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D-Dimer is formed by Plasmin degradation of Factor XIIIa cross-linked Fibrin. D-Dimer is complex of two similar subunit that consists of α, β and γ chain. D-Dimer is a mixture of peptide fragment with different molecular weight, such as DD, DY, XD, XY, DXD, YXD, DXXD.

Elevated D-Dimer levels are a key indicator of thrombotic events, indicating excess fibrinolysis, following activation of coagulation. Its main use is to exclude thromboembolicdisease where the probability is for twenty years at least. In addition, it is used in the diagnosis of the blood disorder disseminated intravascular coagulation.

Anti-D-Dimer monoclonal antibodies

Two latest anti-D-Dimer monoclonal antibodies have been developed by CUSAg. On the LETIA and LFIA, multiple clinical samples have been respectively tested by self-made anti-D-Dimer antibody and high-quality kit, the results had good correlation between them. This product can be used for IVD assay development.

PROPERTIES	SPECIFICATION
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human D-Dimer
Purification method, purity	Protein G affinity chromatography, >90%(SDS-PAGE)
Presentation	MAb solution in Nacl with 15 mM NaN_3 (pH 7.2)
Application	LETIA, LFIA and other possible application
Catalog Number	CSB-DA220HmN①
	CSB-DA220HmN②

Note: Product contains sodium azide as a preservative. Although the amount of sodium azide is very small, appropriate care must be taken when handling this product.

1 Linearity

A.LETIA

The human D-Dimer reacts with the anti-human D-Dimer antibody-coated latex, resulting in agglutination and increase in turbidity.Turbidity changes are then measured by using a spectrometer to quantitatively measure the D-Dimer concentration in the sample. The linear relationship is shown in Figure 1. The linear range is about 30 μg/mL.

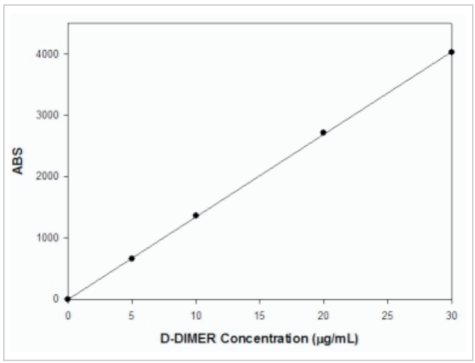

Fig.1 Calibration curve for D-Dimer

B.LFIA

The calibrator were spiked with human D-Dimer at 0,1,2,4,10,20 and 30 μg/mL in saline buffer . The D-Dimer test requirements consists of a pad containing monoclonal anti-D-Dimer antibodies conjugated to colloidal gold, a nitrocellulose strip containing a test line which contains monoclonal anti-D-Dimer antibodies, and a control line which contains polyclonal anti-mouse IgG antibodies. The best selected MAb combinations for the development of quantitative human D-Dimer immunoassays are (capture-detection) respectively:

CSB-DA220HmN②-CSB-DA220HmN①

No prozone hook effect was observed up to 30 μg/mL.

2 Clinical analysis

A.LETIA

An amount of samples from donors (n=51) were respectively detected by the high-quality kit and D-Dimer LETIA . The results had good correlation between D-Dimer between CUSAg D-Dimer LETIA assays and other comparison kits, and the sensitivity reached to 0.2 μg/mL.

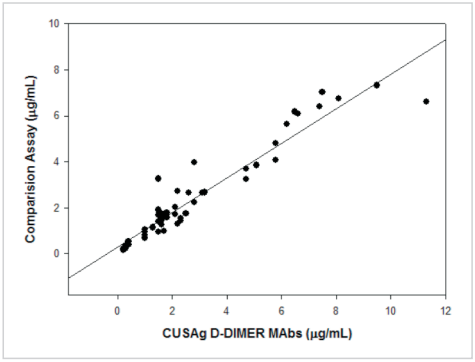

Fig.2 Comparison between D-Dimer LETIA and diagnostic kit

B.LFIA

50 samples from donors were quantitatively tested with the comparison kit. The quantitative assays for the detection of D-Dimer were developed in house. There was good correlation between the high-quality comparison kit and immunoassay using CUSAg anti-D-Dimer antibodies for the 50 samples, and the sensitivity reached to 0.2 μg/mL.

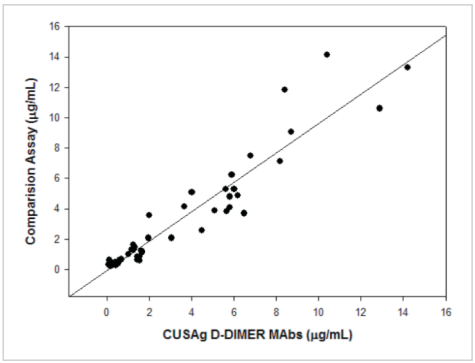

Fig.3 Comparison between D-Dimer LFIA and diagnostic kit

References

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