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Insulin-like growth factor-binding protein-1(IGFBP-1) is synthesized and secreted by fetal or adult liver cells and decidualized endometrial cells during pregnancy.

In maternal circulation, the concentration of IGFBP-1 increases after pregnancy, and IGFBP-1 is a major protein from the beginning of the second trimester to childbirth in amniotic fluid.

Premature rupture of fetal membranes (PROM) refers to rupture of fetal membranes before onset of labor. In perinatal period, PROM is relatively common complication as its occurrence rate is about 10%. PROM may cause serious consequences such as increased risk of preterm delivery rates, perinatal mortalityand intra-amniotic infection.

IGFBP-1 is a highly sensitive biomarker for early diagnosis of PROM. IGFBP-1 could be sensitively detected in vaginal fluid after the leakage of tiny amounts of amniotic fluid as the concentration of IGFBP-1 in amniotic fluid is 100 to 1000 fold higher compared to that in human blood.

Anti-IGFBP-1 monoclonal antibodies

CUSAg provides new antibodies for IGFBP-1 assay design.The sensitivity and specificity of anti-IGFBP-1 monoclonal antibodies have been repeatedly tested by gold immunochromatography assay (GICA).

Properties	Specification
Target species	Human
Host animal	Mice Balb/c
Cell line used for fusion	Sp2/0
Immunogen	Human IGFBP-1
Purification method, purity	Protein G affinity chromatography, >90%
Presentation	MAb solution in NaCl with 15 mM NaN_3 (pH 7.2)
Application	Gold immunochromatography assay (GICA)
Catalog Number	CSB-DA286GmN①
	CSB-DA286GmN②

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

The calibrator were spiked with human IGFBP-1 at 0, 10, 20, 50, 100, 200 and 500 ng/mL in saline buffer. The IGFBP-1 test requirements consists of a pad containing monoclonal anti-hIGFBP-1(CSB-DA286GmN①)antibodies conjugated to colloidal gold, a nitrocellulose strip containing a test line which contains monoclonal anti-hIGFBP-1 antibodies(CSB-DA286GmN②) , and a control line which contains polyclonal anti-mouse IgG antibodies. The minimal detection limit of CUSAg GICA IGFBP-1 assay is 20 ng/mL of hIGFBP-1 in saline buffer compared to a high-quality comparison kit and no prozone hook effect was observed up to 500 ng/mL.

2 Clinical analysis

At an in-house laboratory, a PROM test with known clinical outcomes was used to compare with the CUSAg anti-hIGFBP-1 antibody. Three amniotic fluid (AF1-AF3) samples from pregnant women were diluted to 1:10, 1:100, 1:1000, 1:2000, 1:5000 and 1:10000. 21 samples were tested, of which 3 vaginal secretion samples (VS4-VS6) from non-pregnant women were tested as the negative controls. There was 100% agreement between the results obtained from the high-quality comparison kit (A) and immunoassay using CUSAg anti-hIGFBP-1 antibodies(B).

Table1. Clinical comparison of diagnostic kit (A) and immunoassay using CUSAg anti-IGFBP-1 antibodies (B).

Dilution / Samples	1:1		1:10		1:100		1:1000		1:1200		1:5000		1:10000	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
AF1			+	+	+	+	+	+	-	-	-	-	-	-
AF2			+	+	+	+	+	+	+	+	-	-	-	-
AF3			+	+	+	+	+	+	+	+	+	+	-	-
VS4	-	-												
VS5	-	-												
VS6	-	-												

"+" : positive, "-" :negative. "A" :high-quality kit,
"B" :immunoassay using CUSAg anti-hIGFBP-1 antibodies

3 Specificity

A. Human urine

The negative samples (0, 10 ng/mL human IGFBP-1) were respectively spiked in three urine samples (U1-U3). Addition of urine had no effect on the tests.

B. Maternal blood

Three maternal blood samples (M1-M3) were randomly collected from pregnancy women. The samples were diluted to 1:1, 1:10 and 1:100 with saline buffer. There was also 100% agreement between the results obtained from the high-quality comparison kit (A) and immunoassay using CUSAg anti-hIGFBP-1 antibodies(B), showing the prefect capacity of resisting interference of our in-house assays.

Table2. Comparison of the specificities of diagnostic kit (A) and immunoassay using CUSAg anti-IGFBP-1 antibodies(B).

Dilution / Samples	Undiluted		1:1		1:10		1:100	
	A	B	A	B	A	B	A	B
M1	+	+	+	+	+	+	-	-
M2	+	+	+	+	-	-	-	-
M3	+	+	+	+	-	-	-	-
U1	-	-	-	-				
U2	-	-	-	-				
U3	-	-	-	-				

"+" : positive, "-" :negative. "A" :high-quality kit,
"B" :immunoassay using CUSAg anti-hIGFBP-1 antibodies

4 Thermal Stability

CSB-DA286GmN① and CSB-DA286GmN② were stored at -20℃, 2-8℃ and 37℃ for 14 days. Amniotic fluid (AF3) sample was diluted to 1:500, 1:1000, 1:2000 and the calibrator were spiked with human IGFBP-1 at 0, 20, 50, 200 ng/mL. After then, these samples were detected, respectively (Table 3). The results show that the stability of CUSAg anti-hIGFBP-1 antibody is perfect.

Table3. Thermal stability of CUSAg anti-IGFBP-1 antibodies

temperature / Samples	-20℃		2-8℃ (14 days)		37℃(14 days)	
0 ng/ml	-	-	-	-	-	-
20 ng/ml	+	+	+	+	+	+
50 ng/ml	+	+	+	+	+	+
150 ng/ml	++	++	++	++	++	++
AF3(1:500)	+++	+++	+++	+++	+++	+++
AF3(1:1000)	+++	+++	+++	+++	+++	+++
AF3(1:2000)	++	++	++	++	++	++

"+" : general positive, "++" :positive, "+++" :intense positive. "-" : negative.

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