CYSC

Cystatin-C (CYSC) is a non-glycosylated, low molecular weight, cation protein that is regularly synthesized by most nucleated cells. Cystatin-C is an endogenous protein that is known to be affected little by age, race, and muscle mass. It is not only used as a biomarker of renal function but also has positive associations with obesity, insulin resistance, hypertension, and cardiovascular mortality. Higher levels of serum cystatin-C were associated with increased prevalence of diabetic conditions.

Under normal circumstances, cystatin C in serum is 0.47-1.09 mg/L. When renal function is impaired, cystatin C concentration in blood will change with GFR.
In renal failure, GFR decrease while cystain C concentration in blood can increase more than 10 times. Under normal glomerular filtration rate and renal tubules dysfunction can hinder cystatin C absorption and its rapid decomposition in the renal tubules, increasing its concentration in urine over 100 times.

Anti-Cystatin-C (CYSC) monoclonal antibody

A new generation of anti-CYSC monoclonal antibodies, which was recently produced by CUSAg, makes possible the development of LETIA assay. Anti-CYSC monoclonal antibodies can be used for a broad range CYSC assay, which is a simple, rapid, sensitive and homogeneous assay that can be performed using automated systems for high-throughput immunoassays.

Properties	**Specification**
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human Cystatin-C (CYSC) protein
Purification method, Purity	Protein G affinity chromatography, >90%
Presentation	MAb solution in NaCl with 15 mM NaN_3 (pH 7.2)
Application	LETIA etc.
Catalog Number	CSB-DA004AmN①
	CSB-DA004AmN②

Calibration curve

The human CYSC reacts with the anti-human CYSC antibody-coated latex, resulting in agglutination and increase in turbidity. Turbidity changes are then measured using a spectrometer to quantitatively measure the CYSC concentration in the sample. Fig.1 shows that the absorbance was increasing gradually along with the CYSC concentration.

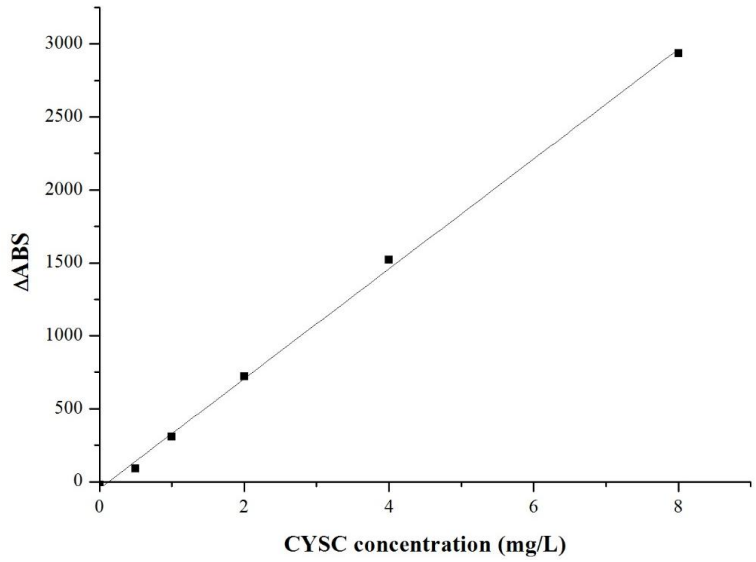

Fig.1 Calibration curve for CYSC LETIA assay

Accuracy

Two levels of CYSC serum were analyzed in replicates of three at two separated time on the CUSAg LETIA assay. Data from this study are summarized in the below table.1, the relative bias was <5%.

Table.1 Accuracy of CYSC reagent

Reagent Lot	Control Target value (mg/L)	Determined Con.(mg/L)			Mean Con. (mg/L)	Bias (%)
1	0.593	0.57	0.56	0.58	0.57	-3.88
2	0.716	0.72	0.67	0.66	0.68	-4.56

Precision

Two members of serum samples based panel were assayed, using a single lot of reagents, in replicates of ten on the CUSAg LETIA assay (from 0.47 to 1.09 mg/L as normal). As shown in table.2, the system shows excellent precision with CV≤5%.

Table.2 Precision profile of CYSC reagent

Panel Member	n	Mean Conc. (mg/L)	SD	%CV
1	10	0.85	0.04	4.24
2	10	6.27	0.02	0.27

Repeated freeze-thaw cycles

Our CUSAg antibodies (CSB-DA004AmN① and CSB-DA004AmN②) were dealt with subsequent freeze-thaw cycles, the number of which is 1 time and 5 times from -20℃ to 20℃, and after that we toke the anti-CYSC antibodies into the reagents on LETIA assay. As shown in Fig.2, the antibodies were stable after 5 times repeated freeze-thaw cycles.

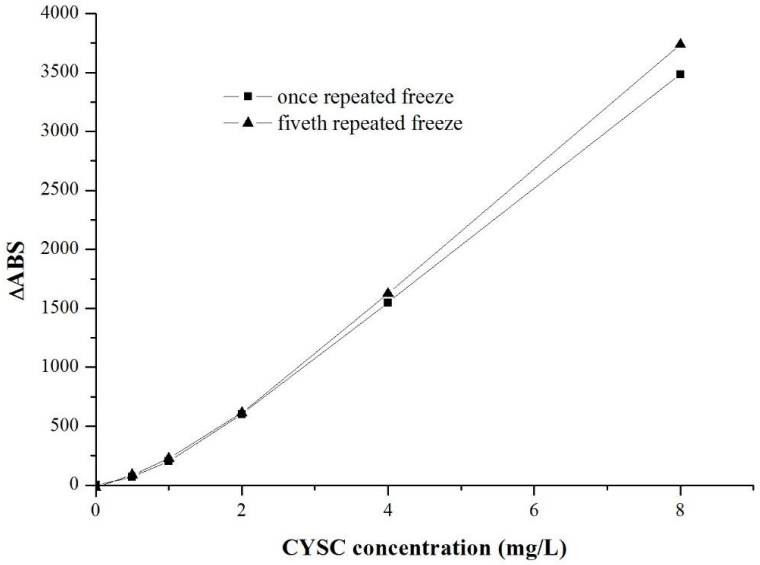

Fig.2 Effect of repeated freeze-thaw on CYSC antibodies

Clinical Comparison

Anti-CYSC monoclonal antibodies were also evaluated in medium-scale clinical trials with random blood samples from donations (n=50). Fig.4 shows that the correlation coefficient (r) is as high as 0.99 between in-house CYSC assay and commercial LETIA assay. These results show good agreement between the two systems.

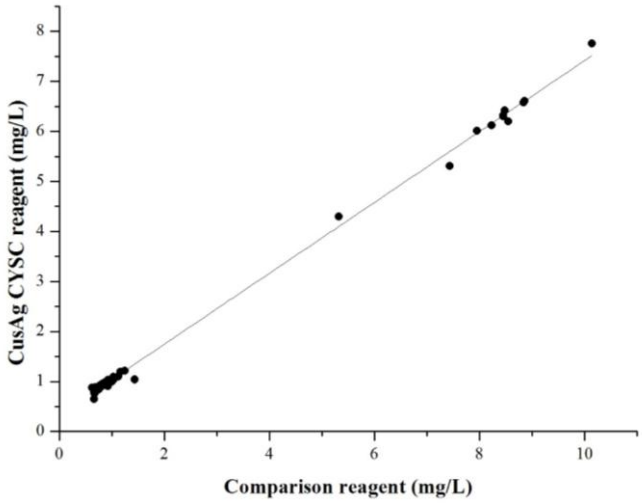

Fig.4 Clinical comparison of in-house CYSC reagent and commercial kit

References

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