Human Epididymis Secretory Protein E4 （HE4）

Human epididymis secretory protein E4 （HE4）is a protein in humans that is encoded by the WFDC2 gene.This gene encodes a protein that is a member of the WFDC domain family. The WFDC domain contains eight cysteines forming four disulfide bonds at the core of the protein, and functions as a protease inhibitor in many family members. This gene is expressed in pulmonary epithelial cells, and was also found to be expressed in some ovarian cancers.

HE4 is a serum biomarker to aid in differentiating benign and malignant disease in women with a pelvic mass.Serum HE4 levels are relatively stable across the menstrual cycle of reproductive aged women and can be determined on any day to evaluate risk of ovarian malignancy.

HE4 is a tumor marker of ovarian cancer.It has important clinical significance in the early diagnosis, monitoring and prognosis evaluation of treatment, also brings more powerful basis for early ovarian cancer detection.

Anti-Human HE4 Monoclonal Antibody

A new generation of anti-HE4 monoclonal antibodies, which was recently produced by CUSAg, makes possible the development of highly sensitive and rapid sandwich immunoassays. The sensitivity and specificity of anti-HE4 monoclonal antibodies have been repeatedly tested by chemiluminescence immunoassay(CLIA).Our in-house assays have a linear detection range from 2.3 to 1400 pmol/L. All recommended MAb combinations were evaluated in medium-scale clinical trials with blood samples.

PROPERTIES	SPECIFICATION
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human HE4
Purification method, Purity	Protein G affinity chromatography，＞90% (SDS-PAGE)
Presentation	MAb solution in PBS (pH 7.4)
Application	Chemiluminescence immunoassay(CLIA)
Catalog Number	CSB-DA018BmN①；CSB-DA018BmN②；CSB-DA018BmN③

Calibration Curve

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 two best two-site combinations are shown in Fig.1(R^2 >0.99). The best selected MAb combinations for quantification of human HE4 are (capture-detection respectively):

Mab combination A: CSB-DA018BmN②- CSB-DA018BmN③

Mab combination B: CSB-DA018BmN③- CSB-DA018BmN①

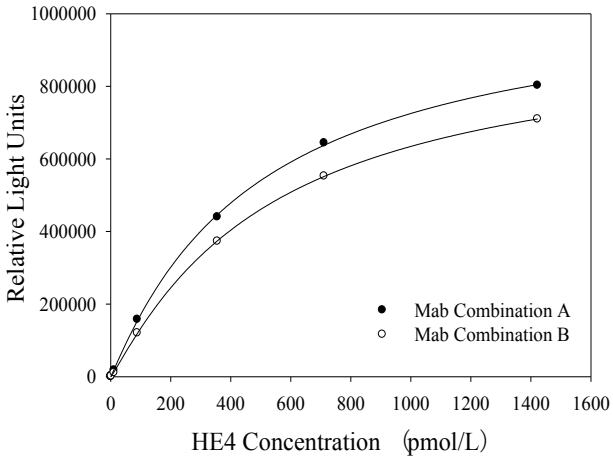

Fig.1 Calibration curves for HE4 in sandwich chemiluminescence immunoassay (CLIA)

Precision

Two levels of HE4 controls were analyzed in replicates of ten using our anti-HE4 monoclonal antibodies on the CUSAg CLIA platform. Data from this study are summarized in the following table, the relative bias was <10%.

Pairs	Control	n	Mean Conc. (pmol/L)	SD	CV (%)
A	Control Low	10	9.22	0.61	6.6
	Control High	10	547.64	33.95	6.2
B	Control Low	10	10.14	0.53	5.2
	Control High	10	592.44	46.55	7.8

Recovery

The known concentration of HE4 was determined using the CUSAg CLIA platform and the resulting recovery percentage was calculated. The recovery percentage mean values of the HE4 immunoassays using two MAb combinations were 103.2% and 102.1%, respectively.

Clinical Comparison

A study was performed where 40 specimens were tested using two antibody combinations on the CUSAg CLIA platform and compared to a high-quality comparison assay. Data from this study is analyzed and summarized in the following figure (Fig.2).These results reveal CUSAg MAb combinations can be applied on double-MAb-sandwich-immunoassays.

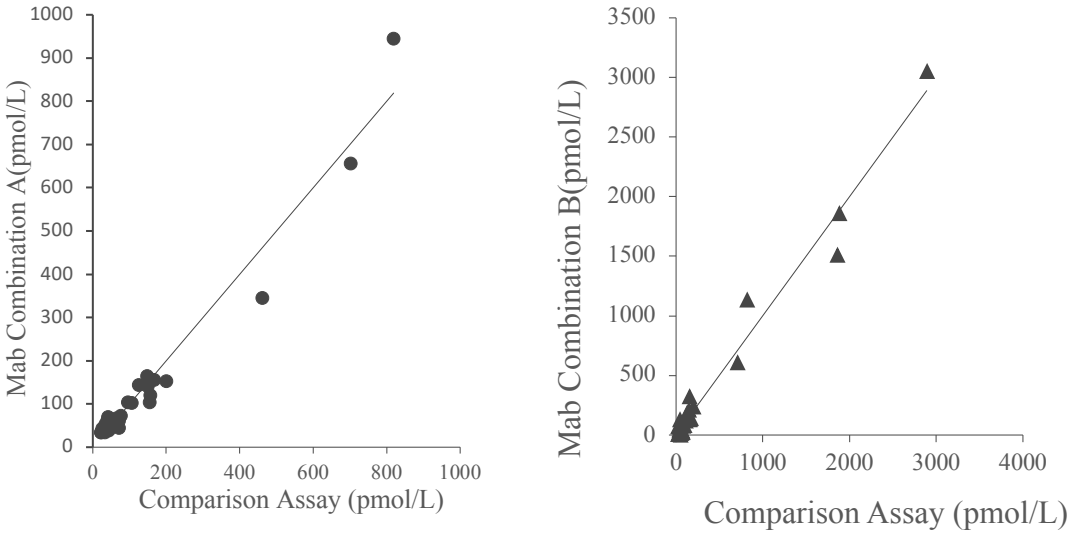

Fig.2 Determination of clinical samples using two MAb combinations on CLIA platform

HE4 Protein

A certain amount of excellent HE4 protein (Cat: CSB-DP018B) is also offered by CUSAg. It could be used as calibrator in immunoassay and applied on Western Blotting.

References

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