TOMORROW

non invasive prenatal test

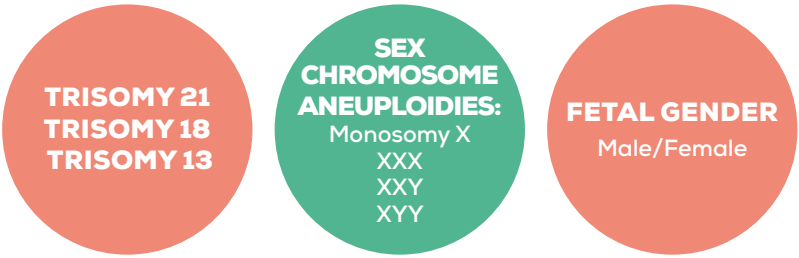
Information for healthcare professionals

CGC genetics

ABOUT TOMORROW PRENATAL TEST

TOMORROW Prenatal Test is a new CGC Genetics test performed in maternal blood and based on a non invasive technique to investigate the presence of trisomy of chromosomes 21, 18 and 13 in fetal DNA, to identify fetal gender and to detect aneuploidies of sex chromosomes (Monosomy X, XXX, XXY, XYY).

TOMORROW PRENATAL TEST INVESTIGATES



BECAUSE TOMORROW IS SO IMPORTANT TODAY

EARLY DETECTION
Can be performed as early as 10 weeks of pregnancy.

SAFE
No risk of abortion, usually associated with invasive procedures.

SIMPLE
Only a simple blood collection required, with no prior preparation.

HIGH DETECTION RATE
Detection of the most common syndromes: Trisomy of chromosomes 21, 18 and 13, fetal gender identification and investigation of sex chromosome aneuploidies (Monosomy X, XXX, XXY, XYY).

RELIABLE ANALYSIS
False positive and false negative rate is less than 0,5%[1,2,3].

FAST
Clinical report will be ready in 8-10 business days.

WHO SHOULD USE TOMORROW PRENATAL TEST?

PREGNANT WOMEN AT ANY AGE AND RISK STATUS
TOMORROW Prenatal Test has been clinically validated to be performed on pregnant women at any age or risk status.

TOMORROW Prenatal Test can be used by all pregnant women, but it is recommended especially for:
› Pregnant women who wish to screen for the presence of these chromosomal aneuploidies in the fetus without risking the pregnancy through an invasive procedure.
› Pregnant women 35+ years-old.
› Pregnant women with increased risk for trisomies 21, 18 and 13.
› Pregnant women with diagnosed trisomy in previous pregnancy.
› Pregnant women with recurrent abortions history.
› Pregnant women with ecographic abnormalities suggestive of the tested chromosomopathies.
› Pregnant women who wish to know more about her baby.

TOMORROW Prenatal Test can also be performed in:
› Twin pregnancies (2 fetuses)*.
› IVF/Egg donation (self-donation or not).

WHAT DOES TOMORROW PRENATAL TEST INCLUDE?

› TOMORROW
Detection of trisomies 21, 18 and 13, fetal gender identification and sex chromosome aneuploidies (Monosomy X, XXX, XXY, XYY).

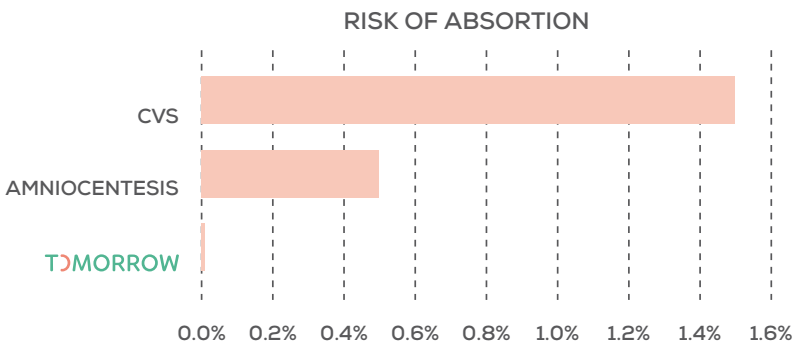
CGC Genetics offers other solutions for the non invasive prenatal test:
› TOMORROW plus
detection of trisomies 21, 18 and 13, fetal gender identification, sex chromosome aneuploidies and panel comprising 5 microdeletion syndromes.
› T21, T18, T13 only
detection of trisomies 21, 18 and 13 and fetal gender identification.

For more information, please contact us.

*Detection of trisomies 21, 18 and 13 and fetal gender identification. Test cannot be performed in case of pregnancies with more than 2 fetuses.
Fetal gender identification is performed by detecting the presence or absence of Y chromosome in maternal blood. In case of Y chromosome detection in twin pregnancy (2 fetuses), it is not possible to confirm if one or both fetuses are male.

THE MEANING OF A NON INVASIVE PRENATAL TEST

There are several options available for prenatal screening. In comparison with TOMORROW Prenatal Test, traditional screening methods have a lower accuracy and a higher false positive/negative rate. Also, invasive diagnostic testing, such as amniocentesis or chorionic villus sampling (CVS), involve a risk of abortion of 0.5% or 1-2%, respectively.



TOMORROW Prenatal Test performance in detecting of the most common aneuploidies[2,4]

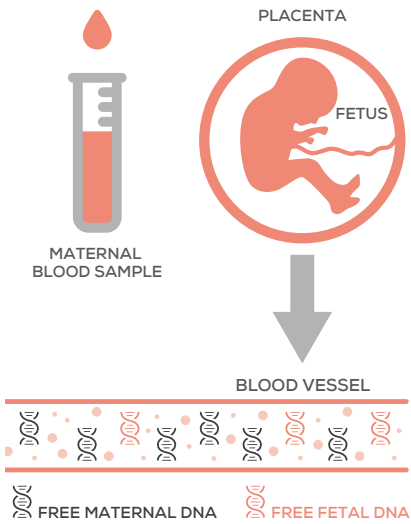
	Sensitivity	95% CI	Specificity	95% CI
T21 › Down Syndrome	99.14%	98.0 - 99.7	99.94%	99.90 - 99.97
T18 › Edwards Syndrome	98.31%	95.0 - 99.6	99.90%	99.86 - 99.93
T13 › Patau Syndrome	98.15%	90.0 - 99.9	99.95%	99.91 - 99.97
MX › Turner Syndrome	95.0%	75.1 - 99.9	99.0%	97.6 - 99.7

TOMORROW PRENATAL TEST USES THE MOST ADVANCED TECHNOLOGY AVAILABLE

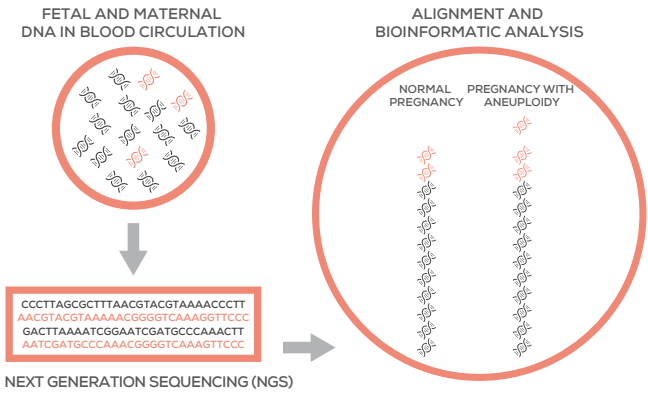
› From a simple maternal blood sample, circulating DNA fragments can be harvested of both from maternal and fetal origin.

› During pregnancy, small fragments from the fetal-placental unit enter the mother's blood circulatory system. These DNA fragments are normally described simply as fetal DNA.

› Circulating DNA fragments, both from the mother and the fetus, are analyzed by TOMORROW Prenatal Test.



A CLOSER APPROACH TO DEEP-SEQUENCING TECHNOLOGY



› Maternal and fetal circulating DNA fragments are analyzed through Next Generation Sequencing (NGS) technology.

› Afterwards, the number of sequences correspondent to each chromosome are aligned and analyzed through a complex bioinformatic analysis, using ILLUMINA platform.

› Fetal gender identification (fetal sex) is determined by detecting the presence or absence of Y chromosome in maternal blood.

› Potential aneuploidies are detected by comparing maternal and fetal genomic material to reference values.

WHAT TYPE OF INFORMATION CAN TOMORROW PRENATAL TEST PROVIDE?

TOMORROW Prenatal Test delivers clear information on the most common fetal aneuploidies, which may minimize the maternal anxiety and, in case of a positive result, guide for invasive procedures to have a definitive diagnosis.

Possible results:
› "**Not detected**", in case there is a **highly reduced** probability for the tested aneuploidies;
› "**Detected**", in case there is a **highly increased** probability for the tested aneuploidies.

In case of a positive result ("detected"), according to ACOG, ACMG and SMFM*, confirmation by invasive prenatal diagnosis is recommended by amniocentesis or chorionic villus sampling, and chromosomal analysis by FISH, QF-PCR or karyotyping.
In this case, CGC Genetics offers confirmation analysis free of charge, by QF-PCR, with results available within 24-48h, and also chromosomal analysis (karyotype).

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

ADDITIONAL INFORMATION

› The test cannot be performed before 10^{+0} 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).

› The test cannot be considered a diagnostic test, even though all recent publications demonstrate its high precision (~99%) and low false positive/ false negative rate (< 0.5%).

› **False negatives**: in rare cases, a tested aneuploidy may be present, even if the test result is of "not detected".

› **False positives**: a result of "detected" for a tested aneuploidy may not be present in the fetus but, in reality, is identified only in the placenta.

› Test results of "not detected" do not eliminate the possibility of the fetus having other chromosomal disorders, besides the ones mentioned and within technique limitations (< 1%), birth defects or health problems.

› 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.

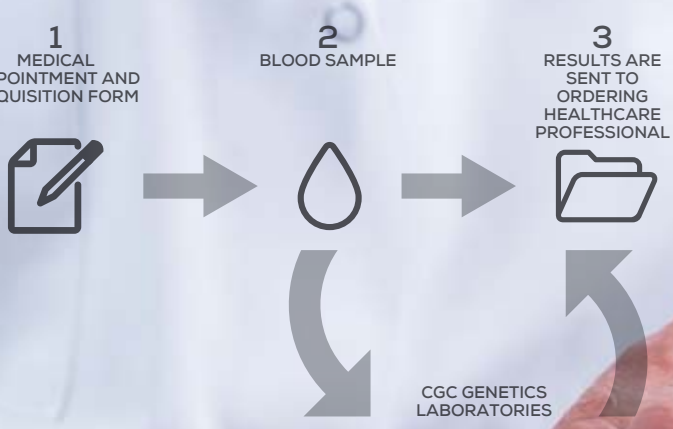
* ACOG – American College of Obstetricians and Gynecologists; ACMG – American College of Medical Genetics and Genomics; SMFM – Society for Maternal-Fetal Medicine.

TOMORROW PRENATAL TEST WORKFLOW

TOMORROW Prenatal Test is a perfect fit in any Medical Centre, providing healthcare professionals the flexibility needed to schedule the non invasive prenatal test with other prenatal procedures, such as ultrasound imaging.

TOMORROW Prenatal Test in a simple three-step process

1 Order the test as early as 10 weeks of pregnancy.
2 Send maternal blood sample (7-10 mL) to analysis using the provided kit.
3 Get the clinical report within 8-10 business days.



THE ASSURANCE OF PROFESSIONALS. YOU ARE IN GOOD HANDS.

Over the last 20 years CGC Genetics has been the leading provider of Medical Genetic testing in Portugal and a main one in Europe. Due to its high technical and clinical expertise CGC Genetics is involved in several research projects. Today we are pleased to offer you a new non invasive test with the assurance of experienced health professionals and the use of the most advanced technologies.

Founded in 1992, CGC Genetics is one of the main European clinical genetics laboratories and leader in medical genetic tests in Portugal. CGC Genetics, with headquarters in Porto, has reinforced its investment in Lisbon, USA (Newark) and Spain (Madrid) and currently receives samples for genetic tests from all over the world, including hospitals, national and international, public and private, medical clinics, insurance companies and universities.

Using vanguard technologies and strict quality policies, CGC Genetics has a clinical department with 7 Medical Genetics Specialists. In addition, more than 80 highly qualified Geneticists are divided into 5 different laboratory areas: Clinical Genomics, Molecular Diagnostics, Cytogenetics, Prenatal screening and Pathology, offering more than 3.800 genetic tests of prenatal, diagnostic and screening, hematology, oncology, neurology, ophthalmology, cardiology, preventive medicine, common and rare diseases, pharmacogenetics/clinical trials. It offers wide experience in the array CGH, NGS panels and Disease Exome, analyzed and interpreted with a strong clinical integration.

The great investment in research and development of new and unique tests, placed CGC Genetics as an international reference center (with more than 3.000 entries in different directories of genetic tests), being the exclusive provider of diagnostic tests for some diseases.

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SUPPORT TO YOUR MEDICAL PRACTICE

If you need assistance integrating TOMORROW Prenatal Test in your medical practice, CGC Genetics team is available to help you.

Contact us:
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