Print Form

REQUEST FORM PRENATAL GENETIC ANALYSIS

version1/20210901

Label sample fetus | Label sample mother | Label sample father

CENTRE FOR MEDICAL GENETICS
UZ Brussel
Laarbeeklaan 101 - 1090 Brussel
email: cmg.laboratory@uzbrussel.be
tel. +32 (0)2 477 64 79
https://www.uzbrussel.be/web/centrum-voor-medische-genetica/

Universitair Ziekenhuis Brussel

BELAC 141-MED BELAC 141-MED accreditd according to quality standard ISO15189:2012

Identification mother * (* Mandatory data)

Name: Sticker
First name:
Date of birth:
Residential address: identification patient
Invoice address:
Email address:
Phone:
National registry N°:
Ethnic origin:

Identification father *

Name: Sticker
First name:
Date of birth:
Residential address: identification patient
Invoice address:
Email address:
Phone:
National registry N°:
Ethnic origin:

Identification fetus *

Name:
First name:
Date of birth:
National Registry N°:

Identification referring physician *

Name: Stamp
First name:
Referring service:
Address: referring physician
Email address:
Phone:
RIZIV/INAMI number:
Signature*:

Sample data fetus *

- CV ☐ Chorion villi
- AC ☐ Amniotic fluid
- NS ☐ Fetal blood (umbilical cord blood)
- FB ☐ Fetal biopsy Specify:
- ☐ DNA from Specify:
- ☐ Stock sample Reason:

Collection date:

Sample mother *

E ☐ EDTA blood min. 4ml Collection date: ☐ DNA

Sample father *

E ☐ EDTA blood min. 4ml Collection date: ☐ DNA

Request date*:
Your reference:
Copy result to:
Address:

☐ Genetisch rapport in Nederlands ☐ Genetics report in English

Data pregnancy *

Gestational age: ____ weeks ____ days

☐ Spontaneous ☐ IVF ☐ ICSI ☐ PGT ☐ egg donation ☐ sperm donation

G: ___ P: ___ A: ___ ☐ Miscarriage ☐ TOP ☐ Extra uterine ☐ Mola

Number of fetusses: ☐ 1 ☐ 2 ☐ vanishing twin

Chorionicity: ☐ DC/DA ☐ MC/DA ☐ MC/MA

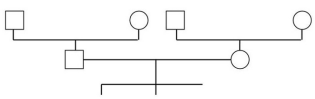
Indication *

- ☐ Fetal ulrasound anomaly(s) Specify:
- ☐ Aberrant NIPT Specify:
- ☐ Increased trisomy risk Specify:
- ☐ (Recurring) miscarriage Number: Specify:
- ☐ History genetic disease
  - ☐ In previous pregnancy/ies ☐ In mother ☐ In father ☐ In family ☐ Consanguinity Specify:

Clinical findings (*preference HPO-terms*): addition clinical report required

Genetic defect in family member: addition genetic report required

- ☐ Prereduction
- ☐ CMV / toxoplasmosis seroconversion
- ☐ HLA-compatibility
- ☐ Psycho-social
- ☐ Other Specify:



☐ man ☐ woman ☐ fetus
☐ normal ☐ carrier ■ affected ☐ deceased

Genetic test

Sampling fetus	Sampl. parent(s)	Prenatal test ** FB: 1-12 weeks / ***: detailed information gene panel http://www.brightcore.be/gene-panels	TAT
CV AC FB NS	E	☐ Chromosomal analysis ☐ QF-PCR (chr X,Y,13,18,21) & CGH-array ☐ FISH:	**5-10 working days
CV AC FB	E	☐ Congenital malformation syndrome/MCA ☐ gene panel*** ☐ targeted:	2-6 months
CV AC FB NS	E	☐ Targeted mutation testing (monogenic) Specify:	10 working days

We strive to complete the analyses within the set turnaround times (TAT). In exceptional situations, we may deviate from the standard turnaround time

INFORMED CONSENT PRENATAL GENETIC ANALYSIS

Universitair Ziekenhuis Brussel

CENTRE FOR MEDICAL GENETICS - UZ Brussel
Laarbeeklaan 101 - 1090 Brussel
email: cmg.laboratory@uzbrussel.be - tel. +32 (0)2 477 64 79

GENETIC TEST

1. Diagnostic genetic test

We, the undersigned, agree to perform a diagnostic genetic test on blood samples, or other samples, from us and our fetus for the following condition:

.....

The diagnostic genetic test that will be performed is:

- ☐ a limited analysis or 'targeted' analysis of gene(s)
- ☐ a broad analysis or 'non-targeted' genome-wide analysis**

2. Scientific research

After a diagnostic genetic test is done for a condition, some material usually remains. This material can be preserved as it can be useful for further diagnostic testing with broader genetic analyses** at a later date and/or for scientific research (see explanation below).
With regard to the preservation of remaining samples, the genetic data, and medical data for later scientific research:

- ☐ we agree
- ☐ we do not agree

** Broad genetic analysis:
A broad genetic analysis can lead to an incidental and/or secondary discovery of genetic results unrelated to the condition for which the test was performed. We realise that such results can have implications for us and the family. We would like to be informed about genetic results that present an increased risk for diseases for which:

- ☐ appropriate follow-up, prevention, or treatment is available (such as a risk for cancer, heart disease)
- ☐ no prevention or treatments exist (such as for dementia; NB only adult mentally competent persons may choose this option)

With regard to the storage and exchange of data/samples as part of the diagnostic process and scientific research, we understand that:

- the exchange of medical and genetic data between experts is important to improve the knowledge of genetic diseases.
- this exhange can be done in the context of diagnostic testing and/or scientific projects approved by the relevant ethics committee.
- the exchange of data may lead to improved diagnosis for our fetus, ourselves or others, improved healthcare, improved prevention, imprvoed therapeutic means; and may be published in scientific journals, or presented at scientific meetings
- our fetus and our samples, genetic and relevant medical data are labelled with a code (see explanation on next page).
- our fetus and our encoded genetic samples can be used as control material for the general improvement or development of tests.
- genetic and relevant medical data can be re-analysed in the context of diagnostic tests and/or approved research projects, that are available at a later stage and /or within approved research projects, without us being informed in advance.
- the knowledge and possibilities for analysis and interpretation of genetic research will increase in the future and re-analysis can reveal a (new) diagnosis. There is currently no systematic re-analysis of data.
- if our health insurance does not reimburse the costs for the original the genetic tests, these will be invoiced to us in full.
- we reserve the right to change our consent at any time, for one or more of the various points described. The withdrawal of consent will not adversely affect our fetus or our general medical treatment (unrelated to the genetic test, for which this consent was given). We understand that our withdrawal cannot be applied to the results and data collected before our request for withdrawal.
- our participation is voluntary and will not be linked to financial benefits.

- ☐ we agree with the above
- ☐ we do not agree with the above

To be completed by mother or representative *

I confirm that I am well informed about the objectives and nature of the analyses related to my condition. I received the necessary information from the healthcare provider and/or I read the corresponding information leaflet. I have had the time and opportunity to ask questions and I am satisfied with the answers and supplemented explanations.

Name mother: Sticker
First name mother:
Date of birth:
Residential address: identification patient
Email address:
Phone:
National registry N°:
Date:
Signature*:

To be completed by father or representative *

I confirm that I am well informed about the objectives and nature of the analyses related to my condition. I received the necessary information from the healthcare provider and/or I read the corresponding information leaflet. I have had the time and opportunity to ask questions and I am satisfied with the answers and supplemented explanations.

Name father: Sticker
First name father:
Date of birth:
Residential address: identification patient
Email address:
Phone:
National registry
Date:
Signature *:

To be completed by healthcare provider *

I hereby confirm that I have informed the undersigned patient and answered questions in the best possible way with regard to the possible results, limitations and options for the test(s) mentionned above.

Name: Stamp
First name:
Date:
Signature*: healthcare provider

* Mandatory data

INFORMED CONSENT FOR PRENATAL GENETIC ANALYSIS (continued)

Universitair Ziekenhuis Brussel

CENTRE FOR MEDICAL GENETICS - UZ Brussel
Laarbeeklaan 101 - 1090 Brussel
email: cmg.laboratory@uzbrussel.be - tel. +32 (0)2 477 64 79

EXPLANATION ON STORAGE AND USE OF SAMPLES

After a diagnostic genetic test is done, a part of the material remains for which there is no immediate purpose. This material could be destroyed, but often it is useful not to do so. In some cases, it can be used in a meaningful way. The following four possibilities are considered:

1) a different diagnostic test within the scope of your original question;

2) scientific research within the scope of your original question

3) genetic research of a general nature, with which you mainly help other people;

4) you and/or your descendants have a new question or condition that requires genetic testing

Explanation
It is possible that a different diagnostic test can be done at a later date, for a condition that affects your fetus, yourselves or your family (1). Moreover, scientific research could be carried out in order to search for more understanding on this condition (2). The material that was previously obtained from your fetus and you can be used for these tests. This material, and any encrypted medical data, will then be used further and examined at a national or international level. For research into rare diseases, such an approach can speed up the identification of an explanation for the condition. When performed, your fetus and your data will always be encrypted in order to fully protect the privacy of your fetus and you and your fetus' and your genetic and medical information.
Body material is often valuable for developing new scientific knowledge or for testing diagnostic devices in the laboratory (3). This scientific knowledge is usually not directly applicable in practice at the beginning, but can become important for patients at a later date. A great deal of knowledge that is now used daily by doctors in patient care has arisen from such scientific research, of which the practical significance was initially not entirely clear.

Examples of further use
1 and 2) After diagnostic genetic testing the remaining material is stored after use but identified via a code. This means that your fetus and your personal data will be replaced by random numbers. The list that indicates which number (code) belongs to which patient is stored by an administrator in a safe place. The people who use the material only see the random numbers (codes) associated with the material. The code can be traced back to your fetus and/or your personal data if a researcher - sometimes years later - finds a genetic change in a coded sample, which explains your original question or may be of interest to your fetus or your state of health. An example is an inherited predisposition to cancer or to heart disease, for which prevention, treatment or surveillance options possible with timely research. The chance of such a genetic change is usually small. There is also a chance that we may find a genetic change that can affect your treatment, such as an adjustment in your medication. The researcher who makes such a discovery then passes on the code number(s) to the administrator who can link the code to the name of a patient and to the name of the practisioner/ doctor with whom that patient has been in contact. Subsequently, an assessment is made on whether the genetic change is indeed important for your fetus, you and your fetus' and your health. This assessment is done in consultation with an independent committee of doctors and other experts, which helps to decide whether the genetic change should be linked back to you. If so, you will be contacted by your treating physician to inform you of the genetic change. This finding will then have to be confirmed with a new independent test on your fetus and/or you.
3) Your fetus and your material can also be used for scientific research that only provides general knowledge and can not be individually applied. An example of this is when your fetus and your material is used as control sample for a test, which has nothing to do with the condition for which you had genetic testing in the first place. Body material and coded data from groups of patients are then compared with those from other groups of patients or healthy people. The results of such scientific research are usually not reported back to you. In case that there would be feedback, it could be many years later.
4) After your original question has been answered, you and/or your descendants may have a new question concerning genetics. In that case your fetus and your remaining material can be used for a new genetic test.

In conclusion
We hope to have given you sufficient information to make an informed decision about the storage and use of your fetus and your samples and your fetus' and your medical and genetic data. For more information you can always contact the Centre for Medical Genetics at the UZ Brussel: https://www.uzbrussel.be/web/genetics.
More information on privacy can be found at: https://www.uzbrussel.be/web/neem-zelf-uw-zorg-in-handen-/patiëntenrechten.

version1/20210901

Print Form