

WOMEN'S HEALTH



A comprehensive offer
to support women from
conception to childbirth

- BIOSYNEX® hCG 10 BSS, BIOSYNEX® hCG 20 BSS
 - Detection of β -hCG hormone in urine in 3 to 5 minutes
- Amnioquick® range
 - Detection of a premature rupture of the fetal membranes
- Premaquick®
 - Prediction of threatened pre-term delivery
- BIOSYNEX Ampliflash® GBS (Group B Streptococcus)
 - Intrapartum screening by isothermal Molecular Biology

CONCEPTION

BIOSYNEX offers a wide range of qualitative tests for the detection of human chorionic gonadotropic hormone (hCG) in urine, serum or plasma.

These *in vitro* diagnostic medical devices make it possible to identify a pregnancy from its early stages, for use in the laboratory or in Point of Care (POC).

- Sensitivity >99.9 %
- Easy to use and easy to interpret
- Two hCG thresholds: 10 or 20 mIU/mL



POC or MBL



2-30°C



24 months



Transfer pipettes provided

BIOSYNEX hCG 10 BSS



- Cassette format
- hCG detection threshold: 10 mIU / mL
- Ref: SW10003



50 tests



3 to 5 minutes



Urine, serum, plasma

Manufacturer: BIOSYNEX SWISS S.A. (Switzerland)

BIOSYNEX hCG 20 BSS



- Cassette format
- hCG detection threshold: 20 mIU / mL
- Ref: SW10002



40 tests



3 à 5 minutes



Urine, serum, plasma

Manufacturer: BIOSYNEX SWISS S.A. (Switzerland)



RUPTURE OF MEMBRANES

Almost 10% of full term pregnancies are affected by a Premature Rupture of the Membranes (PROM) while PROM occurs in 2-3% of pregnancies before 37 weeks of amenorrhea. These PROMs are responsible for a third of prematurity and almost 20% of perinatal mortality.



AMNIOQUICK® range

Qualitative rapid tests for the detection of IGFBP-1 +/- AFP parameters, signs of rupture of fetal membranes.

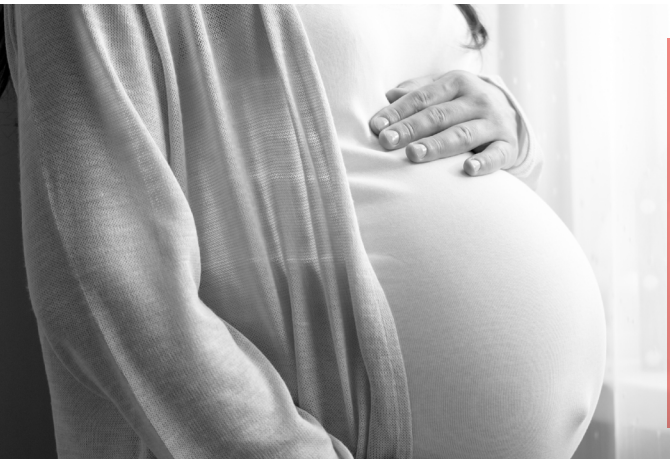
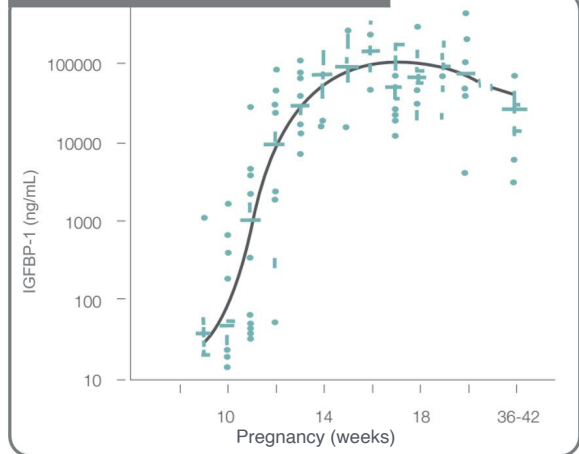
IGFBP-1

Insulin like growth factor binding protein 1.

L'IGFBP-1 is produced by the decidua.

IGFBP-1 accumulates very early in the amniotic fluid. This high level, which persists until childbirth, makes it a useful marker for detecting rupture of membranes in the early stages of pregnancy.

IGFBP-1 in the amniotic fluid



AFP

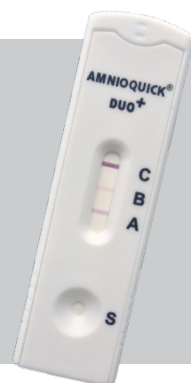
Alpha-fetoprotein

AFP is a protein synthesized by the fetal liver and is then found in the amniotic fluid during the pregnancy.

The peak concentration of AFP in the amniotic fluid is reached at the end of the second trimester while IGFBP-1 slowly decreases. Coupled with IGFBP-1, AFP increases the sensitivity of the PROM test and thus the reliability of the diagnosis.

AMNIOQUICK® Duo+

- Designed, developed and patented by BIOSYNEX
- Unique combination of two biomarkers (IGFBP-1 & AFP) in a single assay
- Adjusted IGFBP-1 threshold for best combined performance
- Evaluated in 7 independent studies
- Individually wrapped for room use: swab, test, diluent, patient card (procedure + result)



BVCert. 6346983


RUPTURE OF MEMBRANES

FEATURES OF AMNIOQUICK® RANGE

A complete range of PROM tests available in different formats to adapt to your practice

 10 tests
  Individually wrapped for room use
  18-24 months
  2-30°C

	AMNIOQUICK®	AMNIOQUICK® CARD	AMNIOQUICK® DUO+
Reference	1090003	1090005	1090004
Format	strip	cassette	cassette
IGFBP-1	5 ng/mL	5 ng/mL	10 ng/mL
AFP	-	-	5 ng/mL
Sensitivity / Specificity	98.5% / 100%	98.5% / 100%	97.9% / 97.6%


 ALSO AVAILABLE FOR USE WITH THE BSX READER
 AMNIOQUICK Card BSX ref: 1090005_BSX
 AMNIOQUICK Duo+ BSX ref: 1090004_BSX

PROCEDURE

Study shows that a weak positive sample usually appears within 3 to 4 minutes³.

1



Easy collection:
With or without speculum.

2



Quick sample preparation:
unload and break swab¹.

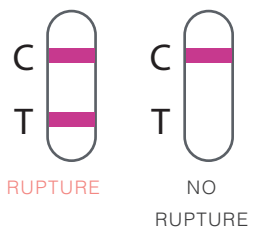
3



Simple performance of the test:
3 drops in the well².
Read the result at 10 minutes.

RESULTS

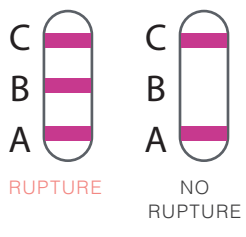
AMNIOQUICK®



C: Control T: IGFBP-1

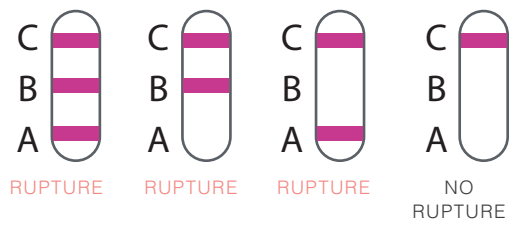
AMNIOQUICK® Duo+

BEFORE 37 GA



C: Control B: IGFBP-1 A: AFP

FROM 37 GA⁴



Manufacturer: BIOSYNEX S.A. (France)

1 Strip format: simply unload the swab in the tube

2 Strip format: immerse the strip, arrows down, in the tube

3 J. Guibourdenche et al. Diagnosis of premature rupture of membranes: comparative study of the analytical performances of biological diagnostic tests. Ann Biol Clin, vol. 76, n° 3, May-June 2018

4 Only take AFP results into account from 37 GA

THREAT OF PREMATURE DELIVERY

In 50% of cases, preterm deliveries are preceded by a threat of preterm delivery, but only 20% of these patients give birth prematurely. It is therefore essential to reliably predict imminent delivery when there is a risk of preterm delivery.

Fetal fibronectin, the most documented biomarker of imminent delivery, shows a good negative predictive value but its positive predictivity remains modest (around 15 to 48% in the prediction of delivery at 7-10 days).

PREMAQUICK®

By combining 3 biomarkers, the PREMAQUICK® test integrates the main pathogenic mechanisms responsible for preterm delivery and provides high positive and negative predictivity of delivery within 7 and 14 days in women between 22 and 37 weeks of amenorhea.

IGFBP-1 Native

Marker of cervical maturity, significant lysis of decidual cervical cells and transudation of amniotic fluid during contractions.

IGFBP-1 Total

Witness of significant local proteolytic activity and fetal stress due to contractions

INTERLEUKIN-6

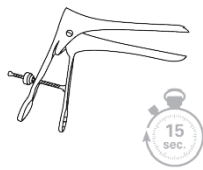
Marker of inflammation / infection of the amniotic cavity and the cervico-vaginal sphere.



Ref: 1090009
Manufacturer: BIOSYNEX S.A. (France)

PROCEDURE

1



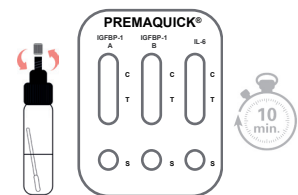
Collect using a speculum

2



Prepare the sample

3



Transfer 3 drops in each well.
Read the result at 10 minutes.

Reading algorithm:

- IGFBP-1 NATIVE : 3 points
- IGFBP-1 TOTAL : 2 points
- IL-6 : 1 point

Sum \geq 2

POSITIVE
Result



HIGH probability
of delivery

Sum \leq 1

NEGATIVE
Result



LOW probability
of delivery

THREAT OF PREMATURE DELIVERY

PERFORMANCES

Evaluation in 97 women with threat of premature delivery at less than 35 WA.

The sample was taken during the speculum examination, before vaginal examination. The women were then followed for 14 days after admission.

	Probability of delivery ≤ 7 days	Probability of delivery ≤ 14 days
Sensitivity	93.5%	94.3%
Specificity	90.9%	96.8%
PPV	82.9%	94.3%
NPV	96.8%	96.8%

Triple NEGATIVE
(score = 0)

VPN 98%

Triple POSITIVE
(score = 6)

VPP 96%



ALSO AVAILABLE FOR USE WITH THE BSX READER
PREMAQUICK BSX ref: 1090009_BSX

BSX READER®

The BSX READER® is a very sensitive and robust measurement system for rapid diagnostic tests (RDTs) provided by BIOSYNEX. This flexible and reliable system allows users to easily perform BSX Series RDTs. The instrument will guide you through the analysis procedure with a series of messages and animations displayed on the touch screen.

Automated calibration

Wide range of tests available

Several compatible cassette formats



Easy to use and intuitive

Technician time optimization

Automatic or manual incubation

Ergonomic design

Manufacturer: BIOSYNEX S.A. (France)

RDTs BSX Range

Women's health:

AMNIOQUICK® Card BSX
REF:1090005_BSX

AMNIOQUICK® DUO+ BSX
REF:1090004_BSX

PREMAQUICK® BSX
REF:1090009_BSX

Virology:

BIOSYNEX® COVID-19Ag BSX
REF:SW40006_BSX

INFLUENZATOP® BSX
REF:SW40002_BSX

RSVTOPBSX
REF:1150006_BSX

Bacteriology:

TETANOTOP® BSX
REF:1030016_BSX

EasyTETANOTOP® BSX
REF:502880_BSX

BIOSYNEX® S. pneumoniae BSX
REF:1030002_BSX

BIOSYNEX® L. pneumophila BSX
REF: SW30002_BSX

BIOSYNEX® STREP A BSX
REF:1030005_BSX

Toxicology:

DRUGCHECK®+ THC BSX
REF:1140013_BSX

DRUGCHECK®+ 10 BSX
REF:1140015_BSX

DRUGCHECK®+ 11 BSX
REF:1140016_BSX

BSX READER®

REF. 5060029

- Reader BSX READER®
- Power cable
- Barcode reader
- User manual

ACCESSORIES

- Dymo printer LabelWriter 450 (ref. 502250) or Dymo printer LabelWriter 550 (ref. 502252)

The BSX READER® is intended to be used only in combination with the TDRs of the BSX range and only for the applications described by BIOSYNEX. For more information, contact the BIOSYNEX sales representative in your area.

INTRAPARTUM SCREENING BY ISOTHERMAL MOLECULAR BIOLOGY

BIOSYNEX AMPLIFLASH® GBS

Intrapartum screening for vaginal or rectal GBS with BIOSYNEX AMPLIFLASH® GBS allows the appropriate administration of antibiotic prophylaxis to positive parturients.



10 to 30% of pregnant women are healthy carriers¹

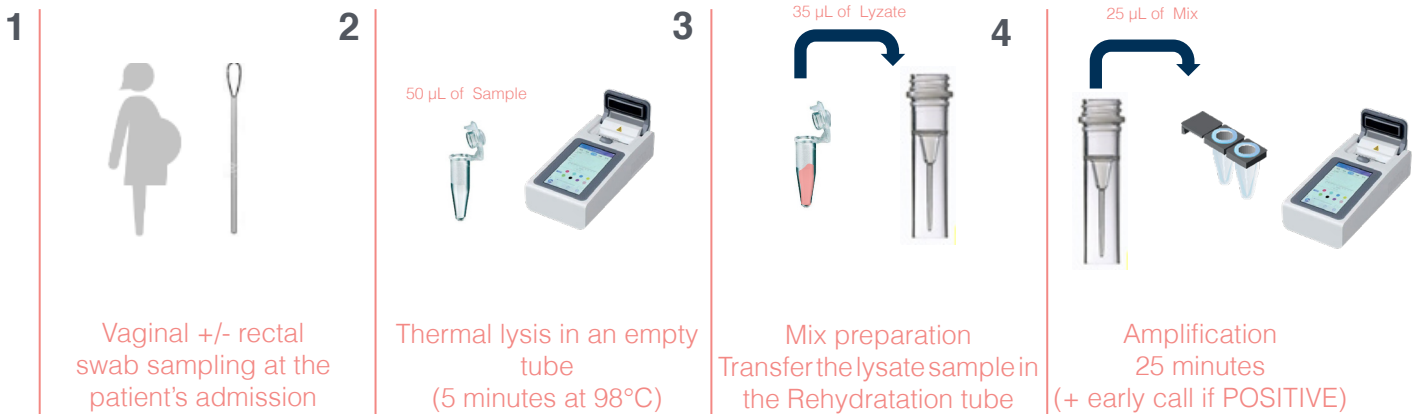
Change of carrying during pregnancy²

Major cause of **sepsis & neonatal meningitis**³

4 to 6 % of infected infants do not survive⁴

61% of infected infants were born to **culture-negative mothers** at 8 months⁵

PROCEDURE



	Sensibility	Specificity	Precision
Vaginal swabs	99%	100%	99.6%
Vagino-rectal swab	97.8%	100%	99.2%

DISCOVER OUR NEW
AMPLIFLASH® GBS VIDEO



1. Edward MS, Nizet V. Group B streptococcal infections. In: Jack S, Remington JS, Klein JO, Wilson CB, Nizet V, Maldonado YA, editors. Infectious diseases of the fetus and newborn infant. 7th ed. Philadelphia: WB Saunders. 2011;pp.417–467.
 2. Yow MD, et al. The natural history of group B streptococcal colonization in the pregnant woman and her offspring. I. Colonization studies. *Am J Obstet Gynecol* 1980;137:34-8.
 3. Melin P, Efstratiou A. Group B streptococcal epidemiology and vaccine needs in developed countries. *Vaccine*. 2013;31S:D31–D42
 4. Schrag SJ, Zell ER, Lynsfield R, et al. A population-based comparison of strategies to prevent early-onset group B streptococcal disease in neonates. *The new england journal of medicine*. 2002;347:233–9.
 5. Van Dyke et al. Evaluation of universal antenatal screening for group B Streptococcus. *The new england journal of medicine*. 2009;360;25:2626-36

AMPLIFLASH READER®

Nucleic Acid Amplification Tests (NAATS) are diagnostic tests based on molecular biology. NAATS can use many different methods to amplify and detect a pathogen's nucleic acids including Real time PCR or isothermal amplification such as LAMP (Loop-mediated isothermal amplification). Our AMPLIFLASH® range based on isothermal amplification technology, provided fast results obtained in less than 30 minutes in order to manage emergencies.

**From sample to result
in 30 minutes**

**QR codes that guarantee
traceability and implement
protocols**



Complete kit for 25 tests.

**Intuitive all-in-one
system**

Manufacturer: Allsheng (China)

AMPLIFLASH® range

SARS-COV-2:
Ref. 3150069

KIT CONTENT:

- 25 PCR tube strips prefilled with lyophilised master mix
- Transparent caps for sealing
- 25 tubes of Lysis buffer
- 25 tubes of rehydration buffer
- 1 Method Card with QR Code

GBS:
Ref. 3150072

KIT CONTENT:

- 25 PCR tube strips prefilled with lyophilised master mix
- 25 empty tubes for the thermal lysis
- 25 tubes of rehydration buffer
- Transparent caps for microplate sealing
- 1 Method Card with QR Code

AMPLIFLASH® READER

REF. 5150001

- AMPLIFLASH READER® Instrument
- Throughput: 1 patient per run up
- Userfriendly software to control up to 5 devices at once



In vitro diagnostic medical devices.
Read the instructions for use carefully.

FLY_WHC_EN_V02202203R02
Rev : 02/23

BIO SYNEX

BIOSYNEX S.A.
22 Boulevard Sébastien Brant
67400 ILLKIRCH-GRAFFENSTADEN - France
Phone: +33 3 88 77 57 52 - Fax: +33 3 88 78 76 78
E-mail: export@biosynex.com
www.biosynex.com