SECTION FOR THE AUTHORISED LABORATORY

eurofins | Biomnis

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

PRACTITIONER

Surname : ..... First name: .....
Address: .....
Post code: ..... City:..... Country: .....
Tel.: .....Fax:.....

Doctor's stamp

SONOGRAPHER

Surname: ..... First name: .....
Adress: .....
Post code: ..... City:.....
Tel.: .....Fax:.....

PATIENT

Surname : ..... First name: .....
Address: .....
..... Tel.: .....
Date of birth: |_|_|/|_|_|/|_|_|

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 alternatively: Expected delivery date: |_|_|/|_|_|/|_|_| (at 40.3 weeks of amenorrhoea)
Last menstrual period: |_|_|/|_|_|/|_|_|

Number of fœtuses |_| If there is a twin pregnancy (only if the 2 fœtuses are ≥ 14.0 weeks of amenorrhoea)

☐ monochorionic ☐ bichorionic NT (T2) |_|,|_| mm CRL(T2): |_|_|,|_| mm

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 trisomy 21 pregnancy (free and homogenous)? ☐ Yes ☐ No
- Origin
  - ☐ Europe/North Africa
  - ☐ Sub-Saharan Africa and West Indies
  - ☐ Asia
  - ☐ Other (i.e. mixed race): .....

Comments:

☐ Vanishing twin (fœtal loss at ..... weeks of amenorrhoea) ☐ Chronic renal failure
☐ Ovum Donation - Age of the donor |_|_| years
☐ Others: .....

PRESCRIPTION

☐ **1st trimester:** **combined risk assay** (PAPP-A + free βhCG + NT)
Sample between |_|_|/|_|_|/|_|_| and |_|_|/|_|_|/|_|_|

☐ **2nd trimester:** **integrated sequential risk**
☐ Triple test (hCG + AFP + uE3 + NT)

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

LABORATORY

Sample collection date: |_|_|/|_|_|/|_|_|

Form RQF 931
Issue Number: 1.01
Active date: 11.05.2017

Reserved for the Biomnis bar-code sticker

DECLARATION OF CONSULTATION AND INFORMED CONSENT

Information, request and consent of the mother for testing based on the analysis of maternal serum markers

I, the undersigned .....

attest that I have been fully informed by doctor:

.....

during a medical consultation of the following points:

1. I have received information in regards to the risk that the unborn child suffering from a serious condition, notably trisomy 21 (or Down's syndrome);
2. I have received information on the test offered which involves analysis of maternal serum markers:
   - a risk calculation is performed which mainly takes the 1st trimester prenatal ultrasound results into account as long as these results are available and the ultrasound measurements are considered as reliable;
   - the result is presented in terms of the risk that the unborn child is suffering from the condition. This risk assessment on its own cannot make or exclude the diagnosis of this condition;
   - the result of the risk calculation will be given and explained to me by my doctor or a practitioner experienced in prenatal screening, notably trisomy 21:

- If the risk is low, this does not fully exclude the possibility that the foetus is not suffering from the condition;
- if the risk is high, the collection of a sample of amniotic fluid, chorionic villi or foetal blood will be recommended. Only the result of a foetal karyotype can confirm the presence of this condition. The risks, constraints and possible consequences of each technique of sample collection will be explained to me.

Consent to blood sampling and the quantification of serum markers.

The quantification of serum markers will be performed in a medical pathology laboratory authorised to perform these tests.

The original copy of this document is kept in my medical file.

A copy of this document will be given to me and the practitioner performing these tests. The public health centre or the medical pathology laboratory where the practitioner performs these tests will store the document under the same conditions as those for the result.

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

Practitioner's signature

Patient's signature

SECTION TO BE KEPT BY THE PRACTITIONER

DECLARATION OF CONSULTATION AND INFORMED CONSENT

Information, request and consent of the mother for testing based on the analysis of maternal serum markers.

I, the undersigned, ... **attest that I have been informed by doctor:** during a medical consultation of the following points:

1. I have received information in regards to the risk that the unborn child suffering from a serious condition, notably trisomy 21 (or Down's syndrome);
2. I have received information on the test offered which involves analysis of maternal serum markers:

- a risk calculation is performed which mainly takes the 1st trimester prenatal ultrasound results into account as long as these results are available and the ultrasound measurements are considered as reliable;
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The quantification of serum markers will be performed in a medical pathology laboratory authorised to perform these tests.
The original copy of this document is kept in my medical file. A copy of this document will be given to me and the practitioner performing these tests. The public health centre or the medical pathology laboratory where the practitioner performs these tests will store the document under the same conditions as those for the result.

Date : |__|__|/|__|__|/|__|__|

Doctor's signature	Patient's signature

SECTION TO BE KEPT BY THE PATIENT

DECLARATION OF CONSULTATION AND INFORMED CONSENT

Information, request and consent of the mother for testing based on the analysis of maternal serum markers.

I, the undersigned, ... **attest that I have been informed by doctor:** during a medical consultation of the following points:

1. I have received information in regards to the risk that the unborn child suffering from a serious condition, notably trisomy 21 (or Down's syndrome);
2. I have received information on the test offered which involves analysis of maternal serum markers:

- a risk calculation is performed which mainly takes the 1st trimester prenatal ultrasound results into account as long as these results are available and the ultrasound measurements are considered as reliable;
- the result is presented in terms of the risk that the unborn child is suffering from the condition. This risk assessment on its own cannot make or exclude the diagnosis of this condition;
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Date : |__|__|/|__|__|/|__|__|

Doctor's signature	Patient's signature