CENTER FOR HUMAN GENETICS AND LABORATORY DIAGNOSTICS
Dr. Klein, Dr. Rost and Colleagues
Lochhamer Str. 29 - 82152 Martinsried - GERMANY

Prenatalis®

Genetic Counseling
Imma Rost, M.D. (Director) · Sandra Dölken, M.D. · Monika Cohen, M.D.
Babett Heye, M.D. · Julia Höfele, M.D. · Dagmar Wahl, M.D.

Reproductive Genetics
Annett Wagner, Ph.D.
Thomas Harasim, Ph.D.

NIPT Laboratory
Thomas Harasim, Ph.D.
Christian Heberle, Application Specialist

Prenatalis® - Non-Invasive Prenatal Test (NIPT)

NAME, first name (pat.) _____

Date of birth: _____

Street: _____

ZIP, City, Country: _____

Phone: _____

Regulations and payment information

NIPT is a genetic test and - if carried out in Germany - subject to the German Genetic Diagnostics Act (GenDG). The order form is only valid in combination with **genetic counseling** and a signed **Informed Consent** (see reverse side).
Duration, turn-around time: 8-10 working days after sample reception.
Reporting: exclusively to the supervising physician.

Our payment policy requires **upfront payment** of the analysis fee of *Prenatalis*® *Prior*: **532,85 €** (incl. gonosomes **649,42 €**) or *Prenatalis*®: **427,94 €** (incl. gonosomes **544,51 €**) by electronic money transfer to
Deutsche Apotheker- und Aerztebank
BIC: DAAEDEDD
IBAN: DE 52 3006 0601 0006 3411 79

Prenatalis® *Prior* (5 working days)

- ☐ Chromosomes 21 18, 13 acc. to German Med Fee Schedule **532,85 €**
- ☐ Chromosomes 21, 18, 13 + gonosomal aberrations (X0,XXX,XXY,XYY)* acc. to German Med Fee Schedule **649,42 €**

Prenatalis® (8-10 working days)

- ☐ Chromosomes 21 18, 13 acc. to German Med Fee Schedule **427,94 €**
- ☐ Chromosomes 21, 18, 13 + gonosomal aberrations (X0,XXX,XXY,XYY)* acc. to German Med Fee Schedule **544,51 €**

Gender information*: ☐ yes (available only after 12th week of gestation) ☐ no

* not available for twin pregnancies

Required field: Supervising physician

Print NAME, first name, phone, fax and SIGN

Sample material

☐ 2x10 ml venous blood (BCT tubes – provided by the Medical Lab Martinsried) Sampling date: _____ time: _____

Please note: not properly marked specimens have to be rejected!

Required field: (incomplete forms and analysis requests cannot be processed!)

Week of gestation (week + day): ☐☐ + ☐ ☐ Single pregnancy ☐ Twin pregnancy

Height: ☐☐☐ cm Body weight (before pregnancy): ☐☐☐ kg

Indication for the test (please mark)

- ☐ Maternal age (≥ 35 years): ☐☐
- ☐ Abnormal First-Trimester Screening (FTS risk calculation):
  - Trisomie 21: 1: ☐☐☐☐
  - Trisomie 18: 1: ☐☐☐☐
  - Trisomie 13: 1: ☐☐☐☐
- ☐ Abnormal ultrasound:
- ☐ no elevated risk

Further specifications

- ☐ Genetically inferred aneuploidy risk (i.e. parental Robertsonian translocation involving chromosome 21 or 13)
- ☐ Previous pregnancies/spontaneous abortions involving chromosomal aberrations (if so, please specify):
- ☐ IVF ☐ ICSI transfer of single embryos ☐ yes ☐ no Number of embryos ___ ☐ Medication with Heparin-derivatives during pregnancy

Possible results of the *Prenatalis*®- Tests

Conspicuous: high probability of chromosome 21, 18, 13, resp. X or Y aberration. The result should be confirmed by invasive prenatal diagnostics (i. e. amniocentesis).

Incconspicuous: high probability of **NO** aberration of chromosomes 21, 18, 13, resp. X or Y.

Limitations of the *Prenatalis*®-Test: The test covers only chromosomes 21, 18, 13, and, if requested, X and Y chromosome. The test is currently not validated for the detection of triploidies, mosaics or subchromosomal changes. In some rare cases, the results cannot be interpreted and the analysis has to be repeated. In very rare cases, the phenomenon of a „vanishing twin" can lead to a false-positive result. Invasive prenatal diagnostics is recommended to confirm questionable or clearly pathological results. **False-negative** and **false-positive** results can generally not be excluded. Statistically, low risk pregnancies have an increased risk of a **false-positive** result.

Testing material: exclusively 2 x 10 ml venous blood (BCT tubes are provided) – order a test kit free of charge online at www.prenatalis.de
Transportation: before shipping a sample, please call +49.89.895578-0 (Monday - Thursday 8.00 am - 1.00 pm)
Please note: Do not freeze the specimens. Testing material should arrive in the laboratory within 48 hours after sampling.

Medical Lab Martinsried
Lochhamer Str. 29
82152 Martinsried

Medical Directors
Hanns-Georg Klein, M.D.
Imma Rost, M.D.

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www.medical-genetics.de

Deutsche Apotheker- u. Aerztebank
BIC (Swift-Code): DAAEDEDD
IBAN-Nummer: DE 52 3006 0601 0006 3411 79

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Required field: Informed Consent for the *Prenatalis*® test according to German GenDG

Dear Patient,

German GenDG (§10) requires detailed genetic counseling and a written Informed Consent in case for prenatal testing. Please read this information carefully and delete statements you do not agree with.

I agree/confirm that I

- was informed about type, chances, risks, limits and significance of the *Prenatalis*® test according to German GenDG by the supervising physician. There was adequate time to ask questions and to understand the principles of the test,
- understood that the test is not a diagnostic test (such as a chromosomal analysis) but a statistical procedure with a risk calculation,
- cannot receive gender information before the 12th week of pregnancy according to GenDG §15/ 1
- gave my permission for blood sampling required for the analysis,
- consent to the analysis of the *Prenatalis*® test,
- consent to the storage of my blood sample after the analysis is performed, without claiming storage,
- consent to my blood sample to be utilized anonymously for scientific purposes and quality management.

Moreover, I was informed that

- I can stop the analysis at any time, asking for the elimination of all results,
- I can withdraw my Informed Consent in total or in part at any time without any reason,
- I have to pay for the costs of the analysis that were generated until my withdrawal,
- I have the right **not** to know the results of the analysis (right of genetic ignorance),
- the genetic analysis and possible findings are focussed on the medical reason indicated above,
- an inconspicous result does not completely exclude a chromosomal abnormality

_____
Place, date

_____
Patient's signature

Required field: Disclosure and Genetic Counseling for the *Prenatalis*® test according to German GenDG

I agree/confirm that

- the pregnant woman was informed about the *Prenatalis*® test according to German GenDG (§9)
- the pregnant woman was genetically counselled according to German GenDG (§10)

_____
Place, date

Print NAME, first name, institution, mailing address (stamp, seal)

_____
Supervising physician's signature

Required field: CreditCard information - to be completed by the patient

Type of Card

☐ MasterCard
☐ Visa
☐ AmericanExpress

Owner of the Card _____

Credit Card number _____ Security Code _____ Expiration Date _____

Amount authorized ☐ 427,94 € ☐ 544,51 €

Place _____ Date _____ Signature (Owner of the Card) _____