Patient data (please fill out clearly in **block letters**)

Family name

First name

Date of birth

Day Month Year

Id. No.

16006 541 006 8

Request form

PRENATAL SCREENING
(BIOCHEMICAL GENETICS)

Client data

Physician

BIOSCIENTIA HUMAN GENETICS

Konrad-Adenauer-Str. 17
55218 Ingelheim, Germany
Phone +49-6132-781-240
Fax +49-6132-781-236
E-mail: int.support@bioscientia.com
Website: www.bioscientia.com

Sampling material

- ☐ Serum
- ☐ Serum, **frozen** (First trimester screening only)

No. of tubes sent

Sampling date: Day Month Year

Date of second sampling: (Integrated screening only) Day Month Year

Medical / family history

Biochemical analysis required

Serum

Integrated screening

- ☐ 5 parameters **including** / **without** NT
  - ☐ First analysis PAPP-A (10+0 - 11+6 weeks gestation)
  - ☐ Second analysis AFP, hCG, uE3, Inhibin A (14+0 - 17+6 weeks gestation)

First trimester screening (combined test)
(CRL 45-84 mm)

- ☐ PAPP-A, free β-hCG, if applicable ultrasound markers (analysis including risk calculation)

First time senders please indicate FMF licence ID:

Second trimester screening
(14+0 - 17+6 weeks gestation)

- ☐ Quadruple test: AFP, hCG, uE3, Inhibin A
- ☐ Triple test: AFP, hCG, uE3
- ☐ Sequential screening: (14+0 - 17+6 weeks gestation) AFP, hCG, uE3, Inhibin A after suspect combined test

Clinical data (all tests)

Indication

Number of fetuses
- ☐ singleton
- ☐ twins

chorionicity

week and day of gestation at date of sampling +

CRL mm

date of ultrasound Day Month Year

maternal weight kg

- ☐ smoker

Ethnic origin:

- ☐ in-vitro fertilization (IVF)
- ☐ parity

Ovulation stimulation ☐ yes ☐ no

Previous pregnancy
- ☐ Trisomy 21
- ☐ other:

Clinical data (test specific)

NT , mm date ultrasound Day Month Year

Nasal bone
- ☐ present ☐ absent
- ☐ ambiguous

CRL: crown rump length **US**: ultrasound **NT**: Nuchal translucency **MoM**: Multiple of the Median **p.t.o.**

Declaration of Informed Consent

With my signature I declare that I was briefed on

_____._____._____

by_____
(physician)

about the nature, importance and implications of the genetic test and that I give my consent to the following genetic analyses and to the collection of the blood and tissue samples needed for this purpose:

_____

I consent to the storage, in accordance with legal requirements, of the recorded data in paper and/or electronic form and to their use and/or publication in pseudoanonymized form for scientific purposes or for quality assurance.

I agree that, contrary to legal requirements, my test results will not be destroyed after 10 years (to allow my family access to them in the event of my death).

I consent to the results of the tests being made available to the following persons in addition to the doctor who submitted them:

_____

I hereby agree to the transfer, in accordance with § 950 BGBl, of any test material remaining at the end of the analysis to the laboratory that carried out the analysis and I consent to its use for scientific purpose in pseudoanonymized form.

I consent to the communication of my data to a medical billing clearing house for invoicing purposes.

I am aware that I may withdraw this consent at any time, verbally or in writing, without giving reasons and without this having any adverse consequences for me.

-Please delete as appropriate -

Place, date:

_____

Name of patient / legal representative:

_____

Signature of patient / legal representative:

_____

Please tear off this strip before sending.

These labels are for the patient´s tube(s). Those labels not needed - please tear off and discard - do not send to us.

Important information

Integrated screening

- **Blood sampling (first analysis)**
  recommended 10+0 to 11+6 weeks gestation
  possible up to 13+6 weeks gestation
- **Blood sampling (second analysis)**
  14+0 to 17+6 weeks gestation
  in exceptional cases up to 19+6 weeks gestation
- **NT value** can be measured and filed subsequently
  at **11+0 to 13+6 weeks gestation**
  at **least 100 previous operator-specific NT measurements are mandatory**
- Gestational dating should be based on early
  CRL (2 - 67 mm)

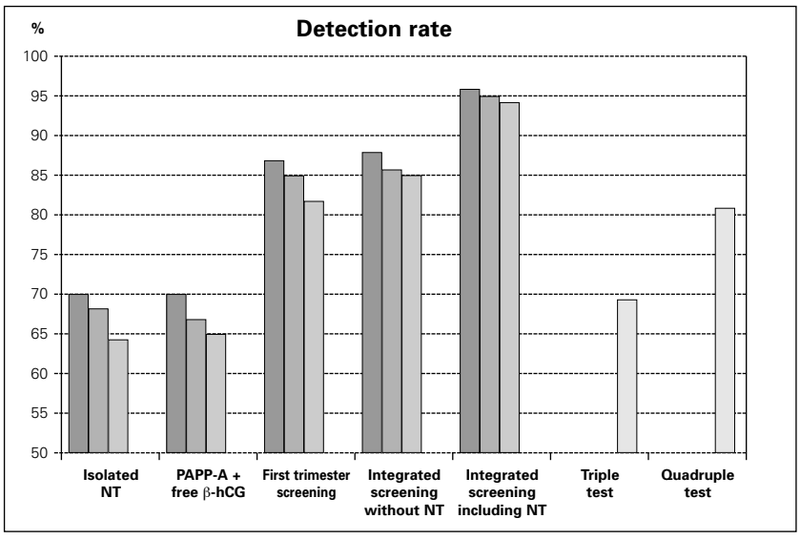
First trimester screening

- Can only be performed
  11+1 to 13+6 weeks gestation
- Gestational dating is based on
  CRL (45 - 84 mm)

Second trimester screening

- **Blood sampling 14+0 to 17+6 weeks gestation**
  in exceptional cases up to 19+6 weeks gestation
- Gestational dating is based on early
  CRL (2 - 67 mm) from the first trimester
  or according to physician

Detection rate at 5% false-positive results dependent on the time of blood sampling



Detection rate at 5% false-positive results if blood sampling occurs at:

- 11 weeks gestation
- 12 weeks gestation
- 13 weeks gestation
- 14 to18 weeks gestation

Please note:
The figure takes into consideration the most current data of a population study (FASTER[1]). This means that the average data of a population of pregnant women is shown.

A fixed false-positive rate of 5% was assumed in order to yield a direct comparison. Actually, screen-positive rates depend on cut-offs and on the maternal age of the patient.

Detection rates depend on the maternal age of the patient also, e.g. for women aged 40 detection rates will be higher than those depicted in the graph and for women aged 20 detection rates will be lower.

[1] Fergal D. Malone, et.al. (2005) First-Trimester or Second-Trimester Screening, or Both, for Down's Syndrome. N Eng J Med 353, 2001-11