



RESERVED
CGC Genetics

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REQUEST FORM PRENATAL SCREENING

ORDERING PHYSICIAN

PHYSICIAN'S NAME*

DEPARTMENT

MEDICAL CENTER*

PHONE

EMAIL*

CITY

COUNTRY

PATIENT INFORMATION

NAME*

DATE OF BIRTH* (dd/mm/yyyy)

MEDICAL RECORD NO.

PREGNANT WEIGHT*

ETHNIC GROUP

GENDER*

BILING INFORMATION (if receipt is issued on patient's behalf):

Kgs

feminino

VAT No.

ADDRESS

ZIP CODE

CITY

COUNTRY

TEST*

COMBINED 1ST TRIMESTER

NT + NB + PAPP-A + freeβhCG (11w – 13w+6d)

EARLY COMBINED SCREENING

PAPP-A + freeβhCG (9w – 11w)] + [NT + NB (11w – 13w+6d)

2ND TRIMESTER

AFP + freeβhCG (14-22 weeks)

NTD only

AFP (14-22 weeks)

COLLECTION DATA*

DATE AND TIME OF COLLECTION
(dd/mm/yyyy) _____ / _____ / _____ : _____

LOCATION OF COLLECTION _____

LMP (dd/mm/yyyy) _____ / _____ / _____

GESTATIONAL AGE AT TIME OF COLLECTION:

by LMP _____ weeks, _____ days.

by ULTRASOUND _____ weeks, _____ days.

ULTRASOUND DATA*

ULTRASOUND DATE (dd/mm/yyyy) _____ / _____ / _____

GESTACIONAL AGE (US) _____ weeks, _____ days.

NO. OF FETUSES _____

CHORIONICITY _____

CRL _____ mm

NT _____, _____ mm

NASAL BONE

present

absent

not evaluated

CLINICAL INFORMATION*

YES NO

Other screening in this gestation YES NO

Pregnant woman was insulin-dependent before pregnancy YES NO

If not, is she presently being treated with insulin? YES NO

Smoker YES NO

Loss of blood in this pregnancy YES NO

Previous chromosomal studies YES NO

Family history of Down Syndrome YES NO

Valproic Acid / anticonvulsants in this pregnancy YES NO

Previous child with Neural Tube Defects (NTD) YES NO

Family history of non-NTD abnormalities YES NO

YES NO

MEDICALLY ASSISTED REPRODUCTION YES NO

EXTRACTION DATE (dd/mm/yyyy) _____ / _____ / _____

METHOD _____

EMBRYO TRANSFER (dd/mm/yyyy) _____ / _____ / _____

Donor age _____

Donor DOB (dd/mm/yyyy) _____ / _____ / _____

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

I certify that (i) I was informed about the benefits, risks and limitations of the test to be performed, (ii) I put all the questions that I consider relevant and understood the answers provided and (iii) that I understand that a normal result does not guarantee a normal baby. I give authorization to proceed with the requested genetic test and the use of the sample exclusively to this end.

I agree I do not agree

The sample can also be used for scientific research purposes.

I agree I do not agree

PHYSICIAN'S SIGNATURE _____

(mandatory)

PATIENT'S SIGNATURE _____

(to be used in case no other informed consent is available)

Date: _____ / _____ / _____

Date: _____ / _____ / _____

PRENATAL SCREENING

This is a brief description about Prenatal Screening test. In case any questions remain, please consult your attending physician.

Combined First Trimester Screening (Ultrasound and Biochemical)

- Performed between 11 weeks and 13 weeks + 6 days of pregnancy, the combined screening combines the ultrasound information with biochemical measurements in maternal blood.
- The ultrasound examination precisely evaluates gestational age and nuchal translucency (NT).
- In maternal blood sample, two elements are quantified – free fraction of Human Chorionic Gonadotropin (free β -hCG) and Pregnancy-Associated Plasma Protein A (PAPP-A) – which are found in the blood of all pregnant women.
- Ultrasound and biochemical results are then used to calculate a specific risk for Down Syndrome (trisomy 21), trisomy 18 and trisomy 13.
- Accuracy of Combined First Trimester Screening: Combined 1st Trimester Screening (NT+free β -hCG+PAPP-A) detects 90% - 92% of babies with Down syndrome and may detect other anomalies.

Early Combined Screening

- Early Combined Screening is another version of Combined 1st Trimester Screening, in which marker evaluation is performed as early as possible: blood collection and biochemical measurements are performed between 9 and 11 weeks; and ultrasound data is taken into account for risk calculation at 11-12 weeks.
- This combination allows to pull the best efficiency of each marker (detection rate of 93% to 97%) and still be possible to provide the result right after ultrasound examination, which may occur in a medical setting, thus shortening the planning process in cases of increased risk.

Second Trimester Prenatal Screening

- Performed between 14 and 22 weeks.
- The sample is analyzed to quantify two chemical elements designated as Alpha-fetoprotein (AFP) and Human Chorionic Gonadotropin β -hCG, which are present in the blood of all pregnant women.
- The results allow to calculate the risk for Down syndrome, trisomy 18, trisomy 13 and NTDs.
- Accuracy of Second Trimester Prenatal Screening: 2nd trimester screening detects > 98% of babies with anencephaly, 90% with spina bifida and 80% with Down syndrome.

When Prenatal Screening shows an increased risk

- 3 to 5% of women have an increased risk result.
- In case screening results shows an increased risk, you should consider other screening and/or diagnostic methods.
- Your doctor will always explain the results to you, suggesting which subsequent tests to perform (such as Non-Invasive Prenatal Test, detailed ultrasound or prenatal diagnosis, which requires amniocentesis or chorionic villus biopsy for fetal chromosomal analysis).
- As an alternative to invasive diagnosis (*i.e.*, amniocentesis or chorionic villus) it is now possible to perform, as early as 10 weeks of pregnancy, a non-invasive prenatal test, such as TOMORROW Prenatal test, that from a maternal blood sample, detects trisomy 21, 18 and 13, identifies fetal gender and aneuploidies in sex chromosomes (Monosomy X, XXX; XXY, XYY). TOMORROW Prenatal Test has sensitivity above 99% for trisomy 21.

When Prenatal Screening shows a reduced risk

- In order to increase detection rate, it is now possible to perform, as early as 10 weeks of pregnancy, a non-invasive prenatal test, such as TOMORROW Prenatal test, that from a maternal blood sample, detects trisomy 21, 18 and 13, identifies fetal gender and aneuploidies in sex chromosomes (Monosomy X, XXX; XXY, XYY). TOMORROW Prenatal Test has sensitivity above 99% for trisomy 21.

Important notice

Prenatal screening test result indicating a reduced risk does not exclude the possibility of the baby having Down syndrome, trisomy 18 or any other chromosomal anomaly, neither it eliminates the possibility of congenital defects, mental retardation or any other disorder not traceable by Prenatal Screening. It only indicates that there is a decreased risk for the described anomalies. If you have any questions, please consult with your physician or contact CGC Genetics.

LEGAL NOTICE

Test Procedure. To perform prenatal screening test, a blood sample from the pregnant woman is required, in filter card, which should 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.

Test Limitations. Consult with your healthcare professional to learn more about the test, including its limitations and risks, detailed description of the tested genetic changes and what the result could mean to you. Medical counselling is recommended before and after the testing is performed. Prenatal screening does not investigate the health condition of the pregnant woman. The following limitation may be associated with the prenatal genetic test: the laboratory may not be able to process the test if 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 alternative.

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 requesting healthcare provider. 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 your healthcare provider regarding any questions about your genetic test.

Patient rights. The patient can request the right of access, modification and cancellation of the data provided by letter addressed to CGC Genetics, Clinical Director to customer-care@cgcgenetics.com.