SECTION FOR THE AUTHORISED LABORATORY

eurofins | Biomnis

Test request form
Estimated risk of fetal trisomy 21
by analysis of maternal serum markers - 1st and 2nd trimester

INTERNATIONAL DIVISION - Tel.: **+33 (0)4 72 80 23 85** - Fax: **+33 (0)4 72 80 73 56** - E-mail: **international@biomnis.eurofinseu.com**

PRESCRIBING CLINICIAN

First name(s) : ..... Surname: .....
Address: .....
Post code: ⌊_⌊_⌊_⌊_⌊_⌋ City:..... Country:.....
Tel.: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ Fax: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋

Doctor's stamp

Reserved for Eurofins Biomnis bar-code sticker

SONOGRAPHER

Identification number: ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋
First name(s) : ..... Surname: .....
Adress: .....
Post code: ⌊_⌊_⌊_⌊_⌊_⌋ City:..... Country:.....
Tel.: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ Fax: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋
E-mail: .....

PATIENT

First name(s) : ..... Surname: .....
Address: .....
City: ..... Tel.: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋
Country: ..... Date of birth: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌊_⌊_⌋
E-mail: .....

DATA REQUIRED FOR THE TRISOMY 21 RISK CALCULATION

Date of ultrasound: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋
Nuchal Translucency: ⌊_⌋,⌊_⌋ mm **Crown Rump Length:** ⌊_⌊_⌋,⌊_⌋ mm
(must be between 45 and 84 mm)
Date of conception as indicated on the ultrasound: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋
Or expected delivery date: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ (at 40.3 weeks of amenorrhoea)
Number of fetuses ⌊_⌋ If there is a twin pregnancy: ☐ monochorionic ☐ bichorionic

Patient information and details used in the risk calculation:

- Patient's weight ⌊_⌊_⌋,⌊_⌋ kg
- Smoker (given up for at least 2 weeks-no)? ☐ Yes ☐ No
- Insulin Dependent Diabetes? ☐ Yes ☐ No
- Previous pregnancy with T21 (except translocation)? ☐ Yes ☐ No
- Origin: ☐ Europe/North Africa ☐ Sub-Saharan Africa and West Indies ☐ Asia ☐ Other (i.e. mixed race): .....

Comments:

☐ Vanishing twin (fetal loss at ..... weeks of amenorrhea)
Seen on 1st trim. ultrasound ? ☐ No ☐ Yes, Crown Rump Length: ⌊_⌊_⌋,⌊_⌋ mm
☐ Oocyte donation - Age of the donor ⌊_⌊_⌋ years old
☐ Frozen embryo transfer: Date of freezing: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋
☐ Chronic renal failure ☐ Others: .....

Once anonymised, the data received are forwarded to the Biomedicine Agency (ABM). These data are electronically processed for the purposes of monitoring and evaluating the quality of trisomy 21 (Down's syndrome) screening. In compliance with the French data protection act of 6 January 1978 as amended in 2004, you have a right to access or correct information relating to you, which you can exercise by contacting your physician. You can also object, giving legitimate reasons, to the processing of data relating to you.

PRESCRIPTION

☐ **1st trimester:** **combined risk assay** (PAPP-A + hCGβ + nuchal translucency)
Sample between ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ and ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋

☐ **2nd trimester:** **maternal serum markers without Nuchal Translucency**
☐ Triple test (hCGβ + AFP + uE3)
Sample between ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ and ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋

LABORATORY

Sample collection date: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋

DECLARATION OF CONSULTATION AND INFORMED CONSENT

Information sheet and consent form for pregnant women agreeing to the conduct of analysis of maternal serum markers (in reference to article R. 2131-1 of the French Public Health Code).

I, the undersigned .....
‣ hereby declare that I have received information from the doctor, midwife or genetic counsellor under the responsibility of the geneticist-physician (*) *(surname, first name)*:

.....
as part of a consultation on [date]:
⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋ has supplied me with information about the test for maternal serum markers that I wish to have performed, in particular concerning:

- the characteristics of trisomy 21 and the measures taken for carriers of trisomy 21; the test is to evaluate the risk that the unborn child may be affected by a disease of particular severity, including trisomy 21;
- the procedure for this test:
  - a blood sample will be collected at a specific point in the pregnancy;
  - a calculation of the risk of trisomy 21 will be performed; the calculation takes into particular account the data from prenatal ultrasound in the first trimester, if the results are available and usable;
  - the result is expressed as the risk of the unborn child being a carrier of trisomy 21. This risk does not in itself make it possible to establish a diagnosis.

The result of the risk calculation will be returned to me and explained by the doctor who prescribed the test or by another practitioner with experience in prenatal screening:

- If the risk is < 1/1000, it is considered low enough to end the screening procedure and continue a standard monitoring of the pregnancy, even if it does not completely rule out the possibility of the foetus being affected by the disease.
- If the risk is between 1/51 and 1/1000, a screening test of cell-free fetal DNA will be suggested to complement the screening.
- If the risk is ≥ 1/50, diagnostic fetal karyotyping will be suggested at once. This test requires an invasive sample (amniotic fluid, chorionic villi or fetal blood).

Only the result of fetal karyotyping can confirm or rule out the existence of the condition. I consent to the performance of the measurement of maternal serum markers. The original copy of this document will be stored in my medical records. A copy of this document will be given to me and to the person responsible for conducting the biological assay and, if applicable, the risk calculation. The medical laboratory authorised by the regional health agency at which the person responsible for conducting the assays and, if applicable, the risk calculation, is employed shall keep this document under the same conditions as the report of the examination.

Date: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌋

Signature of the physician, midwife or genetic counsellor

Signature of the patient

(*) Delete as applicable

SECTION TO BE KEPT BY THE PRACTITIONER

DECLARATION OF CONSULTATION AND INFORMED CONSENT

Information sheet and consent form for pregnant women agreeing to the conduct of analysis of maternal serum markers (in reference to article R. 2131-1 of the French Public Health Code).

I, the undersigned .....**hereby declare that I have received information from the doctor, midwife or genetic counsellor under the responsibility of the geneticist-physician (*) (surname, first name):** ..... as part of a consultation on [date]: |_|_|/|_|_|/|_|_| has supplied me with information about the test for maternal serum markers that I wish to have performed, in particular concerning:

• The characteristics of trisomy 21 and the measures taken for carriers of trisomy 21; the test is to evaluate the risk that the unborn child may be affected by a disease of particular severity, including trisomy 21;
• The procedure for this test:
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- a calculation of the risk of trisomy 21 will be performed; the calculation takes into particular account the data from prenatal ultrasound in the first trimester, if the results are available and usable;
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(*) Delete as applicable

Date : |_|_|/|_|_|/|_|_|

Signature of the physician, midwife or genetic counsellor	**Signature of the interested party**

SECTION TO BE KEPT BY THE PATIENT

DECLARATION OF CONSULTATION AND INFORMED CONSENT

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• The procedure for this test:
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- a calculation of the risk of trisomy 21 will be performed; the calculation takes into particular account the data from prenatal ultrasound in the first trimester, if the results are available and usable;
- the result is expressed as the risk of the unborn child being a carrier of trisomy 21. This risk does not in itself make it possible to establish a diagnosis.

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• If the risk is between 1/51 and 1/1000, a screening test of cell-free fetal DNA will be suggested to complement the screening.
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(*) Delete as applicable

Date : |_|_|/|_|_|/|_|_|

Signature of the physician, midwife or genetic counsellor	**Signature of the interested party**

B2-INTGB - November 2022