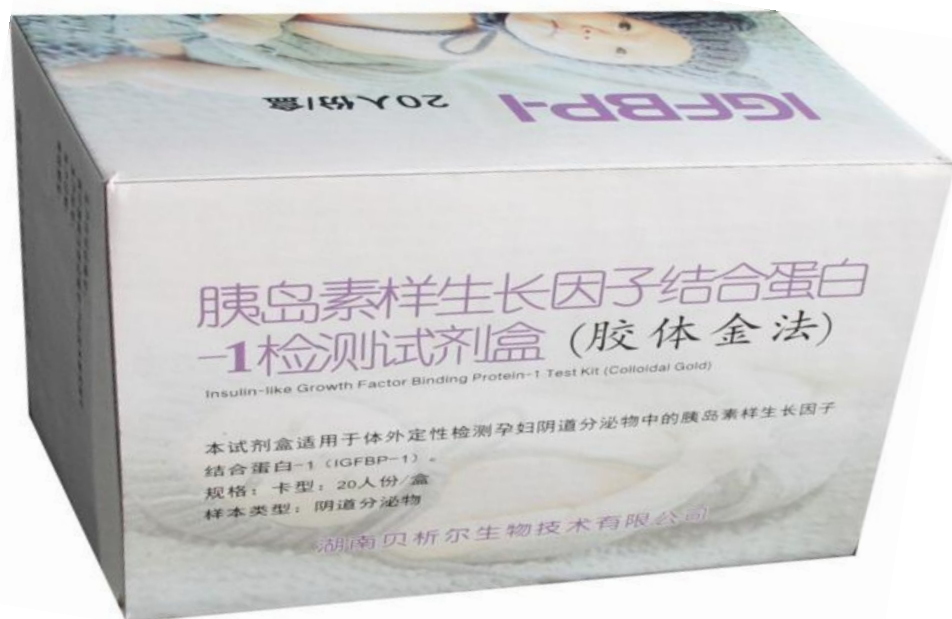


Scientific prediction of premature rupture of membranes

Comprehensive care for the health of mothers and babies



Insulin-like Growth Factor Binding Protein-1 Test Kit (Colloidal Gold)

Rapid diagnosis kit for premature rupture of membranes

- ♥ Precise
- ♥ Fast
- ♥ Convenient
- ♥ Non-invasive

Clinical background

Rupture of membranes before labor is called premature rupture of membranes (PROM). Premature rupture of membranes is one of the most common causes of complications of premature delivery and neonates who need to enter the emergency ward.

♦ Dangerous consequences of premature rupture of membranes:

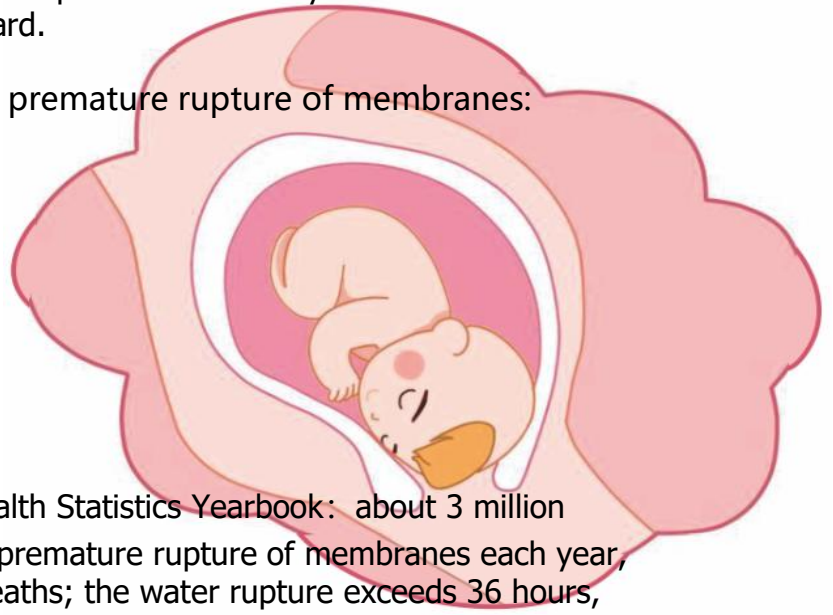
Premature delivery

Fetal abnormalities

Umbilical cord sagging

Early placenta dissection

Mother and child infection



According to the 2010 China Health Statistics Yearbook: about 3 million pregnant women in China have premature rupture of membranes each year, resulting in 330,000 newborn deaths; the water rupture exceeds 36 hours, and the infection rate is as high as 53%.

The 2015 "Guidelines for the Diagnosis and Management of Premature Rupture of Membranes" recommended biochemical detection methods such as IGFBP-1 kits for the diagnosis of suspected premature rupture of membranes.

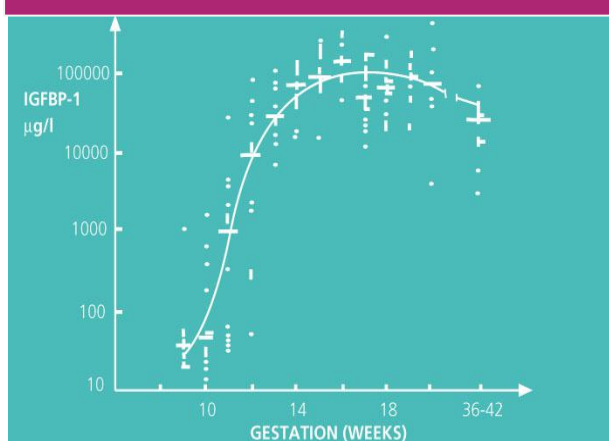
Detection principle

Insulin-like growth factor binding protein-1 (IGFBP-1) mainly exists in amniotic fluid and is synthesized by decidual cells. It is a characteristic protein in amniotic fluid after 3 months of pregnancy and before delivery.

The concentration level of IGFBP-1 in amniotic fluid is 100 to 1000 times higher than that in mother's blood, and it is less in other body fluids, such as semen, urine, and cervical mucus.

When fetal membranes rupture, IGFBP-1 in the amniotic fluid leaks from the rupture of the fetal membranes into the cervix and vagina. Become a sign of premature rupture of membranes.

Concentration level of IGFBP-1 in amniotic fluid
Wathen et al.1993



The concentration of IGFBP-1 in different body fluids
Rutanen et al. 1993

Sample	IGFBP-1 concentration
Urine	< 0.5 ng/ml
Semen	< 0.5 ng/ml
Vaginal and cervical secretions	0.5-8 ng/ml
Blood (healthy adult)	0.5-30 ng/ml
Serum (pregnant woman)	58-600 ng/ml
Amniotic fluid	10500-350000 ng/ml

Applicable object

- ♥ Routine screening of asymptomatic high-risk pregnant women after 15 weeks of gestation;
- ♥ Reasonable examination for pregnant women with suspected premature rupture of membranes (increased or slippery vaginal discharge) at 15-40 weeks of gestation.
- ♥ If you have reached 37 weeks of gestation, the IGFBP-1 test can be used to predict the time of delivery (most pregnant women with a positive test result give birth within 24-48 hours; while pregnant women with a negative test result have no symptoms of labor within 24-48 hours)



Inspection steps

1

Sampling

Ask the patient to lie down on his back, carefully insert a disposable swab into the vagina to the posterior fornix (about 5-7 cm in depth), gently dip in vaginal secretions, take out the swab after about 30 seconds

2

Elution

Dip the swab end into the sample buffer bottle and stir for about one minute, Wash thoroughly

3

Reaction

Open the aluminum foil bag, take out the test reagent, and add 100ul (or 3 drops) of sample eluate to the sample hole

4

Interpretation of results

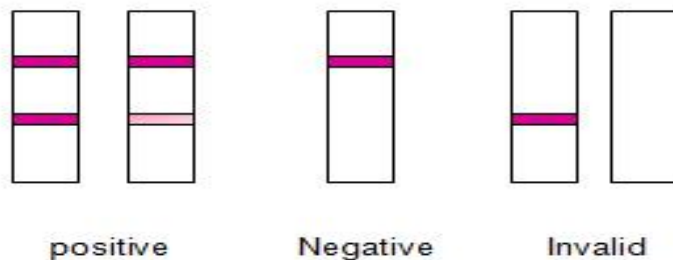
Observe the results in 5-20 minutes

Interpretation of results

Positive result: A color band appears on the detection line (T) and the quality control line (C), indicating that the concentration of IGFBP-1 in the sample buffer is $\geq 20\text{ng/ml}$, indicating the possibility of membrane rupture. For the gestational age greater than 37 weeks, the fetus is mature, consider zero-interference delivery; the gestational age is less than 37 weeks, or the fetus is immature (or there are other conditions that are not suitable for immediate delivery), consider fetal protection measures, and follow-up feelings.

Negative result: Only a color band appears on the quality control line (C), indicating that the concentration of IGFBP-1 in the sample buffer is less than 20ng/ml , indicating that the fetal membranes are intact. Combined with clinical manifestations and auxiliary examinations, the possibility of membrane rupture is basically ruled out.

Invalid result: There is no color band on the quality control line (C), indicating that the test is invalid and the test should be repeated.



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