

IGFBP-1 liquid Positive Control

Positive control for test AMNIOQUICK® and AMNIOQUICK® CARD.



INTENDED USE

IGFBP-1 liquid Positive Control is a positive control intended for use with AMNIOQUICK® and AMNIOQUICK® CARD. It should be used at each new kits reception, for any new lot or when changing operator. It aims to validate AMNIOQUICK® and AMNIOQUICK® CARD devices and should be used in conjunction with Good Laboratory procedures.

IGFBP-1 liquid positive Control is intended for use by biologists in professional environment, or directly on the ground by medical personnel (technicians, nurses, midwife).

TEST PRINCIPLE

IGFBP-1 liquid Positive Control has been designed for use with the AMNIOQUICK® and AMNIOQUICK® CARD assays to validate the correct performance of the device by the user. IGFBP-1 liquid Positive Control comes in liquid.

IGFBP-1 is obtained from Pooled amniotic fluid. IGFBP-1 liquid Positive Control is negative for HBs Ag, HIV type 1 and 2 antibodies, HCV and syphilis.

IGFBP-1 liquid Positive Control has no assigned quantitative value. Each lot of materials has been designed to produce a positive reaction when tested on AMNIOQUICK® and AMNIOQUICK® CARD.

MATERIAL PROVIDED

- Dropper containing 0.5 mL of positive control.
- Instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

- Material provided in AMNIOQUICK® and AMNIOQUICK® CARD kits:
 - Tests packed in individual pouches with desiccant
- Plastic tube (hemolysis tube)
- Timer

STORAGE AND STABILITY

- IGFBP-1 liquid Positive Control is stable until the expiry date indicated on the dropper.
- Positive control should be stored at 2-8°C for 12 months.
- Close tightly the cap after each use.

PRECAUTIONS

Follow the precautions for use indicated in instruction for use of AMNIOQUICK® or AMNIOQUICK® CARD kit.

TEST PROCEDURE

Use the positive control with a strip test AMNIOQUICK® or AMNIOQUICK® CARD.

- **For AMNIOQUICK®:**
1. Add 2 drops of positive control in an empty plastic tube (hemolysis tube), and put the strip vertically in this tube.
 2. Start the timer. As the test begins to work, you will see a reddish colored liquid front moving across the membrane.
 3. Let migrate for 10 minutes. Remove the strip from the tube and read the result immediately.

- **For AMNIOQUICK® CARD:**
1. Dispense 2 drops of positive control into the round sample well of the test device by applying a gentle pressure to the walls of the tube. Avoid air bubbles in the sample well or splashes of liquid into the result window.
 2. Start the timer. As the test begins to work, you will see a reddish colored liquid front moving across the membrane.
 3. The result should be read after 10 minutes.

RESULTS INTERPRETATION

Results should be read the same way as for a clinical sample. IGFBP-1 liquid Positive Control has no assigned quantitative value. Each laboratory should determine its acceptability area.

If a purple line (even of weak intensity) appears at the level of the test zone, the result is positive.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control zone (C) ensures that sufficient specimen volume has been loaded and that the correct procedure has been followed by the operator.

LIMITATIONS OF PROCEDURE

- IGFBP-1 liquid Positive Control has been validated to be used with AMNIOQUICK® and AMNIOQUICK® CARD.
- To obtain confident results, please refer to the instructions for use of AMNIOQUICK® or AMNIOQUICK® CARD before performing the test with AMNIOQUICK® or AMNIOQUICK® CARD® devices.









PERFORMANCES

IGFBP-1 liquid Positive Control should lead to positive results when used with AMNIOQUICK® or AMNIOQUICK® CARD and when instructions for use are followed.

Literature

1. Seppala M., Ruoslahti E. Alpha fetoprotein in Amniotic fluid: An index of gestational age. *Am. J. Obstet. Gynecol.* 1972, November, 595-596
2. Rochelson BL, Richardson DA, Macri JN. Rapid assay: possible application in the diagnosis of premature rupture of the membranes. *Obstet Gynecol* 1983;62:414-418
3. Rutanen EM, Pekonen F, Kärkkäinen T. Measurement of insulin-like growth factor binding protein-1 in cervical/vaginal secretions: comparison with the ROM-check membrane immunoassay in the diagnosis of ruptured fetal membranes. *Clin Chim Acta* 1993;214:73-81
4. Kishida et al. Diagnosis of premature rupture of the membranes in pterm patients, using an improved AFP kit: comparison with ROM-Check and/or nitrazine test. *European Journal of Obstetrics and Gynecology and Reproductive Biology* 1996, 69, 77-82
5. Rutanen et al. Evaluation of a rapid strip test for insulin-like growth binding protein-1 in the diagnosis of ruptured fetal membranes. *Clinica Chimica Acta*, 1996, 253, 91-101
6. Guibourdenche J, Luton D, André E, Noël M, Porquet D. Détection rapide de l'Insulin-like growth factor-binding protein-1 et de la fibronectine fœtale dans les sécrétions cervico-vaginales pour le diagnostic de la rupture prématurée des membranes. *Ann Clin Biochem* 1999 ;36 :388-390
7. Gallot D., Sapin V. Menace d'accouchement prématuré et marqueurs de rupture prématurée des membranes : de la physiopathologie au diagnostic. *Spectra Biologie*, 2007, 161, 59-63
8. Rutanen et al. Radioimmunoassay of placenta protein 12: levels in amniotic fluid, cord blood and serum of healthy adults pregnant women and patients with trophoblastic disease. *Am. J. Obstet. Gynecol.* 1982
9. Rutanen et al. Decidual transformation of human extrauterine mesenchymal cells is associated with the appearance of insulin-like growth factor binding protein-1. *J. Clin. Endocrinol. Metab.* 1992 72: 27-31

SYMBOLS

	Attention, see instructions for use		Lot number
	For <i>in vitro</i> diagnostic use only		Manufacturer
	Store between 2-8°C		Catalog number
	Tests per kit		Expiry

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