

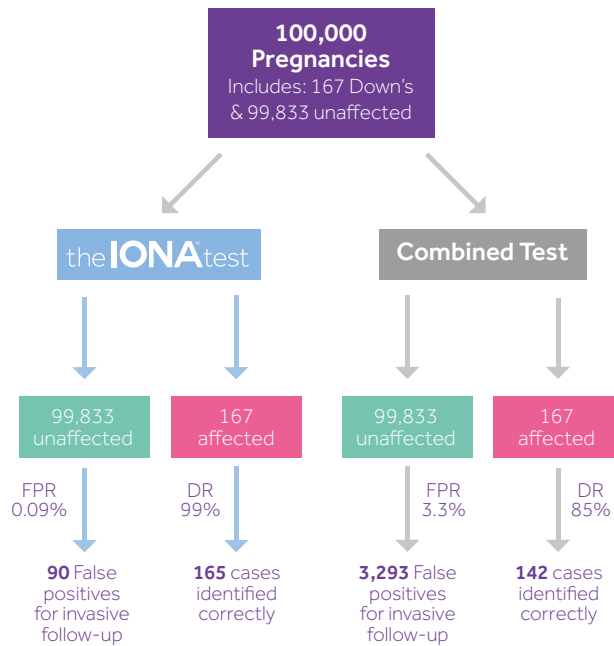
FOR PREGNANT WOMEN

the **IONA** test
non-invasive prenatal screen: safe, fast, accurate



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%
Combined test False Positive Rate (FPR) = 3.3%
IONA® test DR > 99%
IONA® test FPR = 0.09%

Where can I get an IONA® test?

The IONA® test is available through different healthcare providers. A list is available on: www.the-iona-test.com.

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

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About Premaitha Health

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

www.premaitha.com

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Non-invasive prenatal screening test for Down's syndrome and other 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 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 3-5 days from sample receipt.

What does the IONA® test 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.

If fetal sex determination is requested, the accuracy is greater than 99%. In rare cases 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.

Advantages of the IONA® test?

Safe: Non-invasive with no risk of miscarriage.

Fast: Provides results within 3-5 days from sample receipt.

Accurate: Greater than 99% detection of trisomy conditions and fetal sex determination.

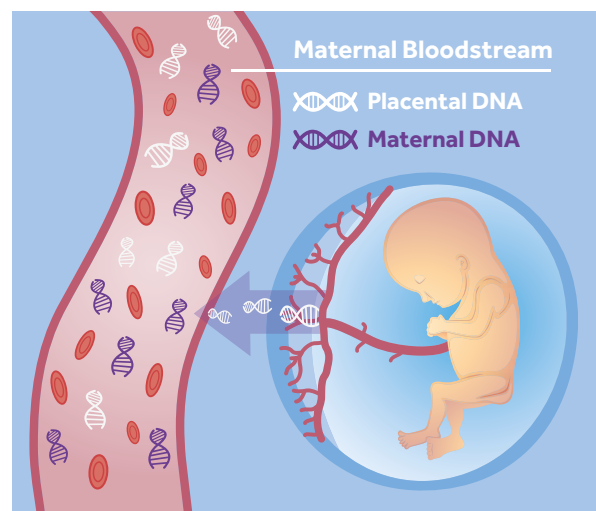
Simple: Uses a simple maternal blood sample.

Local: The IONA® test is available in many laboratories worldwide to enable local processing with fast turn-around times.

Quality: The IONA® test is a regulated test, 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-placental and maternal circulating cell-free 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 fetal cell-free DNA when a fetal trisomy 21, 18 or 13 is present.



How do I get the most complete prenatal screening?

Traditional first trimester screening offered during pregnancy is called the First Trimester Combined Test (FTCT). This is an ultrasound scan to measure the nuchal translucency (NT) and a blood test.

This method is less accurate for detecting fetal trisomies (85-90%), but can help with the early detection of both maternal and fetal complications. The IONA® test is the only NIPT that has the option to incorporate the result of the FTCT into the calculation to offer you the most comprehensive and tailored prenatal screen.

You can still get accurate trisomy screening even without the FTCT result. Many women choose to have an IONA® test from 10 weeks gestation following an ultrasound, which is an essential requirement for IONA®.

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

Who can have the IONA® test?

- ✓ From 10 weeks gestation
- ✓ Singleton or twin pregnancies
- ✓ IVF, donor egg or surrogate pregnancies

Unsuitable if the mother has:

- ✗ Cancer
- ✗ Trisomy
- ✗ Undergone Stem Cell Therapy or Immunotherapy
- ✗ Received an organ transplant

How are the IONA® results reported?

- **Low risk:** It is very unlikely your pregnancy is affected by trisomy 21, 18 or 13.
- **High risk:** 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.

Talk to your healthcare provider to find out if the IONA® test is right for you.

*Chorionic villus sampling