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

Family name

First name

Date of birth

Day Month Year

Id. No.

Age

0001 160065190076

ABC123S DFÜ-ID: 12345

PRENATAL DIAGNOSTICS

BIOSCIENTIA INTERNATIONAL

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

Client data

Physician

Sample type

- ☐ Amniotic fluid
- ☐ Chorionic villi
- ☐ Umbilical cord blood
- ☐ Product of conception
- ☐ EDTA blood

Sampling date **Time** **No. of tubes sent**

Chromosome analysis

- ☐ **Chromosome analysis**
- ☐ **Chromosome analysis and OF-PCR** (Rapid aneuploidy screening)

  Exclusion of aneuploidy of chromosomes 13, 18, 21, X, Y (only in combination with conventional chromosome analysis)
- ☐ **Chromosome analysis and Metaphase FISH**
  - ☐ Exclusion of cryptic translocation
    - ☐ Trisomy 13
    - ☐ Trisomy 18
    - ☐ Trisomy 21
  - ☐ Prader-Willi / Angelman syndrome
  - ☐ Miller-Dieker syndrome
  - ☐ DiGeorge / Velocardiofacial syndrome
  - ☐ Smith-Magenis syndrome
  - ☐ Williams-Beuren syndrome
  - ☐ Cri-du-Chat syndrome
  - ☐ Wolf-Hirschhorn syndrome
  - ☐ Others

Biochemistry

- ☐ **From amniotic fluid**
  - ☐ AFP
  - ☐ AChE

Array-CGH

- ☐ **Array-CGH** (indicated in case of an abnormal ultrasound or positive family history for chromosomal changes)

  Please provide EDTA blood from both parents and informed consent for parental array-CGH if needed.

Molecular genetic analysis

- ☐ **Analysis**

Please specify name of the analysis and give further information (indication, family history, previous reports) or please use our request form "Molecular Genetic Analyses".

Clinical data

Number of fetuses

Last menstrual period (LMP)

Gestational age (Ultrasound) +

Indication

- ☐ Request of the patient
- ☐ Advanced maternal age
- ☐ Abnormal ultrasound finding
- ☐ Abnormal maternal serum screening
- ☐ Previous pregnancy or child with
  - ☐ Free trisomy 21
  - ☐ Translocation trisomy 21
  - ☐ Trisomy 21 (without further indications)
  - ☐ Trisomy 13
  - ☐ Trisomy 18
  - ☐ Other chromosome anomaly:

  Please enclose previous reports.
- ☐ Abnormal results of previous chromosome analyses

Declaration of consent for genetic testing in accordance with the Gene Diagnostics Act (GenDG)

I confirm that I have been informed by

with regard to the genetic diagnostic test(s) performed on (me)/(the person represented by me) **(please underline where applicable)**

described in more detail below in accordance with the German Genetic Diagnostics Act (Gendiagnostikgesetz) about the purpose, nature, scope, significance and consequences of the requested genetic test(s), the results that can be obtained, the health risks and the intended use of the genetic sample and the test results.

Exact description of examinations/indications/questions/suspected diagnosis, if applicable

In addition, I confirm that

(1) I have been given sufficient time to think before giving consent.
(2) I consent to the above test(s) and the required collection of the genetic sample.

I confirm that I have been informed about this and that I am aware that I can exercise a **comprehensive right not to know** and that I can also **revoke my consent at any time verbally or in writing to my attending physician,** in which case the test will be discontinued and only the service provided up to that point will be billed.

In addition, I give permission

- to the **storage of the genetic sample** after completion of the genetic test(s) so that the laboratory can use it, if necessary, in anonymized form for **quality assurance measures and scientific purposes** (e.g. statistical evaluations) without laying claim to it,
- for the **storage of the test results** beyond the prescribed period of 10 years, so that they can be used by the laboratory in coded form for **quality assurance measures and scientific purposes** even after this period, without laying claim to this,
- in the **communication of any incidental findings** that may have been made, without laying claim to them,
- for the **forwarding of the test order**, if necessary, to specialized cooperating laboratories,
- to the communication of the examination results in the event of not being able to reach my attending physician, also to **co-treating physicians of the practice/facility or representing physicians**. (Please delete any that do not apply)

Content of the informative discussion

Place, Date, Signature of Patient (parent or guardian)

Place, Date, Signature of Clinician/genetic counsellor

Place, date, signature of other person involved *

* in the case of genetic diagnostics to clarify parentage on the basis of consent, this must be declared by all parties involved

specimen material: amniotic fluid — ABC123S R
specimen material: amniotic fluid — ABC123S R
specimen material: heparin — ABC123S Y
specimen material: heparin — ABC123S Y
specimen material: edta — ABC123S 2
specimen material: — ABC123S 5

ABC123S

This label should be stuck onto the copy attached and kept for your records.

DO NOT SEND TO US.

ABC123S DFÜ-ID: 12345

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

Prior to a prenatal genetic test, and again after the corresponding results have been determined, the pregnant woman shall receive counselling and shall be advised of her right to counselling (Deutsches Gendiagnostikgesetz (GenDG), Bundesgesetzblatt 2009, Teil I Nr. 50: 2529-2538).

Preanalytics and transport material

Prenatal genetic analyses are performed on:

Chorionic villi: (beginning from the 11th pregnancy week)	- minimum amount of 30 mg (incl. array-CGH) - send in a sterile-coated tube with 10 ml physiological NaCl solution - storage and transport at room temperature
Amniotic fluid: (beginning from the 15th pregnancy week)	- 10-15 ml (incl. array-CGH: 15-20 ml); discard the first 2 ml, **please do not centrifuge!** - storage and transport at room temperature
Umbilical cord blood: (beginning from the 20th pregnancy week)	- 2-3 ml Lithium-Heparin blood - storage and transport at room temperature
Product of conception:	- chorionic villi, parts of the umbilical cord, achilles tendon, fascia lata **(material should not be older than 3 days)** - send in a sterile-coated tube with 10 ml physiological NaCl solution - storage and transport at room temperature

To exclude the most common aneuploidies (of chromosomes 13, 18, 21, X and Y), **a prenatal rapid aneuploidy screening (QF-PCR)** can be performed on the amniotic fluid specimen. For this purpose, please remove additional 3 ml amniotic fluid.

Please do not freeze samples. Do not sent in formalin!

Please order request forms, shipping supplies and transport materials at Bioscientia International: int.support@bioscientia.com