Test Request and Patient Consent Form

IONA care

Ordering Clinician Details

Hospital/Clinic Sample ID

Healthcare Professional

Hospital/Clinic Name

Hospital/Clinic Address

Phone Number

Email Address

Patient Information

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

Details of Pregnancy

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 ◯

To be completed in the laboratory:

Date of sample receipt: _____ Initials: _____

First Trimester Combined Test Result (FTCT)

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

◯ IONA® Care (Sex Chromosome Aneuploidies (SCA) and Autosomal Aneuploidies (AA))

Only available for singleton and monochorionic twin pregnancies

SCA ◯ AA *excl Chr 19 ◯ SCA & AA *excl Chr 19

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.

Patient Signature

Date

Clinician Signature

Date

What is IONA®?

IONA care

The IONA® test estimates the risk that a fetus is affected with an aneuploidy by analysing placental cell-free DNA (cfDNA) isolated from a sample of the mothers' blood. The IONA® test enables screening for the following fetal aneuploidies: Trisomy 21 (Down's Syndrome), Trisomy 18 (Edwards' Syndrome) and Trisomy 13 (Patau's Syndrome). The IONA® test can also optionally be used for the determination of fetal sex. IONA® Care includes additional, optional screening for Sex Chromosome Aneuploidies (SCAs): XO (Turner Syndrome); XXY (Klinefelter syndrome); XYY (XYY Syndrome), XXX (Trisomy X) and Autosomal Aneuploidies (AAs) *excluding Chromosome 19.

A small blood sample (10ml) is taken for analysis by Whole Genome Next Generation Sequencing (NGS).

How does IONA® work?

During pregnancy, the placenta leaks cell-free DNA which circulates in the maternal bloodstream. As a result, a maternal blood sample contains a mixture of fetal and maternal circulating DNA. The IONA® test directly measures the amount of cell-free DNA and can detect small changes in the DNA ratio between the maternal and placental DNA when a fetal aneuploidy is present.

For full Clinical Performance Data, please scan the QR code and navigate to the 'Post-Market Surveillance' section

IONA® is a screening test and all high-risk results should be disussed with your healthcare provider.

If fetal sex determination is requested, the accuracy is greater than 99%. A "sex determination failure" result may be reported if there is insufficient data to support the sex determination analysis. A "sex determination failure" does not impact the trisomy result. ***Please note sex determination, sex chromosome or autosomal aneuploidy analysis is not available for dichorionic twin pregnancies.***

IONA® test suitability and limitations

You can have IONA® if you are:
At least 10 weeks pregnant, carrying a singleton or a twin pregnancy and became pregnant naturally or through IVF, donor egg or surrogate pregnancy.

The test is not suitable if:

- You are a recipient of an organ transplant
- You have received any treatment involving the transfusion of heterologous cells in the last 12 months, for example a white cell blood transfusion or stem cell therapy,
- You have cancer,
- You carry a chromosomal imbalance

While the results of the IONA® test are highly accurate, discordant results may occur due to conditions affecting the pregnancy that you are unaware of such as placental or fetal mosaicism, chromosomal balanced or imbalanced abnormalities or a vanishing twin (If you are aware of any of these conditions, please indicate this on the test request form).

IONA® is also not suitable for expectant mothers with complete or partial monosomy X (Turner syndrome). If a sample is received with this condition and generates a result indicative of monosomy X then the healthcare professional will be informed that a repeat test is not recommended for this reason.

Additional patient consent

The IONA® test is developed by Yourgene Health, your sample will be tested at the Yourgene Genomic Services Manchester UK facility. After IONA® has been performed there usually is a small amount (surplus) of sample remaining. Yourgene has a network of laboratories around the world running the IONA® test and on occasion it may be helpful to use this surplus sample in laboratory studies for the purposes of quality control, to ensure consistent test performance and to develop other reproductive health tests within this network. Please tick the box on the previous page to consent to your surplus sample and associated data being used for this purpose. Please also tick the box on the previous page to consent to your sample and pseudonymised data being transferred outside of the UK and EEA.

You are under no obligation to consent and this will have no effect on your standard of care.

Thank you for giving your consent to help us with this valuable work

Data Privacy

The hospital/clinic named overleaf is the data controller of your personal data. Yourgene Genomic Services is the data processor. The lawful basis for the processing is your explicit consent. Your personal data will be retained only for as long as necessary for the purpose of providing you with the test result and any data kept for future research will be anonymised. You have the right to request from the controller access to and rectification, restriction or erasure of your personal data. You also have the right to withdraw your consent to the processing. You have the right to lodge a complaint to the Information Commissioner.