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

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

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Yourgene Health UK Ltd trading as Yourgene Health. It’s registered office is at Citylabs 1.0, Nelson Street, Manchester, M13 9NQ, UK.
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.