

TOMORROW

non invasive prenatal test

REQUISITION FORM



MANDATORY FIELDS

ORDERING PHYSICIAN	PHYSICIAN		DEPARTMENT	
	MEDICAL CENTER			
	ADDRESS	ZIP CODE	CITY	COUNTRY
	EMAIL	PHONE	FAX	
PATIENT INFORMATION	LAST NAME	FIRST NAME	DOB (dd/mm/yyyy)	GENDER
	MEDICAL RECORD NO.	EMAIL	PHONE	female
	BILING INFORMATION (if receipt is issued on patient's behalf):			
	VAT No.	ADDRESS	ZIP CODE	CITY COUNTRY

MANDATORY FIELDS

TEST OPTIONS (select only one option)

1 TOMORROW

DETECTION OF TRISOMIES 21, 18 AND 13, FETAL GENDER IDENTIFICATION AND SEX CHROMOSOME ANEUPLOIDIES (XX, XXX, XXY, XYY)

2 T21, T18, T13 only: detection of trisomies 21, 18 and 13 and fetal gender identification

PREGNANCY

☐ SINGLETON ☐ TWIN ^{1,2,3} (2 fetuses)

¹ Test cannot be performed in case of pregnancies with more than 2 fetuses.

² The fetal sex is evaluated by the presence or absence of the Y chromosome in maternal blood. In the case of detection of the Y chromosome in a twin pregnancy (2 fetuses), it is not possible to confirm if one or both fetuses are male. Likewise, in twin pregnancies it is not possible to determine the presence of aneuploidies of the sex chromosomes, so only the T21, T18, T13 only test can be performed.

³ Please note that Non-Invasive Prenatal Tests are less sensitive when performed in twin pregnancies.

select at least one of the options

- ☐ Advanced maternal age (35+)
- ☐ Positive serum screen
- ☐ Abnormal ultrasound
- ☐ Hx suggestive of increased risk for the specified chromosomal aneuploidies
- ☐ Low risk/maternal anxiety
- ☐

FETAL GENDER IDENTIFICATION

IMPORTANT

- ☐ Tick if patient does NOT wish to receive fetal gender information

CLINICAL INFORMATION

GESTATIONAL AGE AT THE TIME OF BLOOD COLLECTION

_____ weeks, _____ days

DATING METHOD

- ☐ LMP ☐ Date of implantation
- ☐ CRL ☐

DATE AND TIME OF DRAW (dd/mm/yyyy)

____/____/____ at ____:____

INSTITUTION/LOCATION OF BLOOD COLLECTION

MATERNAL HEIGHT

_____ cm
_____ ft in

MATERNAL WEIGHT

_____ Kgs
_____ lbs

☐ HX OF VANISHING FETUS DURING THIS PREGNANCY

COMMENTS:

TOMORROW is certified for singleton and twin pregnancies (2 fetuses), performed from 10 weeks and 0 days onwards, as estimated by the last menstrual period, CRL or by another clinically appropriate method (equivalent to 8 weeks of fetal age, if determined by date of conception).

Attention

It is mandatory that the tube has at least 2 identifiers, e.g., name and DOB of patient.

Test **cannot** be performed if: 1) blood sample is less than 7 mL, 2) the tube is not properly identified, 3) clinical information is not entirely present or 4) patient informed consent is not signed.



Blood collection:
7-10 mL Streck Tube

Delivery at
CGC Genetics within
4 days after collection

I certify that (i) this test is clinically useful, (ii) the patient (or legal representative) has agreed to have this testing performed, by signing the patient informed consent (on the back) after careful reading, (iii) the patient informed consent is in agreement with the legal requirements and that (iv) I am providing CGC Genetics all relevant medical information indispensable for the testing to be performed.

I certify that (i) I carefully read the informed consent, (ii) I was informed about the benefits, risks and limitations of TOMORROW, (iii) I put all the questions that I consider relevant and understood the answers provided. I give authorization to proceed with the TOMORROW test, performed in maternal blood for detection in fetal DNA of numerical changes of chromosomes 21, 18, 13 and optionally of X and Y chromosomes and the use of the sample for this purpose. I declare that I informed the healthcare professional ordering the test about my decision regarding fetal gender identification.

☐ I agree ☐ I do not agree

The sample can also be used for scientific research purposes.

☐ I agree ☐ I do not agree

PHISICIAN'S SIGNATURE _____
(mandatory)

Date: ____/____/____

PATIENT'S SIGNATURE _____
(mandatory)

Date: ____/____/____

powered by CGC GENETICS

1/2

ATTENTION: Patient informed consent is written on the back.



PATIENT INFORMED CONSENT

Introduction. This informed consent describes the benefits, risks and limitations of the non-invasive prenatal test, **TOMORROW**. Before undertaking the test, please seek advice from your healthcare provider and carefully read this informed consent.

Application. The aim of the test is to screen specific chromosomal abnormalities such as trisomy 21, usually recognized as Down syndrome, from DNA of the fetal-placental unit (normally known as fetal DNA). However, it is also possible to detect most cases of trisomy of chromosome 18 (Edwards syndrome), trisomy of chromosome 13 (Patau syndrome) and of numerical changes of sex chromosomes (Turner syndrome, Klinefelter syndrome, Triple X, Double Y). With this test it is also possible to identify fetal gender (sex of pregnancy, optional).

How it works. This test detects specific chromosomal alterations from DNA (genetic material) present in maternal blood. The technology used is Next Generation Sequencing (NGS).

In order to offer a complete service, **TOMORROW** includes:

- Non-invasive prenatal genetic study of the most common numerical changes of chromosomes 21, 18, 13 in maternal blood. Optionally, the study may also include numerical changes of sex chromosomes (X and Y).
- Fetal gender identification. If you do not wish to know the sex of pregnancy, please ask your healthcare provider to indicate on the designated field in the requisition form.
- The test results will be reported as “not detected” or “detected”, in case of a reduced or increased probability, respectively, of the tested numerical chromosomal changes.
- In case of a positive result (“detected”), according to recommendations from ACOG, ACMG and SMFM¹, confirmation by prenatal invasive diagnosis is advised. In this case, CGC Genetics provides, at no additional cost: a quick analysis by QF-PCR, available in 24 to 48 hours, and also chromosome analysis (karyotype), in a fetal sample.

Test Procedure. To perform the test a sample of 7-10 mL of maternal blood is required. The tube containing the blood sample will then be sent to CGC Genetics, Rua de Sá da Bandeira, 706-1, 4000-432 Porto, Portugal. After the testing is performed, CGC Genetics will send the report with the results directly to your healthcare provider. Please note that if amount of blood sample is less than 7 mL, it will not be processed and the test will not be performed. Additionally, the technique may not work because the sample is in poor condition or due to other technical problems that prevent conclusive result. In these situations, and whenever possible, CGC Genetics will contact the patient or responsible healthcare provider to address a possible solution.

Test Limitations. Consult with your healthcare professional to learn more about the test, including its limitations and risks, detection capacity and error rate; detailed description of the tested chromosomal changes and what the result could mean to you. Medical counselling is recommended before and after the testing is performed.

The following limitations are associated with non-invasive prenatal testing:

- This test cannot be performed before 10th weeks of gestation, as estimated by the date of last menstrual period, CRL or another clinically appropriate method (equivalent to 8 weeks of fetal age, if determined by date of conception).
- This test cannot be considered a diagnostic test, even though all recent publications demonstrate its high precision (~99%) and low error rate (< 0.5%). This means that in rare cases a tested chromosomal disorder may be present, even if the test result is of “not detected” (false negative). Also, it is possible to receive a result of “detected” for the tested chromosomal change and, in fact, this change is not present (false positive). Tests with results of “not detected” do not eliminate the possibility of the fetus having other chromosomal changes besides the ones tested and within the technique limitations (less than 1%), birth defects or health problems. A result of “detected” should be subsequently confirmed by an invasive diagnostic procedure in amniotic fluid (amniocentesis) or chorionic villus sampling and analyzed by FISH, QF-PCR or karyotyping.
- The fetal fraction value is not used alone to exclude the sample. However, if the value obtained for fetal fraction is less than 4%, the identification of the number of chromosomes 13, 18, 21, X and Y may not reflect the fetal chromosomal constitution. ACMG¹ best practices in NIPT recommend that a new blood drawn for non-invasive testing should not be performed. To obtain a definitive result performing QF-PCR/karyotype in chorionic villi or amniotic fluid should be considered.
- In case it is not possible to determine the number of chromosomes 13, 18, 21, X or Y, the ACMG¹ best practices in NIPT recommend, as well, that a new blood drawn should not be performed. To obtain a definitive result, performing QF-PCR/karyotype in chorionic villi or amniotic fluid should be considered.
- Studies show that high BMI values (body mass index) affect the sensitivity and specificity of this test, so in those situations it may be worth considering other screening tests.
- If the pregnant woman has recently received a blood transfusion, transplantation, cell therapy or immunotherapy, an accurate assessment of fetal DNA will not be possible.
- This test does not investigate the health condition of the pregnant woman.
- In rare cases, incorrect results of fetal gender identification may occur. In the case of detecting the Y chromosome in twin pregnancy (2 fetuses), it is not possible to determine if one or both fetuses are male.
- In case of a pregnancy with a vanishing twin, the result may be influenced by fetal loss and may not represent the chromosomal constitution of the surviving fetus.

Incidental/secondary findings. This test is validated for chromosomes 13, 18, 21, X and Y, therefore information regarding other chromosomal alterations (secondary findings), that may become evident in the analysis performed for the detection of the tested aneuploidies, will not be reported.

Physical risks. Side effects proceeding from blood sample collection are uncommon but can include dizziness, fainting, soreness, bleeding, bruising and, rarely, infection.

Privacy and test results. CGC Genetics is committed to ensure patient's data protection and confidentiality of all information originated during the whole process, according to the law. The result of your test will be directly sent to the ordering healthcare professional. If desired, please request a copy of the test results directly to him/her. He/She is responsible for the interpretation and explanation of test results to you. CGC Genetics medical team is available to clarify any questions regarding the test over the phone or in person.

Patient rights. The patient can request the right of access, modification and cancellation of the data provided, according to the law, by letter addressed to CGC Genetics, Clinical Direction, Rua Sá da Bandeira 706-19, 4000-432 Porto, Portugal.

It is recommended that no irreversible clinical decision is taken uniquely based on the result of this test.

¹ ACOG – American College of Obstetricians and Gynecologists; ACMG – American College of Medical Genetics and Genomics; SMFM – Society for Maternal-Fetal Medicine.