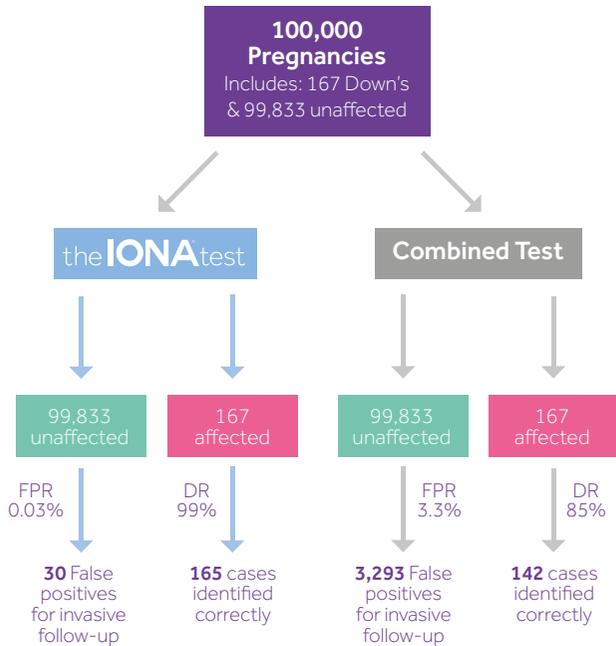


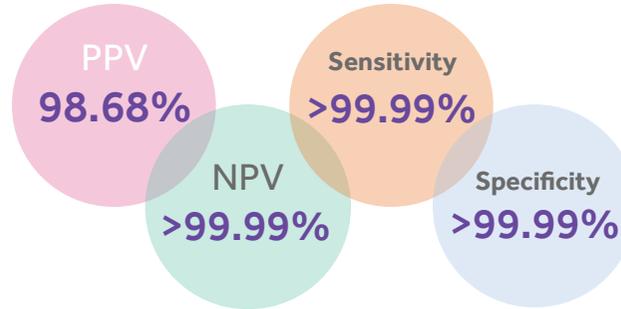
The IONA® test reduces the need for invasive procedures:

An example scenario showing the difference between the screening tests:



**Assumptions:**  
Prevalence of Down's 1 in 400  
Combined test Detection Rate (DR) = 85%  
False Positive Rate (FPR) for combined tests = 3.3%  
IONA test DR > 99%  
FPR = 0.03%

How accurate is the IONA® test?



**Positive predictive value (PPV):** chance my IONA® screened positive pregnancy is truly affected with a trisomy.

**Negative predictive value (NPV):** chance that my IONA® screened negative pregnancy really doesn't have a trisomy

**Sensitivity:** A highly sensitive screening test allows to identify true positive, while avoiding false negatives (affected fetus tested negative), thus fewer cases with the syndrome being missed.

**Specificity:** A highly specific screening test is unlikely to produce false positive results (unaffected fetus tested positive), thus less unnecessary diagnostic procedures.

**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.

IONA® is a registered trademark of Premaitha Health plc. Premaitha Limited trading as Premaitha Health. Its registered office is at Rutherford House, Manchester Science Park, Manchester, M15 6SZ, UK.

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 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.

## 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.

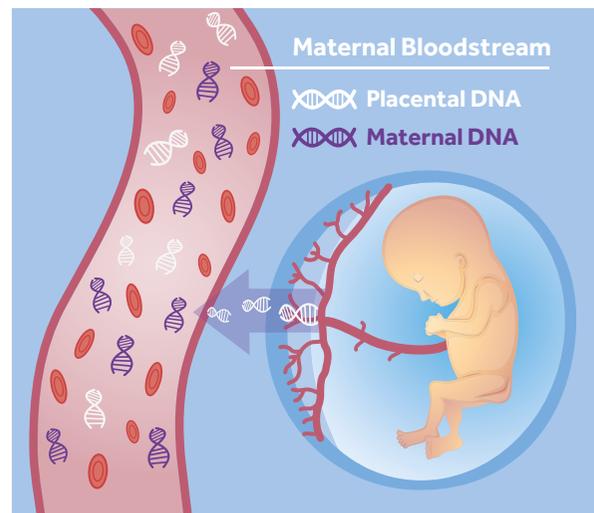
**Simple:** Uses a simple maternal blood sample.

**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 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.



## 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 aneuploidies (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?

- 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, received an organ transplant, carries a chromosomal imbalance, had a transfusion of heterologous cells in last year, has complete or partial monosomy X (Turner Syndrome)

## 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.

\*For Trisomy 21. Detection rate for Trisomy 18 is 92%, 100% for Trisomy 13

\*Chorionic villus sampling