TEST REQUEST AND PATIENT CONSENT FORM

(Please fill out using English alphabet and spelling)

the IONA test

ORDERING CLINICIAN DETAILS

Contact Clinician name: _____ Institution sample ID: _____

Institution name/address: _____

Telephone number: _____ Email: _____

PATIENT DETAILS

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 time: _____

At date of blood draw:

Maternal age: _____ years

Maternal weight: _____ Kg height: _____ cm

Ethnic group: _____

Apply First Trimester Combined Test result: ☐ Yes ☐ No

T21 risk 1 in _____

T18 risk 1 in _____

T13 risk 1 in _____

Previous pregnancy affected by chromosomal/genetic disease**:**
☐ Yes ☐ No

(If yes) Name of condition: _____

Family history of genetic disease: **☐ Yes ☐ No**

(If yes) Give details: _____

DETAILS OF PREGNANCY

Gestational age: _____ weeks _____ days

Multiple pregnancy status: ☐ Single ☐ Twins

Chorionicity (if twins):

☐ Dichorionic ☐ Monochorionic ☐ Not known

IVF: **☐ Yes ☐ No**

Donor egg/embryo: **☐ Yes ☐ No**

Surrogate: **☐ Yes ☐ No**

Maternal age when egg harvested: _____ years
(if different from maternal age)

Sex determination required: ☐ Yes ☐ No

Additional notes (e.g. further notes on pregnancy, history):

PATIENT CONSENT

My signature below indicates that:

- I have read and understood the information on the reverse of this form;
- I have been given the opportunity to ask any questions and receive appropriate counselling about this type of testing by a healthcare provider.
- 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 anonymised as far as is possible for such purposes.
- I have ticked the following box to confirm that I give my consent for any surplus part of my sample, after testing, and associated data to be stored and used for laboratory studies as detailed on the reverse of this form: ☐
- I have ticked the following box to confirm that I give my consent for my personal data to be transferred outside of the United Kingdom and EEA:* ☐

  * Data protection regulation in countries outside of the UK and EEA may not be the same as in the UK. Premaitha contractually oblige any applicable data transferees to meet or exceed UK data protection standards.

Patient Signature: Date: Clinician Signature: Date:

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

WHAT IS THE IONA® TEST?

The IONA® test estimates the risk that a fetus is affected with Down's syndrome (Trisomy 21), Edwards' syndrome (Trisomy 18) or Patau's syndrome (Trisomy 13) by analysing placental cell-free DNA (cfDNA) isolated from a sample of the mothers' blood. In each of these syndromes the cfDNA will include an extra copy of the chromosome concerned (e.g. in Down's syndrome three copies of chromosome 21 are found rather than the two expected to be found in an unaffected fetus).

A small blood sample (10ml) is taken for analysis.

The IONA® test is developed by Premaitha Health, based in Manchester, UK.

HOW DOES THE IONA® TEST 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 cell-free DNA when a fetal trisomy 21, 18 or 13 is present.

The IONA® test has an accuracy rate of >99%. In dichorionic twins, scientific publications suggest, that the test sensitivity is reduced from >99% to about 95%. In the case of a high-risk result, the screening test cannot determine which twin is affected and further testing would be required.

The IONA® test is a screening test and all high-risk results should be confirmed by a follow-up invasive procedure.

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.

WHO CAN HAVE THE IONA® TEST?

You can have the IONA® test if you are:

- ✓ At least 10 weeks pregnant (10w + 0 gestation)
- ✓ Singleton or twin pregnancies
- ✓ IVF, donor egg or surrogate pregnancies

The IONA® test cannot be performed if the mother has:

- × Cancer
- × A trisomy
- × Undergone a blood transfusion in the last 12 months
- × Undergone Stem Cell Therapy or Immunotherapy
- × Received an organ transplant

Sex determination is available for singleton and monochorionic twin pregnancies. Sex determination is not currently available for dichorionic twin pregnancies.

PATIENT CONSENT FOR FUTURE LABORATORY STUDIES

After the IONA® test has been performed there usually is a small amount of plasma sample remaining. With your consent, we would like to keep this sample and the associated data (including birth outcome) to conduct laboratory studies to help further develop and audit the quality of the IONA® test. To protect your identity, the sample will not be associated in any way with your name. You are under no obligation to consent and this will have no effect on your standard of care. Please tick the box on the previous page to consent to any surplus part of your sample being used for such further laboratory studies.

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

WITHDRAWAL OF CONSENT

You may withdraw your consent for the IONA® test and future laboratory studies at any time. Send an email or letter with the heading "CONSENT WITHDRAWAL" to iona@premaitha.com or Premaitha Health, Manchester Science Park, M15 6SZ, UK, setting out your full name provided at the point of testing and your date of birth.