

PHYSICIAN / REFERRING CENTRE



Genoma

NAME/STAMP

EXPECTANT MOTHER'S DATA

Prot. No.: _____ (internal use)
 First Name _____
 Last Name _____
 Date of birth _____ Place of Birth _____
 Tax Code: _____
 Residence address _____
 _____ Postal Code: _____ City: _____
 _____ Phone: _____
 _____ Sampling date: _____
 Trusted gynaecologist: _____
 Address or City of gynaecologist: _____
 Gynaecologist's phone: _____
 Gynaecologist's email: _____

Are you repeating this test for the second time? YES; NO

PREGNANCY DATA

Pregnancy week _____ + days _____
 Date of last menstrual period _____
 Gestational age determined by:
 Ultrasound scan; Last Menstruations; PMA treatment
 Twin pregnancy? NO YES (Monochorial; Bichorial) Presence of
 Vanishing Twin (reabsorbed twin)? NO YES
 Assisted procreation pregnancy? NO YES
 Type of insemination: Homologous Male Heterologous
 Female Heterologous Embryo Donation/Double Heterologous
 Number of embryos transferred in the case of PMA: _____
 Weight _____ kg; Height _____ cm
 Date of last ultrasound _____
 Result: in the norm problems found: _____
 Previous pregnancies: No. _____ Spontaneous abortions _____
 Fetal abnormalities in previous pregnancies

TYPE OF TEST TO BE PERFORMED

- Prenatal**SAFE**® 3 (21,13,18);
 Prenatal**SAFE**® 5 (21,13,18,X,Y) *
 Prenatal**SAFE**® 5 **DiGeorge** (21,13,18,X,Y + deletion 22q11.2 (DiGeorge syndrome) *
 Prenatal**SAFE**® **Plus** (21,13,18,X,Y)
 + Microdeletion Panel *
 + Microdeletion Panel + Trisomies 9 and 16 *
 Prenatal**SAFE**® **Karyo** (non-invasive fetal karyotype test)
 Prenatal**SAFE**® **Karyo Plus** (non-invasive fetal karyotype test + Microdeletion Panel g)*
 Prenatal**SAFE**® **COMPLETE** (Prenatal**SAFE**® **Karyo** + Gene**SAFE**™ **COMPLETE**)
 Prenatal**SAFE**® **COMPLETE Plus** (Prenatal**SAFE**® **Karyo Plus** + Gene**SAFE**™ **COMPLETE**)*
 *(cannot be requested for bichorial twin pregnancies)

Do you want to know the sex of the fetus? YES; NO

Timeframe: Standard Test FAST Protocol

RhSafe® integration? YES; NO

(only applicable in pregnancies with expectant mother Rh negative and partner Rh positive; it is necessary to present medical reports demonstrating the Rh factor of the couple. It cannot be requested for bichorial twin pregnancies).

Request for additional tests (optional):

Female partner genetic disease panel (Cystic Fibrosis 139 mut. +

Hereditary Deafness + Spinal Muscular Atrophy (SMA) + Fragile X)

Other: _____

Request for additional tests Male partner: Should it

become necessary to carry out genetic analyses also on the male partner, it is necessary to fill in Form PR 11 A1 with the related informed consent.

In the event of requesting Prenatal**SAFE**® **COMPLETE** it would be advisable to take a paternal sample for the Gene**SAFE**™ set-up having the partner fill in Form PR 11 H7.

INDICATION FOR THE TEST AND MEDICAL HISTORY OF THE EXPECTANT MOTHER

- Advanced Maternal Age; Advanced Paternal Age; Anxiety; Positive 1st quarter screening (Bi-Test) _____
 Ultrasound scan anomalies (please specify): _____
 Partner genetic disease carrier: Female Male
 Specify disease: _____ Specify mutation and gene: _____
 (Attach medical reports if possible)
 The expectant mother is afflicted by: Autoimmune / inflammatory diseases Tumour or fibromas
 The expectant mother has undergone: Allogeneic transplantation allogeneic stem cell therapy recent transfusions radiotherapy
 immunotherapy heparin therapy Other ongoing pharmacological therapies: _____

BILLING

- PHYSICIAN / REFERRING CENTRE
 PATIENT (note the tax code in the expectant mother's data records)
 Email: _____

(write the patient's email address if they want to receive the invoice)

REPORTING

- PHYSICIAN / REFERRING CENTRE
 PATIENT
 On-Line; Post

To activate online patient reporting, it is mandatory to provide an
 Email: _____

Information for first time access is provided on the website
<https://www.laboratorigenoma.eu/>

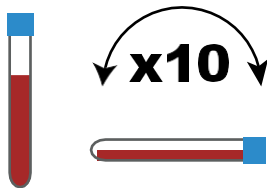
I, the undersigned _____,
 pursuant to EU Reg. 679/2016 authorize sending the medical report as indicated
 above. Signed: _____

Instructions for collecting, packaging and shipping biological samples

Informed consent and test request form

IMPORTANT: Accurately fill in every part of the **information request form** (see back) **and the informed consent form with the signatures of both the expectant mother and the specialist who collected the consent** that you will find in the transport container, in order to avoid delays and guarantee delivery times. Enclose the above-mentioned forms with the samples to be sent to our laboratory. Check that the First Name, Last Name and Date of Birth of the expectant mother written on the form are the same as those on the specimen tube labels.

Collection of samples:



- Take the specimen tube provided with the **PrenatalSafe®** transport container.
- Write the **date of collection** in the specific field of the test request form;
- Write the **First and Last Name** and the **date of birth** of the expectant mother on the specimen tube label;
- Collect approximately **10 ml** (minimum 8 ml) of peripheral blood and put the biological sample into the **10 ml specimen tube** provided with the transport container (be careful **not to fill the specimen tube completely** to avoid accidentally opening the stopper).
- **Gently turn the specimen tube upside down 10 times as shown.**

Keep the specimen tube at **ambient temperature** or in a fridge at **+4°C** until shipment. **Do not keep specimen tubes in a freezer (-20°C)! During the summer the kit may be supplied with a gel pack that will have to wrap around the blood specimen tube. The purpose of this gel is to keep the specimen at a constant temperature, avoiding temperature variations. The gel pack does not need to be placed in a freezer.**

Packaging and shipping:

For shipment to the Laboratory, the biological samples must be packed using our **Transport Container**, assembled to **UN3373** (compliant with European transport regulations for biological samples). The Container comprises:

1. A cylindrical red plastic **Secondary Container** with a grey plastic stopper;
2. A **Specimen Tube Container** (to be inserted inside the secondary container) made of spongy material with no. 14 slots for specimen tubes.
3. A cardboard **Transport Box** bearing the **PrenatalSafe®** test logo with the abbreviation UN3373 printed on one side.
4. The **Test Request Form**.
5. The **Informed Consent Form**.
6. An **Express Courier Plastic Bag**, to be used to insert the container for transporting biological samples inside it.

- Put the **blood specimen tube** inside the **red plastic cylindrical container**, placing it in one of the slots in the spongy specimen tube holder.
- Close the cylindrical container with its **grey plastic stopper**;
- Place the above-mentioned container in the **cardboard transport box** bearing the **PrenatalSafe®** test logo;
- Check that the **test request form and the informed consent** have been completed and duly signed, and put these documents inside the transport box, between the secondary container and the cardboard box;
- Close the transport box and place it inside the **Express Courier plastic bag**;
- **Request collection** of the bag containing the biological samples from your location according to the procedure described below:
 - ▶ Call **+39 068811270** or **freephone 800.501.651**, then **key in option 1**, from Monday to Saturday, 9:00 to 18:00 hours, or send an **email** to logistica.rm.genoma@ctit.eurofinseu.com;
 - ▶ Fully dedicated staff will have the task of taking note of your request for the collection of biological samples, avoiding any waiting for the phone booking through the express courier's call centre.
 - ▶ Subsequently, our staff will choose the most efficient express courier service in your specific geographical area and will book the collection of the samples at your location for you.

IMPORTANT:

The kit has to be kept at ambient temperature or in a fridge at +4°C. After collection, the sample needs to be shipped as soon as possible, preferably within 48h, and arrive at the laboratory no later than 5 days from the day of sampling. Our Customer Service Department is at your disposal on the toll-free number **800.501.651** to assist you with the collection, storage and shipping of the samples.