H9.2-F13 – v7 in voege 24-10-2023

Request form

Non-invasive prenatal test (NIPT) – genome-wide analysis

CENTER MEDICAL GENETICS UZ GHENT BELGIUM T +32 9 332 24 77 F +32 9 332 65 49

Please send the sample to the laboratory as soon as possible (within 24 hours after collection), this before 5 pm (on Friday before 2 pm). Keep the sample at room temperature. Send to:
UZ Gent, Medical Research Building - Center Medical Genetics, Entrance 34, Corneel Heymanslaan 10, 9000 Gent, Belgium.
More information about the collection, storage and transport of human samples and about the specific tests:
https://www.cmgg.be/en/professionals/instructions-for-samples.

IDENTIFICATION MOTHER

First name _____
Last name _____
Birth date _____
Address _____

_____

_____

National insurance nr. _____
Health insurance _____
Membership number _____ **CG1/CG2** _____ / _____

IDENTIFICATION PHYSICIAN

First and last name _____
RIZIV number _____
Address / department _____

_____

_____

Copy result to _____
Signature physician:

BLOOD TEST (10ml in a blood tube suited for cfDNA analysis, e.g. PAXgene ccfDNA tube)

DATE BLOOD TEST: ____ / _____ / _____, Time _____

INFORMATION PREGNANCY

Ultrasound gestational age _____ weeks _____ days **Date ultrasound** _____ / _____ / _____

Expected birth date _____ / _____ / _____

Number of fetuses
☐ **Singleton**
☐ **Multiple pregnancy - chorionicity :** ☐ DCDA ☐ MCDA ☐ MCMA
(DCDA: dichorionic / diamniotic; MCDA: monochorionic / diamniotic; MCMA: monochorionic / monoamniotic)
☐ **Vanishing twin**

Oocyte donation ☐ no ☐ yes

PERSONAL HISTORY

Obstetric anamnesis _____

Previous pregnancy with a chromosomal abnormality? ☐ no ☐ yes name of the disorder _____

Familial genetic disease? Is the pregnant woman carrier of the genetic anomaly?
☐ no ☐ yes name of the disorder _____

INDICATION / CLINICAL INFORMATION

_____

_____

_____

Informed consent

Non-invasive prenatal test (NIPT) – genome-wide analysis

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CONSENT FORM INSTRUCTIONS

The following pages contain a copy of the consent form for the laboratory (pages 3 and 4) and a copy for the patient (pages 5 and 6). Please complete and sign both copies.

Informed consent – COPY FOR LABORATORY

Non-invasive prenatal test (NIPT) – genome-wide analysis

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I hereby declare that I have been clearly informed about the non-invasive prenatal test (NIPT).
NIPT cannot be performed without signing this consent form.

- I have been informed about the possibilities and limitations of this test, as described in the information brochure. I have had the opportunity to ask my doctor for additional information.
- I understand that the NIPT is a non-invasive genetic test that is performed on a blood sample of me, possible from the 12th week of pregnancy, in which the DNA from the placenta will be examined.
- I understand that this test is primarily intended to detect a trisomy 21, 18 and 13 (Down, Edwards and Patau syndrome respectively). However, because all chromosomes are analyzed during the NIPT analysis, the NIPT can in rare cases also detect other chromosome abnormalities, both in the baby and in the mother. These will be communicated if assumed to be of clinical relevance to you and/or your child.
- I understand that this test can determine the sex of the baby with high probability. I have been given the opportunity to indicate whether or not I wish to receive this information.
- I also understand that certain sex chromosome abnormalities (monosomy X and XXY) may be reported with this test and that I must consent if I wish to be informed about these conditions. I understand that, in a twin pregnancy, these sex chromosome abnormalities can only be detected in monochorionic twins (one placenta).
- I understand that other more appropriate tests are indicated when there is an increased risk for specific genetic disorders.
- I understand that this test is very accurate, but not 100%. In case of a normal result, the chance that the baby still has trisomy 21, 18 or 13 is very small, but not completely excluded. On the other hand, with an abnormal NIPT result, the baby may not be carrying the abnormality; an abnormal result should therefore always be confirmed by an invasive prenatal examination (preferably with an amniocentesis).
- In about 2-5% of the cases, no result can be obtained. In most cases, a new blood sample can be taken for a new analysis at no extra cost; however, in some cases reanalysis is not indicated for biological reasons.
- I understand that one NIPT is reimbursed per pregnancy in Belgium and that the co-payment is less than 10 euros. If I am entitled to an increased allowance, I do not have to pay co-payment. With my signature I confirm that I have not yet had an NIPT or combination test performed during my current pregnancy. If I am not affiliated with a Belgian health insurance fund, I know that I have to pay the full cost of this test myself.
- I understand that residual material and genomic data obtained after performing the NIPT can be used anonymously for validation, internal quality control or research purposes (e.g. optimization of the NIPT and new developments).
- I understand that the NIPT result will be available after a maximum of 10 working days (counted from the day of the blood draw). My result will be available digitally via the Collaborative Care Platform (CoZo) (www.cozo.be): the report with the NIPT result (for chromosomes 13, 18 and 21) and, if requested, a report with the sex of the baby(s).

Informed consent – COPY FOR LABORATORY

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Please read the options below thoroughly and indicate the desired options.

1) Regarding the sex:

☐ I wish to know the gender of my baby/babies. (*)

☐ I wish NOT to know the gender of my baby/babies.

2) Regarding abnormalities of the sex chromosomes (monosomy X and XXY):

Important:* *not possible for a dichorionic twin pregnancy and vanishing twin

☐ I do wish to be informed of an increased risk of such an abnormality of the sex chromosomes in my baby/babies.

☐ I do NOT wish to be informed of an increased risk of such an abnormality of the sex chromosomes in my baby/babies. (*)

(*) If nothing is checked, this option will be used.

I am sufficiently informed about the possibilities and limitations of the proposed genetic screening and have received a clear answer to all my questions. I agree that NIPT is performed for the prenatal detection of trisomy 21, 13 and 18.

Name parent _____

Date consultation ____ / ____ / _____

Signature parent _____

The undersigned has explained the information about the NIPT in a personal conversation and in an understandable language.

Name health caretaker _____

Date consultation ____ / ____ / _____

Signature health caretaker _____

Commissioned by responsible doctor _____

Informed consent – COPY FOR PATIENT

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Important:* *not possible for a dichorionic twin pregnancy and vanishing twin

☐ I do wish to be informed of an increased risk of such an abnormality of the sex chromosomes in my baby/babies.

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(*) If nothing is checked, this option will be used.

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Date consultation ____ / ____ / _____

Signature parent _____

The undersigned has explained the information about the NIPT in a personal conversation and in an understandable language.

Name health caretaker _____

Date consultation ____ / ____ / _____

Signature health caretaker _____

Commissioned by responsible doctor _____