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Prolactin (PRL), also known as luteotropic hormone or luteotropin, is an hormone formed by a 199aa mature chain consisting of three disulfide bonds. Prolactin is secreted from the pituitary gland in response to eating, mating, estrogen treatment, ovulation, and nursing. Prolactin is secreted in a pulsatile manner between these events. Prolactin also plays an essential role in metabolism, regulation of the immune system, and pancreatic development.

In normal individuals,prolactin concentrations increase in response to physiologic stimuli such as sleep, stress, exercise, sexual intercourse, and hypoglycemia, and are also elevated during pregnancy, lactation, postpartum, and in the newborn infant. Though, prolactin levels are found elevated ven in non-pregnant and non-breastfeeding woman, or in male. The most common cause is a prolactinoma, a usually benign (not cancerous) prolactin-producing tumor of the pituitary gland.

The prolactin test may be used as part of a work-up for irregular menstrual periods, fertility problems, some types of thyroid or adrenal gland dysfunction, anorexia, and polycystic ovarian syndrome. Prolactin tests were also used to diagnose, or monitor treatment of prolactinoma. Symptoms of a prolactinoma include headaches, vision problems (if tumor growth is causing pressure on an the optic nerve), and galactorrhea (milk production outside pregnancy or breastfeeding, or in a male).

Anti-Human Prolactin Monoclonal Antibodies

A new set of excellent anti-prolactin monoclonal antibodies, which was recently produced by CUSAg, makes possible the development of highly sensitive sandwich immunoassays. Our in-house assays have a linear detection range from 0.25 to 200 ng/mL. All recommended MAb combinations were evaluated in large-scale clinical trials with serum specimens, which were detected in ARCHITECT Prolactin assay.

Properties	Specification
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human purified prolactin
Purification method	Protein G affinity chromatography
Presentation	MAb solution in PBS(pH 7.4)
Application	CLIA and others
Catalog Number	CSB-DA320ImN① CSB-DA320ImN② CSB-DA320ImN③

PRL PRL

PRL

1 Calibration Curve

All monoclonal antibodies were tested in pairs as capture and detection antibodies to filtrate the best two-site MAb combinations for the development of a quantitative sandwich immunoassay. Calibration curves for several best two-site combinations are shown in Fig.1. Detection antibodies were labeled with horse reddish peroxidase (HRP). The best selected MAb combinations for quantification of human prolactin are (capture-detection respectively):

Mab combination A：CSB-DA320ImN①-CSB-DA320ImN②

Mab combination B：CSB-DA320ImN①-CSB-DA320ImN③

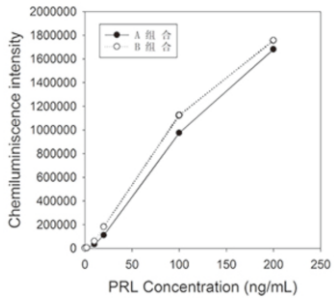

Fig.1 Calibration curves for prolactin in sandwich chemiluminescence immunoassay (CLIA)

2 Precision

In order to ensure the qualities of PRL monoclonal antibodies, three batches of MAbs were evaluated via microplate-chemiluminescent immunoassays. The precisions of two CUSAg CLIA PRL assays are all ≤5% in intra assays and ≤10% in inter assays. Data from these tests are summarized in the following table.

MAB combinations	Control	Intra assay (n=10)			Inter assay (n=30)		
		Mean Conc. (ng/mL)	SD	%CV	Mean Conc. (ng/mL)	SD	%CV
Combinations A	Control Low	4.52	0.34	7.6	4.43	0.41	9.3
	Control High	49.05	1.09	2.2	48.95	1.5	3.1
Combinations B	Control Low	4.61	0.21	4.5	4.71	0.35	7.4
	Control High	49.31	1.67	3.4	50.25	1.93	3.8

3 Recovery

Known concentrations of PRL were added to five aliquots of human serum. The concentration of PRL was determined using the CUSAg CLIA platform and the resulting percent recovery was calculated. The recovery percentage mean values of the PRL immunoassays using two MAb combinations were 99.7% and 97.6% respectively.

4 Clinical Comparison

80 clinical blood samples were separately tested using MAb combination A and B on the CUSAg CLIA platform and compared to a diagnostic kit from Beckman Coulter. 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 immunoassays and comparison assays.

Regression Method	Passing-Bablok regression
Slope	0.94
Intercept	-1.76
Correlation Coefficient (r)	0.98
Number of samples	80

Regression Method	Passing-Bablok regression
Slope	0.92
Intercept	-1.15
Correlation Coefficient (r)	0.97
Number of samples	80

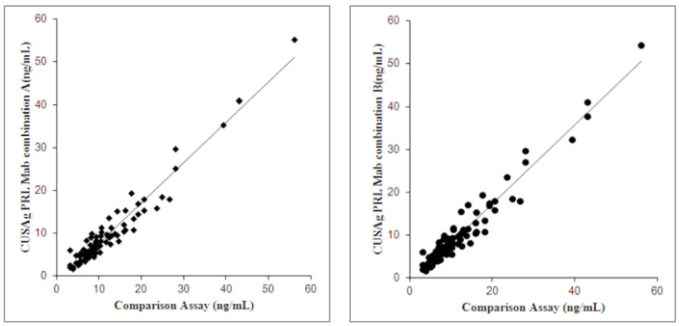

Fig.2 Clinical comparison of CUSAg prolactin immunoassays and Access Prolactin

Prolactin protein

PRL is a protein that in humans is encoded by the PRL gene which encodes a 28-aa signal peptide and a 199-aa mature chain. After SDS-PAGE in reducing conditions, PRL is presented by a single band with apparent molecular mass of 27kDa .

References

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WUHAN HUAMEI BIOTECH CO.,LTD ◎ CUSAg IVD RAW MATERIALS DIVISION

ADDR: No.818 Gaoxin Avenue, Wuhan Hi-tech Medical Devices Park, Donghu High-tech Development Zone 430206, Wuhan City, Hubei Province, P.R. China.

TEL: +86-27-87196282 Ext.837/853 **FAX:** +86-27-87196150

EMAIL:cusag@cusag.cn **WEB:** www.cusag.org