How accurate is the IONA® test for Down's syndrome?

DETECTION RATE
99.99%

FALSE POSITIVE RATE
<1%

The Detection Rate (sensitivity) of IONA® for Down's syndrome is 99.99%, which means that nearly every case of Down's syndrome will be detected with very few false negative results (affected pregnancies falsely screened as low risk).

False Positive Rate (FPR) is the proportion of pregnancies that do not have the syndrome but have screened as high risk. A false positive result means that although NIPT indicates a high risk of trisomy 21, the fetus does not have this condition.

For any high risk IONA® result, your healthcare professional will be able to guide you further.

Performance data is based on the IONA® Nx NIPT Workflow.

For the latest performance data visit www.yourgene-health.com

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

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About Yourgene Health
The IONA® test is developed and manufactured by Yourgene Health UK Ltd, an international molecular diagnostics group which develops and commercialises genetic products and services. Yourgene's mission is to enable scientific advances to positively impact human health.
www.yourgene-health.com

Yourgene® Health

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FOR PREGNANT WOMEN

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

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 2-5 working 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.

If fetal sex determination is requested, the accuracy is greater than 99%. A "sex determination failure" does not impact the trisomy result.

What are the advantages of the IONA® test?

Safe: Non-invasive with no risk of miscarriage.

Fast: Provides results within 2-5 working days from sample receipt.

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

Simple: Uses a simple maternal blood sample.

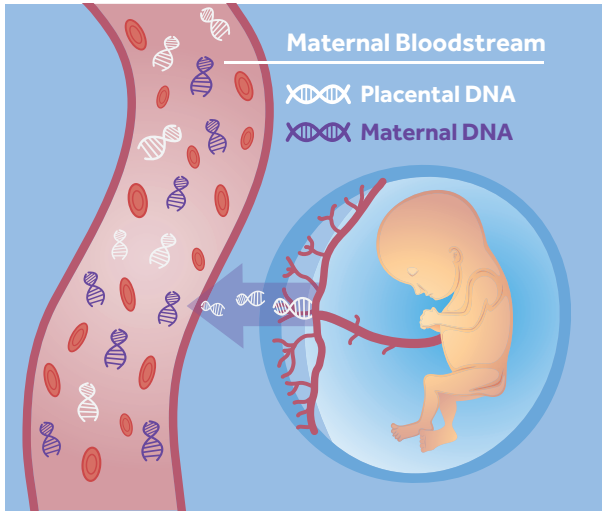
Local: The IONA® test is available in many laboratories worldwide to enable local processing with fast turn-around times.

Quality: The IONA® test is a regulated test, which is CE marked.

* >99.99 % for Trisomy 21, 18 and 13

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 placental 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 at detecting fetal trisomies (85-90%), but can help with the early detection of both maternal and fetal complications. The IONA® test 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 who have cancer, received an organ transplant, carry a chromosomal imbalance, had a transfusion of heterologous cells in the last year or who have complete or partial monosomy X (Turner's 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 we advise you contact your healthcare professional.
- **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