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Alpha-fetoprotein (AFP) has been widely used as a diagnostic marker. AFP is a plasma protein produced by the yolk sac and the liver during fetal development. It is thought to be the fetal form of serum albumin. In pregnant women AFP levels can be measured from urine, maternal blood or amniotic fluid. It is used as part of a screening test for various developmental abnormalities in which AFP will be elevated.

AFP parts into the maternal blood circulation through amniotic fluid.In maternal amniotic fluid or maternal serum AFP can be used in the prenatal fetal monitoring.AFP may also have increased in amniotic fluid when the intrauterine fetal death, teratoma and other birth defects .

In adults, AFP can rise in about 80% of the patients with liver cancer serum, AFP positive rate was 50% in germ cell tumor, AFP may also appear different degree of increase in patients with pancreatic cancer or lung cancer and liver cirrhosis.Liver cells restore the function of producing the protein when it cancerates.AFP has become a specific clinical index of the diagnosis of primary liver cancer.

Anti-Human AFP Monoclonal Antibody

A new generation of anti-AFP 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-AFP monoclonal antibodies have been repeatedly tested by chemiluminescence immunoassay(CLIA). Our in-house assays have a linear detection range from 20 to 1000 ng/mL. 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 AFP
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-DA214HmN① ; CSB-DA214HmN② ; CSB-DA214HmN③

AFP

1 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 AFP are (capture-detection respectively):

Mab combination A: CSB-DA214HmN③-CSB-DA214HmN①

Mab combination B: CSB-DA214HmN②-CSB-DA214HmN①

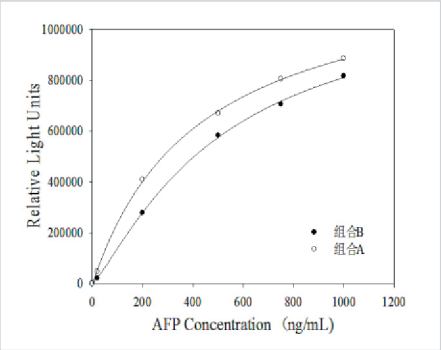

Fig.1 Calibration curves for AFP in sandwich chemiluminescence immunoassay (CLIA)

2 Precision

Two levels of AFP controls were analyzed in replicates of ten using our anti-AFP 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.(ng/mL)	SD	CV(%)
A	Control Low	10	55.01	1.47	2.7
	Control High	10	377.85	30.44	8.1
B	Control Low	10	50.15	2.55	5.1
	Control High	10	338.13	25.94	7.7

3 Recovery

The known concentration of AFP was determined using the CUSAg CLIA platform and the resulting recovery percentage was calculated. The recovery percentage mean values of the AFP immunoassays using two MAb combinations were 100.9% and 100.7%, respectively.

4 Clinical Comparison

A study was performed where 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.

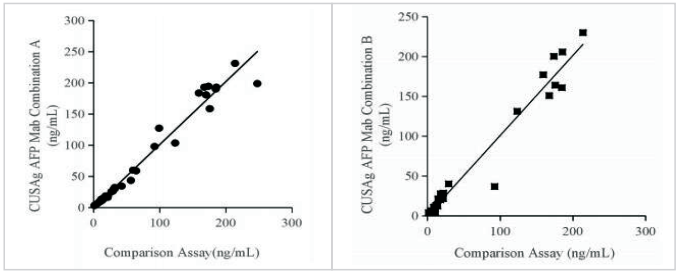

Fig.2 Determination of clinical samples using two MAb combinations on CLIA platform

AFP Protein

A certain amount of excellent AFP protein (Cat: CSB-DP214C) is also offered by CUSAg. It could be used as calibrator in immunoassay and applied on Western Blotting.

References

1. A Portable Immunosensor with Differential Pressure Gauges Readout for Alpha Fetoprot-ein Detection. Sci Rep. 2017 Mar 24;7:45343.

2. Cheng J, Wang W, Zhang Y， et al. Prognostic Role of Pre-Treatment Serum AFP-L3% in Hepatocellular Carcinoma: Systematic Review and Meta-Analysis.PLoS One. 2014 Jan 30;9(1)

3. Lim TS, Kim do Y, Han KH, Kim HS， et al. Combined use of AFP, PIVKA-II, and AFP-L3 as tumor markers enhances diagnostic accuracy for hepatocellular carcinoma in cirrhotic patients.Scand J Gastroenterol. 2016 Mar; 51(3):344-53.

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