Yourgene Health

Tips for Test Request and Patient Consent Form Completion

General notes - Ensure all sections of the consent form are completed, even if they do not apply to the patient/sample e.g. if the pregnancy is not IVF, please tick 'no' on the consent form, if sex determination is not required, please tick 'no' on the consent form. If the form is not complete and Yourgene needs to confirm details with the institution (e.g. whether sex determination is required) this can cause delays with issuing reports.

1a **Hospital / Clinic Sample ID** – this only needs to be completed if the institution has assigned another ID to the sample and you wish for this to be shown on the results report.

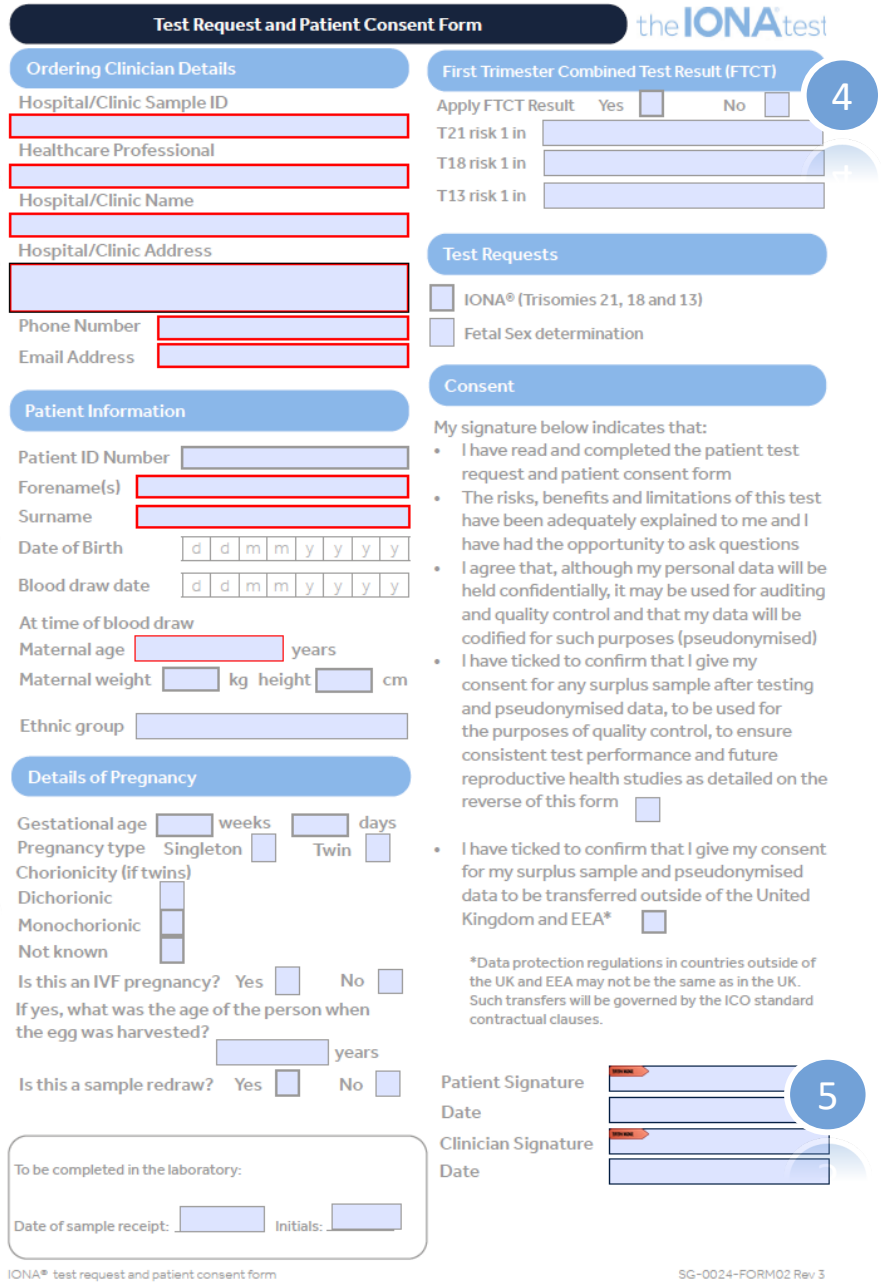
1b **Healthcare Professional** – this is the Person with overall responsibility for NIPT in the institution or the person who has requested the test.
The details provided in this section will appear on the results report.
Yourgene recommend pre-filling out section 1 with the details as provided in the account opening form.

2 **Patient ID Number** – this is the institution's ID number (e.g. the patients NHS number)
Yourgene require 3 patient identifiers to be provided – Patient ID number, Forename and Surname and Date of Birth.
Age MUST be provided.

3 **Gestational Age MUST be provided in weeks and days.**

4 ***Optional* use of First Trimester Combined Test (FTCT) for risk calculation –** tick Yes and provide the FTCT result for T21, T18 or T13 if you wish for the FTCT result to be included in the risk calculation. The FTCT result can be used for any of the trisomy results, it does not have to be provided for all trisomies.

5 **Patient MUST sign and date.**



Test Request and Patient Consent Form — the IONA test

1a 1b **Ordering Clinician Details**
Hospital/Clinic Sample ID
Healthcare Professional
Hospital/Clinic Name
Hospital/Clinic Address
Phone Number
Email Address

First Trimester Combined Test Result (FTCT) 4
Apply FTCT Result Yes No
T21 risk 1 in
T18 risk 1 in
T13 risk 1 in

Test Requests
IONA® (Trisomies 21, 18 and 13)
Fetal Sex determination

Patient Information 2
Patient ID Number
Forename(s)
Surname
Date of Birth d d m m y y y y
Blood draw date d d m m y y y y
At time of blood draw
Maternal age years
Maternal weight kg height cm
Ethnic group

Consent
My signature below indicates that:
- I have read and completed the patient test request and patient consent form
- The risks, benefits and limitations of this test have been adequately explained to me and I have had the opportunity to ask questions
- I agree that, although my personal data will be held confidentially, it may be used for auditing and quality control and that my data will be codified for such purposes (pseudonymised)
- I have ticked to confirm that I give my consent for any surplus sample after testing and pseudonymised data, to be used for the purposes of quality control, to ensure consistent test performance and future reproductive health studies as detailed on the reverse of this form
- I have ticked to confirm that I give my consent for my surplus sample and pseudonymised data to be transferred outside of the United Kingdom and EEA*

*Data protection regulations in countries outside of the UK and EEA may not be the same as in the UK. Such transfers will be governed by the ICO standard contractual clauses.

Details of Pregnancy 3
Gestational age weeks days
Pregnancy type Singleton Twin
Chorionicity (if twins)
Dichorionic
Monochorionic
Not known
Is this an IVF pregnancy? Yes No
If yes, what was the age of the person when the egg was harvested?
years
Is this a sample redraw? Yes No

Patient Signature 5
Date
Clinician Signature
Date

To be completed in the laboratory:
Date of sample receipt: Initials:

IONA® test request and patient consent form
SG-0024-FORM02 Rev 3