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Site : www.ipg.be

n° réception IPG	n° analyse IPG

REQUEST FORM FOR GENETIC NON INVASIVE PRENATAL TEST FOR TRISOMY 21, 18 AND 13 (received accreditation ISO-15189 (MED-381)

DETAILS OF THE MOTHER

Surname:
First name:
Date of birth:
Phone number (facultative):
Complete address:
Street and number:
Post code and town:
Health Insurance Nr: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐
National Insurance Nr: ☐☐☐☐☐☐☐☐☐☐☐

Predicted date of delivery: ……/……/……
Age of pregnancy: ..... WA (min 12 WA) *
Pregnancy:
☐ single
☐ twin ☐ (DC/DA) ☐ (MC/DA) ☐ (MC/MA)

Weight before pregnancy: ……
Height: ……
Sex of the fœtus on sonography ☐ male ☐ female ☐ unknown

REFERRING PHYSICIAN

Surname:
First name:
Hospital/Institution:
Street and number:
Post code and town:
Phone number:
Mobile Phone : ..... *It is **important** to communicate your mobile number in case we need to contact you **rapidly***
Inami nr:

Copy to:

Address:

Sample :
- Date: ……/……/……
- Time: ……h……

TEST RESULTS TRANSMISSION

☐ MEXI ☐ BY POSTAL MAIL

SAMPLE

From Monday to Thursday - For enquiries : ☎ : 071/44.71.81

1 Cell-Free_DNA_BCT tube of the brand Streck 10 ml
(filled with **minimum of 8 ml** of maternal blood in order to obtain sufficient foetal DNA).

Reception : Date : ……/……/…… Time : ……h ……
The sample should be sent to the laboratory **as quickly as possible**
Do not freeze and keep at room temperature
The sample needs to be mixed by multiple (10x) inversions

MEDICAL HISTORY

Gravidity: …… Parity: …… Miscarriages: ……

Interruptions of pregnancy: ……

Previous pregnancies with chromosomal abnormalities (to be detailed):

Family or personal history of genetic disorders (to be detailed):

Previous history of transfusion, transplantation, stem cell therapy, cancer (to be detailed):

ULTRASOUND FIRST TRIMESTER **

* *The screening is reimbursed only from the 12th week of pregnancy, Reimbursement cannot be cumulated with other screening tests for trisomy (triple test, combination test)*

** In case of ultrasound diagnosis of fetal anomalies, an amniotic fluid puncture followed by an array-CGH should be performed.

Non conformity code: ……
Initials LT

CONTACT

Form can be downloaded at : http://www.ipg.be/

See obligatory informed consent (verso)

INFORMED CONSENT*

1. I understand, the indication, the purpose, benefits and limitations of this test. My doctor, Dr _____, answered all my questions.

2. I understand that this test is only used to detect trisomy 21, 18 and 13 in the fetus from 12 weeks of pregnancy (14 weeks of amenorrhea). I also understand that this test is very accurate, but not 100%. In case of a normal result, the risk that the baby has trisomy 21, 18, or 13 is very small, but not entirely excluded. Others chromosomal abnormalities can be found at the fetal or maternal level but this test has not been validated for the detection of these types of abnormalities. In accordance with the recommandations of the BeSHG, anomalies of the sex chromosomes are not reported

3. I was informed that the result will be available in approximatively 1 week following receipt of the sample.

4. I understand that in some cases (about 5%), a result cannot be obtained with the first blood sample. A new blood sample may be necessary due to unforeseen circumstances, including insufficient fetal DNA concentration in the blood sample, sample degradation during transportation,.... If this occurs, a new blood test can be performed and analyzed at no extra cost.

5. I understand that the result should not be considered as a diagnosis. A positive result, indicating an increased risk, should always be confirmed by a diagnostic test, such as a puncture of the amniotic fluid (from the 15th week pregnancy).

6. I agree to provide relevant information regarding the pregnancy, such as any chromosomal anomaly (such as translocation) or genetic disorder in the family. I understand and agree that my doctor can contact me to request such information.

7. I was informed that this test is reimbursed since July 1th 2017 and that I will have to pay the user fee of 8,68 €. This reimbursement cannot be cumulated with other screening tests for trisomy on maternal blood (triple test, combination test)

8. **This test is ISO-15189 (MED-381) accreditated since April 2015.**

9. This informed consent can be explained and then signed after genetic counselling by a specialized medical doctor. In this case, the payment of a supplement for this medical appointment will be asked.

10. The NIPT test is established on basis of the Belgian Society of Human Genetics (BeSHG) recommendations. These lasts can be found on the net: http://www.beshg.be/index.php?page=guidelines sections “Summary of NIPT guidelines” and “NIPT guidelines for incidental findings”.

11. I accept the use of bloodsample and my clinical data by my doctor and / or the laboratory for verification of control quality and research, provided that I remain anonymous and unidentifiable in the data analysis and that all my personal information will be removed from reports or publications. If I disagree with this point, I can indicate it by adding a cross here ❒

12. IPG processes your data in accordance with the security and confidentiality requirements as described in the General Data Protection Regulation (GDPR). You can access more details about this on the IPG website http://www.ipg.be/protection-vie-privee/

I AGREE THAT THIS TEST IS PERFORMED
FOR THE PRENATAL DETECTION OF TRISOMY 21, 18 AND 13.

PATIENT	PHYSICIAN
Name: _____	Name: _____
Date: _____	Date: _____
Signature*: _____	Signature*: _____

(*) *Mandatory signature for analysis*