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Follicle-stimulating hormone (FSH) is a gonadotropin, a glycoprotein polypeptide hormone. FSH is synthesized and secreted by the gonadotropic cells of the anterior pituitary gland, and regulates the development, growth, pubertal maturation, and reproductive processes of the body. FSH and luteinizing hormone (LH) work together in the reproductive system.

In both males and females, primary hypogonadism results in an elevation of basal follicle-stimulating hormone (FSH) and luteinizing hormone (LH) levels. FSH and LH are generally elevated in: primary gonadal failure, complete testicular feminization syndromes and menopause. FSH and LH are both decreased in failure of the pituitary or hypothalamus.

Anti-Human FSH Monoclonal Antibodies

A new generation of anti-FSH 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-FSH monoclonal antibodies have been repeatedly tested by chemiluminescence immunoassay (CLIA).Our in-house assays have a linear detection range from 0.32-200 mIU/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 follicle-stimulating hormone
Purification method,Purity	Protein G affinity chromatography,>90%(SDS-PAGE)
Presentation	MAb solution in PBS(pH 7.6)
Application	CLIA, LFIA
Catalog Number	CSB-DA443BmN①
	CSB-DA443BmN②

FSH
FSH
FSH

1 Calibration Curve

All MAbs 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 curve for the best two-site combination is shown in Fig.1. Detection antibodies were labeled with horse reddish peroxidase (HRP) and capture antibodies were coated onto 96-microwell plate. The best selected MAb pair for human FSH immunoassays is (capture-detection respectively):

CSB-DA443BmN① - CSB-DA443BmN②

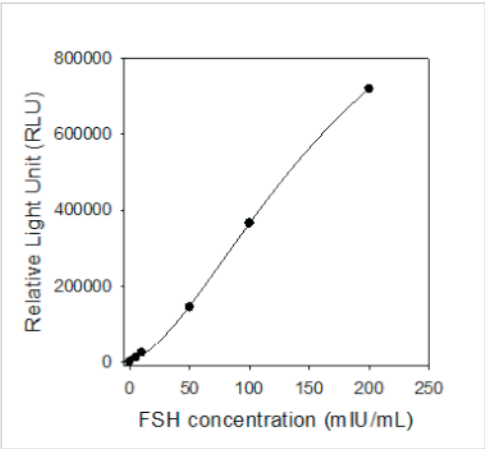

Fig.1 Calibration curve for FSH sandwich chemiluminescence immunoassay (CLIA)

2 Precision

A two member buffered protein based panel was assayed, using a single lot of reagents, in replicates of ten at two separate times on the CUSAg CLIA platform. As shown in table 1, the system showed excellent precision with Cv≤10%.

Panel	n	Mean Conc. (mIU/mL)	SD	%CV
Control 1	10	5.61	0.54	9.6
Control 2	10	64.93	5.42	8.3

3 Recovery

Known concentrations of FSH were added to five aliquots of human serum. The concentration of FSH was determined and the resulting percent recovery was calculated. The recovery percentage mean value of the FSH immunoassay using CUSAg FSH MAb was 104.0%.

4 Clinical Comparison

72 clinical blood samples were separately tested on the CUSAg CLIA platform and compared to a diagnostic kit from Siemens. Data from this study were analyzed using the Passing-Bablok regression method and are summarized in the following table and scatter plot. Results reveal good agreement between CUSAg immunoassay and comparison assay.

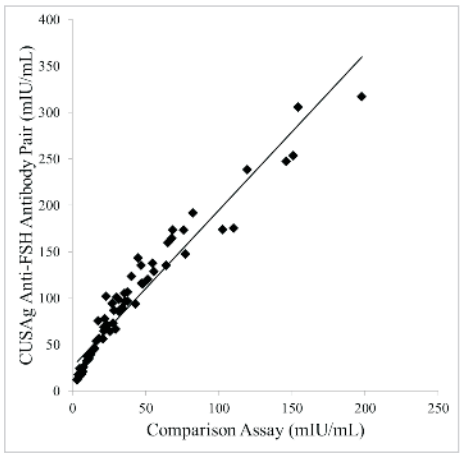

Fig.2 Clinical comparison of CUSAg FSH assay and commercial diagnostic assay

5 FSH protein

A certain amount of excellent FSH protein (Catalog Number : CSB-DP443I) is also offered, it could be used as calibrator in immunoassay.

References

1.Pierce, J G; Parsons, T F (June 1981). "Glycoprotein Hormones: Structure and Function". Annual Review of Biochemistry. 50 (1): 465–495

2.Jiang X, Liu H, Chen X, Chen PH, Fischer D, Sriraman V, Yu HN, Arkinstall S, He X (July 2012). "Structure of follicle-stimulating hormone in complex with the entire ectodomain of its receptor". Proc Natl Acad Sci U S A. 109 (31): 12491–6.

3.Häggström, Mikael (2014). "Reference ranges for estradiol, progesterone, luteinizing hormone and follicle-stimulating hormone during the menstrual cycle". WikiJournal of Medicine. 1 (1)

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