FOR PREGNANT WOMEN

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

Non-invasive prenatal screening test for Down's syndrome and other serious genetic conditions

What is the IONA® test?

The IONA® test is a non-invasive prenatal test (NIPT) for pregnant women which estimates the risk of a fetus having Down's syndrome or some other serious genetic diseases. The IONA® test is an advanced screening test that is carried out on a small maternal blood sample. Pregnant women can expect test results from their healthcare provider within approximately 3-5 days from sample receipt.

What does IONA® screen for?

The IONA® test estimates the risk of a fetus having Down's syndrome (Trisomy 21), Edwards' syndrome (Trisomy 18) and Patau's syndrome (Trisomy 13). Trisomies occur when three, instead of the usual two, copies of a chromosome are present. Edwards' and Patau's syndromes are much rarer than Down's but are very serious and many affected babies do not survive.

The IONA® test also offers optional fetal sex determination.

What are the advantages of the IONA® test?

Safe: non-invasive with no risk of miscarriage.

Fast: the IONA® test is the fastest NIPT available with results provided within 3-5 working days, from sample receipt.

Accurate: greater than 99% for detection of trisomy conditions. Fetal sex determination is greater than 97% accurate.

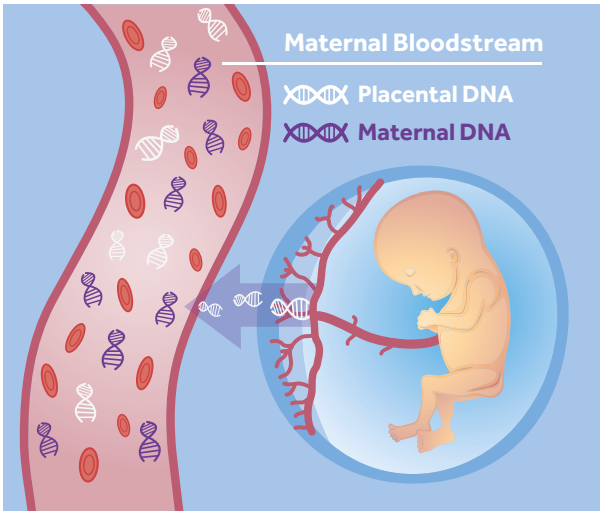
Simple: uses a simple maternal blood sample.

Local: unlike other NIPT's, the IONA® test is performed in a laboratory local to you. So your blood sample is not shipped to the US or China.

Quality: unlike other NIPT's, the IONA® test is a regulated diagnostic, which is CE marked.

How does it 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 this 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.



Why is IONA® better than the current combined test?

Traditional screening offered during pregnancy is currently called the combined test. This is an ultrasound scan to measure the nuchal translucency (NT) and a blood test. This is much less accurate than NIPT and it only detects around 85% of babies with Down's syndrome.

The IONA® test has a higher detection rate than the current combined test offered to pregnant women. This means that fewer pregnant women will undergo unnecessary invasive follow-up procedures such as amniocentesis or CVS* which are stressful, painful and can carry a small risk of miscarriage.

Who can have the IONA® test?

- Suitable for women who are at least 10 weeks pregnant.
- Suitable for all singleton and twin pregnancies.
- Suitable for IVF or surrogate pregnancies.
- Unsuitable for women with cancer or with a trisomy or who have undergone a blood transfusion within the last 12 months.

How are the IONA® results reported?

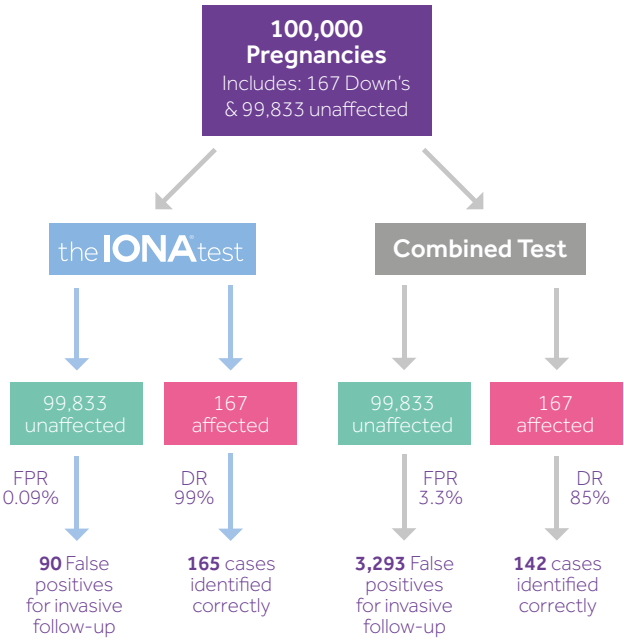
- **Low Risk:** means that it is very unlikely your pregnancy is affected by trisomy 21, 18 or 13.
- **High risk:** means that your pregnancy is at increased risk for trisomy 21, 18 or 13 and the result should be confirmed by a follow up invasive procedure such as amniocentesis.
- **No result:** In rare cases there is insufficient fetal DNA in the sample to obtain a result. You may be asked by your healthcare provider for an additional blood sample.

The IONA® test is a screening test. Suitability for and results from the test must be discussed in detail with your healthcare provider.

*Chorionic villus sampling

The IONA® test reduces the need for invasive procedures:

An example scenario showing the difference between the screening tests:



Assumptions:
Prevalence of Down's 1 in 600
Combined test Detection Rate (DR) = 85%
False Positive Rate (FPR) = 3.3%
IONA test DR > 99%

About Premaitha Health

The IONA® test is developed and manufactured by Premaitha Health, a UK molecular diagnostics company based in Manchester. Premaitha's mission is to develop molecular diagnostic products that will have a positive impact on human health.
www.premaitha.com

Premaitha Limited trading as Premaitha Health, Rutherford House, Manchester Science Park, Manchester, M15 6SZ, UK.

For the latest news and updates about the IONA® test please follow us on:

/theIONAtest @theIONAtest

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Available Monday to Friday 9:00am to 4:00pm

Costs
The cost of the test is £405 and payment can be made using the following:

Payment may be made by cash, cheque, debit or credit card (**VISA, Mastercard/ Eurocard, Switch, SOLO, JCB card, Electron or Delta**). Cheques should be made payable to Central Manchester University Hospitals NHS Foundation Trust (or CMFT).

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