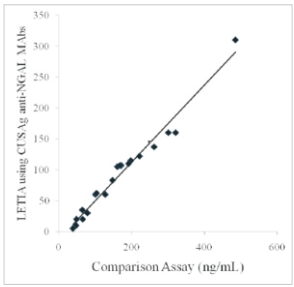


Fig.4 Comparison of CUSAg NGAL LETIA and commercial diagnostic assays

3 Thermal Stability

Our anti-human NGAL monoclonal antibodies presented in PBS buffer without any preservative were stored at -20°C, 2-8°C and 37°C for 15 days, respectively. During this period, the titers of four MAbs were determined per 3 days, respectively. Fig.5 shows the relative titers of the MAbs treated at -20°C or 2-8°C were similar with that at 37°C. All the MAbs were stable from -20 °C to 37°C.

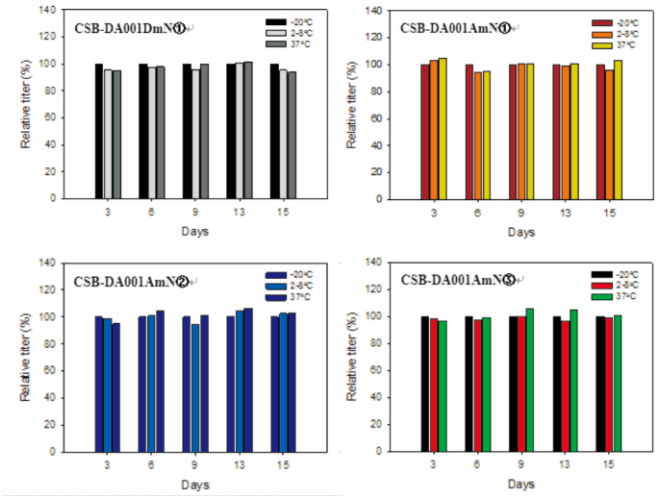


Fig.5 Evaluation of the relative titers of four anti-NGAL MAbs stored at different temperature

NGAL Protein

A certain amount of excellent NGAL protein (Cat: CSB-DP001A) is also offered by CUSAg. It could be used as calibrator in immunoassay and applied on Western Blotting.

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