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

DETECTION RATE
>99%

FALSE POSITIVE RATE
<1%

The **Detection Rate (sensitivity)** of IONA® for Down's syndrome is >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.

Scan this QR code to view the latest performance data

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

About Yourgene Genomic Services
At Yourgene Genomic Services we value the benefits to healthcare that the understanding of unique genomic profiles can bring. Our teams work with healthcare professionals, researchers and pharmaceutical organisations to support and accelerate scientific advances in genomic medicine.

The division's specialist services guide decisions about abnormalities, hereditary risk and treatment in addition to providing novel insights in research and discovery.

Accredited clinical services are provided in Oncology and Reproductive Health within the UK and worldwide. Our team of scientific experts offer consultative services to help guide partners in selecting the right technology and approach for their applications.

genomicservices@yourgenehealth.com

Yourgene Genomic Services' registered office is at Skelton House, Lloyd Street North, Manchester Science Park, Manchester, M15 6SH, UK.

Yourgene Genomic Services

E-87 (Rev 2)

For Pregnant Women

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

Non-invasive prenatal screening test (NIPT) for Down's syndrome and other genetic conditions

What is the IONA® test?

The IONA® test is a non-invasive prenatal test (NIPT) which estimates the risk of a fetus having certain genetic conditions. The IONA® test is an advanced screening test that is carried out on a small maternal blood sample. The test can be performed from 10 weeks gestation. You can expect test results from your healthcare provider within 2-5 working days from sample receipt at the Yourgene Genomic Services laboratory in Manchester, UK.

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 syndrome but are very serious and many affected babies sadly do not survive.

Fetal sex determination is available as an option, and has an accuracy of greater than 99%. It is recommended fetal sex is confirmed by ultrasound. Very rarely, the fetal sex determination may fail, this does not impact the trisomy result in any way.

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.

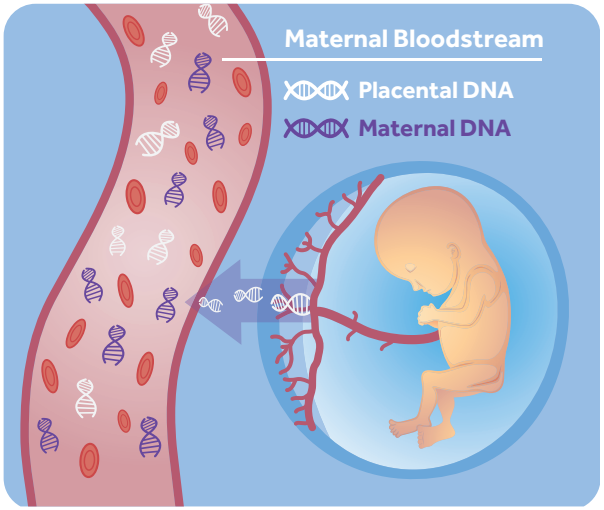
Simple: Uses a simple maternal blood sample.

Local: Your sample will be analysed at the Yourgene Genomic Services laboratory in Manchester, UK.

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

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 cell-free 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 placental 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.

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

You can still get accurate trisomy screening without the FTCT result. The IONA® test can be performed from 10 weeks gestation following an ultrasound. This is an essential requirement for the IONA®test.

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:

X Received an organ transplant

X Cancer

X Carries a chromosomal imbalance

X Had a transfusion of heterologous cells in the last year

X 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. High risk results should be discussed with your healthcare provider.
- **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