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 Wilson, M.D.
Monika Cohen, M.D. Dagmar Wahl, M.D.

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

NIPT Laboratory
Thomas Harasim, Ph.D.

Prenatalis® - Non-Invasive Prenatal Test (NIPT)

Surname, first name (pat.) _____

Date of birth: _____

Street: _____

Postcode, City, Country: _____

Phone: _____

Important information 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).
Turn-around time: 3-5 working days after receipt of sample.
Reporting: exclusively to the supervising physician.

Our payment policy requires **upfront payment** of the analysis fee
Prenatalis®: **427.94 €** (incl. gonosomes **544.51 €**) by electronic money transfer to

Deutsche Apotheker- und Aerztebank
IBAN: DE 52 3006 0601 0006 3411 79
BIC: DAAEDEDD

Prenatalis® (3-5 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

Stamp

Print surname, first name, phone, fax and SIGN

Sample material

☐ 10 ml venous blood (BCT tube is provided) Sampling date: _____ Time: _____

Please note: incorrectly marked or incomplete samples will be rejected.

Mandatory 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):

Trisomy 21: 1: ☐☐☐☐
Trisomy 18: 1: ☐☐☐☐
Trisomy 13: 1: ☐☐☐☐

☐ Abnormal ultrasound:

☐ No increased risk

Further specifications

☐ Genetically inferred increased aneuploidy risk (i.e. parental Robertsonian translocation involving chromosome 21 or 13)

☐ Previous pregnancies/spontaneous abortions caused by 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 an aberation of chromosome 21, 18, 13, or an 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, 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 aberrations. 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 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 10 ml venous blood (BCT tube is provided) – order a test kit free of charge online at www.prenatalis.com
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.

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 Wilson, M.D.
Monika Cohen, M.D. Dagmar Wahl, M.D.

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

NIPT Laboratory
Thomas Harasim, Ph.D.

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

Dear Patient,

German GenDG (§10) requires the patient to be **fully imformed, a written Informed Consent** and in case of prenatal testing **detailed genetic counseling**.
Please read this information carefully and delete statements you do not agree with.

I agree/confirm that I

- was informed about type, chances, risks, limitations and significance of the *Prenatalis®* test according to German GenDG by the supervising physician. There was adequate time to ask questions,
- 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,
- give my permission to perform the *Prenatalis®* test with my sample,
- 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 not to know),
- the genetic analysis and possible findings are focussed on the medical indication given above and no statements are made about other diseases,
- an inconspicous result does not completely exclude a chromosomal abnormality.

_____
Place, date

_____
Patient's signature

Mandatory field: Disclosure and genetic counseling for the *Prenatalis®* test according to German GenDG *to be completed by the supervising physician*

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 surname, first name, institution, mailing address (stamp, seal)

_____
Supervising physician's signature

Mandatory field: Credit card information - to be completed by the patient

Type of card

☐ Mastercard
☐ Visa
☐ American Express

Owner of the card _____

Credit card number _____ Security code _____ Expiration date _____

Amount authorized: ☐ 427.94 € ☐ 544.51 €

Place _____ Date _____ Signature (owner of the card) _____