Patient´s initials ☐☐☐ Date of birth ☐☐ . ☐☐ . ☐☐☐☐ (DD/MM/YYYY)

CentoNIPT® - Request form

› Requested test*

For singleton pregnancy:

☐ **CentoNIPT®** for aneuplodies in chromosomes 21, 18, 13 and gonosomal aneupoidies

For twin pregnancy:

☐ **CentoNIPT®** for aneuplodies in chromosomes 21, 18, 13 and gonosomal aneupoidies[1]

Reporting on fetal gender[1,2]?

☐ **Yes** ☐ **No**

› Clinical information*:

Gestational age at sample collection: ☐☐ weeks

Date of sample shipment: ☐☐ . ☐☐ . ☐☐☐☐ (DD/MM/YYYY)

Maternal weight: ☐☐☐ kg

Maternal height: ☐☐☐ cm

☐ **Normal pregnancy**

- ☐ Abnormality of fetal movement
- ☐ Increase nuchal translucency
- ☐ Short fetal humerus length
- ☐ IVF or egg donor pregnancy (specify in further clinical information)
- ☐ Abnormal ultrasound
- ☐ Advanced maternal age
- ☐ Positive serum screen
- ☐ History of chromosome aneuploidies (specify in further clinical information)

› Further clinical information (e.g. family history, affected siblings, additional clinical symptoms)

NIPT Streck tube number*: ☐☐☐☐☐☐☐☐☐☐

Date of sample draw*: ☐☐ . ☐☐ . ☐☐☐☐ (DD/MM/YYYY)

Samples for NIPT-testing can only be accepted if provided to CENTOGENE within the CentoNIPT® Streck tube.

***) Mandatory fields must be completed for testing to proceed**

[1)] In case of twin gestations chromosome aneuploidies can be detected by this test but cannot be attributed to individual twin fetuses. If a Y chromosome is detected, the fetal gender of each individual twin cannot be determined by the test.

[2)] Please note that under the German Genetic Diagnostics Act the responsible physician is only allowed to report the gender after the 12th week of the pregnancy. Due to legal restrictions - even if requested - fetal gender will not be included and/or disclosed in the report in selected countries (particularly China and India).

If a genome or NIPT test is cancelled after receipt of the sample, but prior to analysis set-up, CENTOGENE charges a processing fee and will send a cancellation report. Once testing is initiated, the full price of the analysis will be charged.

› Patient Information

Last Name

First Name

Date of Birth . . (DD/MM/YYYY) Sex ☐ Male ☐ Female ☐ Other

Your Reference Number Sample Collection Date . . (DD/MM/YYYY)

› Physician or Laboratory - Reporting address

Name of Physician

Clinic Name

Department

Street

Town

Postal Code Country

Phone Fax

E-mail (mandatory)

› Additional Report Recipient

Name of Physician Clinic Name

Department Street

Town Postal Code

Country Phone

E-mail (mandatory)

☐ I hereby confirm that the patient consented to forward the medical report to this additional report recipient.

› Billing

CENTOGENE Quotation No.

› Promo Code - If applicable

Invoice to ☐ Patient ☐ Institution ☐ Insurance* - *Please attach cost coverage authorization

Company/Last name

Department/First name

Street Town

Postal Code Country

Phone

VAT ID (mandatory for institutional customers in the EU)

E-mail (mandatory)

› In case of Direct Billing to the Patient

The patient authorized to request the test(s) outlined on page 1. The patient was also informed about the resulting costs (and possibly applicable German 19% VAT) and requested to be billed directly by email. The address given above is the patient's billing address.

Place, Date

Signature of Physician ✘

Print out to sign and send

Note: CentoNIPT® is unavailable in the U.S.

Information part of consent form for conducting non-invasive prenatal testing CentoNIPT®

CENTOGENE requires a signed consent form from the patient in order to be legally able to conduct the ordered NIPT test/genetic analysis. Please ensure that this signed consent form accompanies the sample(s).

Dear Patient,

Your physician has recommended for you or you have requested (or a person for whom you have custody and you care for) non- invasive prenatal testing (so called "NIPT").
We would like to explain the purpose of this analysis, what occurs with non-invasive prenatal testing and the importance the results could have for you and your family.

How does non-invasive prenatal testing work?
Small amounts of a baby's DNA pass into the bloodstream of its mother during pregnancy. New technology allows us to analyse this DNA directly from the mother's blood and screen for chromosomal abnormalities.

Our DNA carries all the genetic information we require for normal health and development. It appears/exists as 23 pairs of chromosomes in our cells. During pregnancy, chromosomal abnormalities can arise in the developing baby as a result of incorrect egg or sperm formation, or during the earliest stages of the baby's development.
These chromosomal abnormalities can significantly affect the health and well-being of a baby and it is important to identify any abnormalities as early as possible.
CentoNIPT® delivers a clear positive or negative result for chromosomal abnormalities where an extra copy of one chromosome is present (trisomy). Down syndrome, the most common chromosomal abnormality can be detected with an accuracy of >99,9%.
CentoNIPT® also screens for changes in the number of X or Y chromosomes. As the test includes analysis of the sex chromosomes, you can also find out the gender of your baby. The test is also suitable if you are pregnant with twins.

How is the test performed?
A single blood sample, collected by your doctor, is sent to CENTOGENE's laboratory for analysis.

Significance of the results:
The results will show wether any of the described chromosomal abnormalities have been detected to your baby. If the results are normal, this will provide you with the reassurance that these most common genetic abnormalities are not present.
If the CentoNIPT® is positive for a chromosomal abnormality, your physician will offer you additional testing for confirmation of test results and refer you for genetic counselling to discuss the implications and choices available for you and your baby.
It is **not possible to exclude every disease risk** for yourself and your family members (especially your children) utilizing genetic analyses. The knowledge of the results may result in mental stress.
It is always recommended to discuss the details of the genetic report with your local physician.

Limitations of the test:
- CentoNIPT® detects the most common prenatal chromosomal abnormalities. However, the test cannot rule out the possibility of other, less common genetic diseases.
- CentoNIPT® is only designed to analyze full chromosome aneuploidies of the fetus after 10 weeks of gestation and is reporting on aneuploidies for chromosomes 21, 18, 13 and sex chromosomes (X0, XXX, XXY and XYY) in singleton and twin gestations.
- In case of organ transplantation from a male donor for the mother, sex chromosome status for the fetus cannot be determined by this test.
- There is a small possibility that the test results might not reflect the chromosomes of the baby, but instead might reflect chromosomal changes to the placenta (confined placental mosaicism), or in the mother (chromosomal mosaicism).
- Triple or higher gestations cannot be analyzed by this test.
- In case of twin gestations and detection of only one Y chromosome by the test, the fetal gender of each individual twin cannot be determined by the test.
- Chromosome aneuploidies in general for a twin gestation can be detected by this test but cannot be attributed to individual twin fetuses.
- In the case of uncertain or unambiguous test results, the test result must be confirmed by invasive prenatal diagnosis.
- Please note that under the German Genetic Diagnostics Act the responsible physician is only allowed to report the gender after the 12th week of the pregnancy.
- Due to legal restrictions - even if requested - fetal gender will not be included and/or disclosed in the report in selected countries (particularly China and India).
- Negative results (reported as "No Aneuploidy Detected") do not eliminate the possibility of chromosomal abnormalities of the tested chromosomes. A negative result does not eliminate the possibility that the pregnancy has other chromosomal abnormalities (for example microdeletions), genetic conditions or birth defects.
- Test results can be confounded by maternal and /or fetal factors like recent maternal blood transfusion, maternal weight, stem cell therapy and others.

Use of the sample/results:
The sample and the test results will be used for the analysis and in accordance with your consent declaration that is stated below. The test results will also be used - if possible - for treatment decisions by your physician(s).

Right not to know:
You have the right not to be informed about test results (right not to know) and to stop the testing processes that have been started at any time up to being given the results and to request the destruction of all analysis results.

Data protection information for patient and physician:
In the following we want to inform you about the processing of personal data during and after the performance of the non-invasive prenatal testing analysis. "Personal data" is understood to mean all information which relates to an identified or identifiable natural person. To all such collected and processed personal data, the following applies:

- Controller and responsible entity for the processing of your personal data is Centogene GmbH, Am Strande 7, 18055 Rostock, represented by the Executive Board members as can be found on our website (https://www.centogene.com/company/executive-board.html). You can reach our data protection officer under the same address with the addition "Attn: Data Protection Officer" or by email dataprivacy@centogene.com.
- Patient: By virtue of this consent form and through your physician, we collect the following data about you and your unborn child (in each case insofar as provided): personal details (including name and address), family relations, age/date of birth, gender, ethnicity, nationality, insurance information, symptoms and other medical information, disease, the study material / sample with identifiable genetic data, the non-invasive prenatal testing results and findings. All your collected data will be stored for as long as indicated in the consent declaration. The data will be processed – partially also in data centers operated by service providers under our control and instructions - for the performance of the non-invasive prenatal testing requested and for informing your physician of the results of such analysis, in each case on the basis of the consent provided.
- Physician: All your collected data will be processed to communicate with you about the tests and the results, as well as for invoicing, for as long as we keep identifiable data about your patients. This takes place on the basis of legal provisions allowing to process personal data for the purpose of performing a contract and for customer relation management reasons because we have a respective legitimate interest. We use data processors, which have been carefully selected and are subject to our instructions and to regular monitoring. Disclosures to data processors may result in such data being processed in countries outside of the EU (third countries). For each such transmission of data to a third country it is safeguarded that either an adequate level of protection or reasonable guarantees exist; e.g. by concluding a data processing agreement containing EU standard data protection clauses (retrievable at: https://ec.europa.eu/info/policies/justice-and-fundamental-rights_en).
- You (Patient and Physician) do have the following rights regarding personal data relating to you, which you can exercise at any time, e.g. through an email to dataprivacy@centogene.com:

  - Right to be provided with information about and to have access to the personal data stored on you;
  - Right to have the personal data stored on you rectified or erased;
  - Right to obtain restriction of processing your personal data;
  - **Right to object on grounds relating to your particular situation;**
  - Right to data-portability (i.e. receive personal data you provided to us in a structured, commonly used and machine-readable format); and
  - Right to withdraw your consent with effect for the future at any time

- You have the right to lodge a complaint with a supervisory authority regarding the processing of your personal data. You may have further or modified rights under applicable national law, which remain unaffected.
- For a more detailed and regularly updated information about how we process personal data please visit our Data Protection Statement under www.centogene.com/data-protection.

Declaration of consent for NIPT testing

By signing this declaration of consent I acknowledge that

- I have received, read and understood the preceding written explanation of non-invasive prenatal testing and the further explanation contained in the requisition form;
- I have received appropriate explanations (from my physician) with regard to the NIPT, especially the genetic basis, the purpose, scope, type and significance of the planned test(s), achievable results by the planned test, the importance of the analyzed genetic characteristics for my baby´s disease/health disturbance, possibilities of prevention/ treatment of a disease or a health disturbance of my baby as well as with regard to risks associated with (1) the generation of the sample required for the NIPT and (2) the knowledge of the results of the NIPT. All my questions have been answered and I have had the necessary consideration time;
- I have been informed about the limitations of CentoNIPT® such as:
  - CentoNIPT® is only designed to analyze full chromosome aneuploidies of the fetus after 10 weeks of gestation and is reporting on aneuploidies for chromosomes 21, 18, 13 and sex chromosomes (X0, XXX, XXY and XYY) in singleton and twin gestations.
  - In case of organ transplantation from a male donor for the mother, sex chromosome status for the fetus cannot be determined by this test.
  - There is a small possibility that the test results might not reflect the chromosomes of the baby, but instead might reflect chromosomal changes to the placenta (confined placental mosaicism), or in the mother (chromosomal mosaicism).
  - Triple or higher gestations cannot be analyzed by this test.
  - In case of twin gestations and detection of only one Y chromosome by the test, the fetal gender of each individual twin cannot be determined by the test.
  - Chromosome aneuploidies in general for a twin gestation can be detected by this test but cannot be attributed to individual twin fetuses.
  - In the case of uncertain or unambiguous test results, the test result must be confirmed by invasive prenatal diagnosis.
  - Please note that under the German Genetic Diagnostics Act the responsible physician is only allowed to report the gender after the 12th week of the pregnancy.
  - Due to legal restrictions - even if requested - fetal gender will not be included and/or disclosed in the report in selected countries (particularly China and India).
  - Negative results (reported as "No Aneuploidy Detected") do not eliminate the possibility of chromosomal abnormalities of the tested chromosomes. A negative result does not eliminate the possibility that the pregnancy has other chromosomal abnormalities (for example microdeletions), genetic conditions or birth defects.
  - Test results can be confounded by maternal and /or fetal factors like recent maternal blood transfusion, maternal malignancy, maternal weight, stem cell therapy and others.
  - I was informed that in case of a positive aneuploidy finding, invasive testing is recommended.

With my signature at the end of this declaration I give my consent and consent on behalf of my unborn child:

(1) to the non-invasive prenatal testing by Centogene GmbH, Am Strande 7, 18055 Rostock, Germany, (CENTOGENE) for the subject stated above and which is described in more detail in the preceding written explanation of NIPT and in the requisition form, (2) to the collection and processing by my physician and CENTOGENE of my and my unborn child's "Personal (Health) Data" (meaning in particular and in each case insofar as provided: personal details (including name and address), family relations, age/date of birth, gender, ethnicity, nationality, insurance information, symptoms and other medical information, disease, the study material/sample with identifiable genetic data, the non-invasive prenatal testing results and findings) as far as required to conduct the non-invasive prenatal testing including any necessary transfers of my Personal (Health) Data between physician and CENTOGENE across national borders, (3) to the generation of the necessary sample as specified by my physician and above, (4) to the analysis of the obtained sample and its storage for 10 years at CENTOGENE together with my patient file to be able to verify results of the analysis if need be, (5) to add to my record and use for the above purposes – if applicable – personal data on members of my family – if these members have consented, (6) to inform me or my physician or – if CENTOGENE has been instructed by a laboratory acting on behalf of my physician – this laboratory about the results of the NIPT.

By ticking the relevant "YES" box below, I give my additional consent and consent on behalf of my unborn child:

Further storage and use of my and my unborn child's Personal (Health) Data and the sample

I understand that my and my unborn child's Personal (Health) Data and (remaining) sample may help in further research, development and improvement of diagnostic methods and possibly therapeutic solutions. Such measures may in the future also enable and support medical advice and guidance to me and my family members, e.g. related to the diagnosis and treatment of a potential genetic disease.

- I agree that CENTOGENE stores (1) my and my unborn child's Personal (Health) Data and information on (affected) family members - if they consented - and the results of the NIPT a possible future genetic analysis and (2) my sample (including original and processed sample) for a period of 20 years and uses this data and the remaining samples for the purpose of internal research, improvement, development and validation of analysis procedures and related product and service developments. In this regard, my sample may be used in anonymized form also for a genetic analysis of my or - insofar as possible - my unborn child's genetic data.
- I agree that after a period of 20 years my and my unborn child's Personal (Health) Data and (remaining) sample are anonymized and ownership in the sample is then transferred to CENTOGENE. Both will then remain in CENTOGENE's archives for use by CENTOGENE without restrictions.
- I agree that CENTOGENE may at any time process my or my unborn child's anonymized or pseudonymized Personal (Health) Data, e.g. into its databases and datasets concerning NIPT analyses, genetic diseases, for the purpose of scientific and commercial research and to facilitate and contribute to the diagnosis of genetic changes and diseases of other patients. Access to such pseudonymised or anonymised data might be granted to external physicians, scientists and (pharmaceutical) companies for research and development purposes.
- I understand that I will not receive any compensation for the use of my or my unborn child's Personal (Health) Data or sample by CENTOGENE.
- I understand that data in CENTOGENE's databases – once anonymized - cannot be destroyed upon request as it is unidentifiable and untraceable.

☐ YES

I am aware that I can withdraw my consent and the consent on behalf of my unborn child with effect for the future in full or in part at any time and that I have the right not to know the results of the NIPT analyses as described in the preceding written explanation.

If the undersigning is the legal guardian of the Patient, he/she herewith to confirms to provide the above consent declarations not for himself/herself but on behalf of the respective patient and the unborn child.

Date	Name of Patient	Signature of Patient /Legal Guardian	Print out to sign and send

I hereby confirm that the consent as shown above has been declared by the patient or (as the case may be) his/her parent or legal guardian and that I have his/her signature on file if it is not shown above. I confirm that the patient is capable of giving this consent (alternatively that the consent was given by a legal guardian of the patient), that all questions of the patient have been answered, that the patient had the necessary time to consider his/her decision and that the patient until now has not exercised his/her right not to know the results of the NIPT analyses. I understand that the patient may request to have his/her NIPT analyses results eliminated at any time and that I shall forward such requests to CENTOGENE without undue delay. I agree that my own personal data is stored in CENTOGENE's databases for organizational and invoicing purposes.

Date	Name of Physician	Signature of Physician	Print out to sign and send

CENTOGENE GmbH
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