FOR HEALTHCARE PROFESSIONALS

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

The leading and trusted non-invasive prenatal screening test using the latest advances in DNA technology.

Enhancing existing prenatal screening pathways for pregnant women with fast, reliable results and reducing the need for invasive tests and the associated stress and anxiety.

The IONA® test is for pregnant women to estimate the probability that their fetus is affected with:

- Trisomy 21 (Down's syndrome)
- Trisomy 18 (Edwards' syndrome)
- Trisomy 13 (Patau's syndrome)

Fetal sex determination optional

Key features of the IONA® test:

- CE-IVD NIPT which allows local screening for pregnant women
- Results available in 3-5 days
- >99% detection and <1% false positive rate for trisomy 21, 18 and 13
- Low re-draw rate of <0.5%
- Measures fetal fraction, requiring as little as ≥2%
- MyNIPT® portal for safe and secure exchange of results
- The only NIPT with the option to incorporate the prior risk from the combined test

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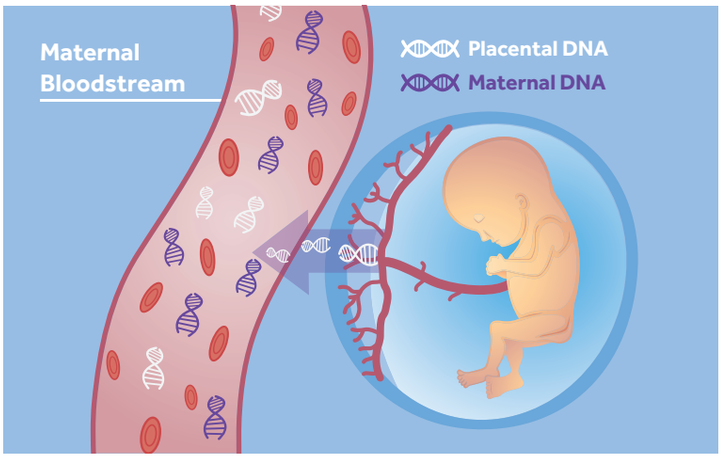
How does the IONA® test work?

The IONA® test directly measures DNA ratios in the maternal plasma to calculate the risks of the fetus being affected with Trisomy 21, 18 or 13. During pregnancy the placenta leaks cell-free DNA which circulates in the maternal bloodstream. As a result, a maternal plasma sample contains a mixture of placental and maternal circulating DNA. The IONA® test employs Next Generation Sequencing (NGS) technologies to count the number of fragments of the chromosomes to calculate this ratio, hence providing a risk of an affected pregnancy.



MyNIPT®

MyNIPT® is a data exchange portal that enables the exchange of patient results easily and securely between the laboratory and the clinician. Healthcare professionals can track the status of the submitted samples and communicate with the laboratory. High risk results are highlighted in the portal and a notification sent to alert you that a high risk result has occurred. The portal also has the capability to monitor and track pregnancy outcomes, order stock and securely communicate with the laboratory.

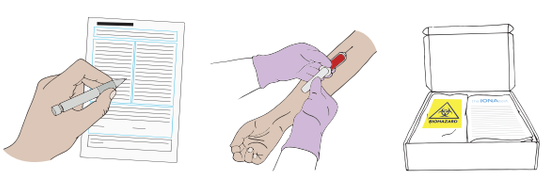
Who can have the IONA® test?

- The IONA® test is available for all singleton and twin pregnancies and also fertility assisted pregnancies including surrogates, donor or IVF pregnancies.
- The IONA® test is suitable for women who are at least 10 weeks pregnant.
- The IONA® test should *not* be used for multiple pregnancies where there are more than two fetuses.
- The IONA® test should *not* be used if the mother has cancer, has had a recent blood transfusion or where the mother is known to be chromosomal aneuploidy for trisomy 21.

Sample

A maternal blood sample is taken from 10 weeks gestation. Premaitha recommend a 10ml blood sample either using Streck or EDTA-based whole blood collection tubes.

- If using Streck cell-free DNA BCT CE tubes, the blood is stable for up to 14 days if stored and transported at 6 – 37°C. The plasma can then be extracted on receipt at the analysis laboratory.
- If the standard K2EDTA or EDTA KE tubes are used, the sample is stable for up to 8 hours at room temperature.



The IONA® test results

The IONA® test incorporates the background risk into its algorithms to give the most accurate result possible. By default this risk is the maternal age, however, results from the combined test can be included to further increase accuracy.

IONA® test results are exportable in common formats to enable further off-line local analysis and test performance monitoring. Reports can be customised to suit clinic requirements and include report translations in the local language. The IONA® test report gives a clear, easy to interpret result of high risk or low risk for each trisomy. High risk results should be confirmed with a follow up diagnostic procedure.

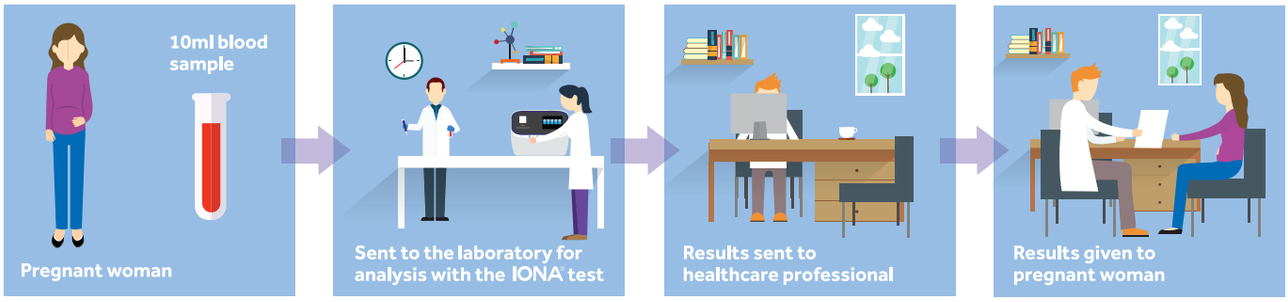
IONA® screening report

An example report showing clear and easy to understand test results. Reports can be customised as required.

TRISOMY	BACKGROUND RISK	The IONA® test RISK SCORE	CLINICAL SUMMARY
TRISOMY 21	1 : 307	> 95%	HIGH RISK INVASIVE TEST RECOMMENDED
TRISOMY 18	1 : 797	1 : 516,727 (0.0002%)	LOW RISK
TRISOMY 13	1 : 2487	< 1 : 1,000,000 (<0.0001%)	LOW RISK

Fetal Fraction	4%
Fetal Sex	Female

the IONA® test



How can I get an IONA® test?

The IONA® test is the first complete CE-IVD product enabling regional clinical laboratories to establish non-invasive prenatal testing in-house, with results available in as little as 3 days.

Premaitha have established a network of IONA® customers that will accept samples from healthcare professionals for analysis with the IONA® test.

In addition, Premaitha have a CQC (Care Quality Commission) registered NIPT clinical service laboratory in Manchester, UK where samples can be sent for analysis using the IONA® test. Results are available in as little as 3 days from sample receipt.

Consent forms and compliant sample packaging kits are available from Premaitha Health for simple and convenient shipping of samples.

Please visit **www.the-iona-test.com** or contact us for further information about where to send your samples for the IONA® test.

Clinical Performance

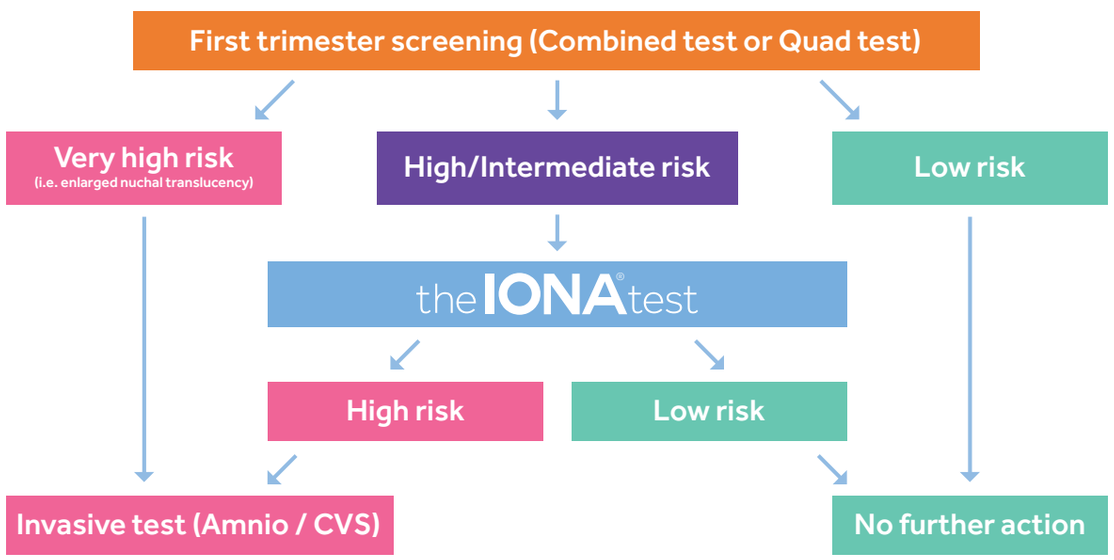
The IONA® test	Detection rate (Sensitivity)	False Positive Rate (FPR)
Trisomy 21 (Down's syndrome)	>99%	<1%
Trisomy 18 (Edwards' syndrome)	>99%	<1%
Trisomy 13 (Patau's syndrome)	>99%	<1%

1. Clinical evaluation of the IONA test: a non-invasive prenatal screening test for Trisomy 21, 18 and 13. Papageorghiou A, Khalil A, Forman M, Hulme R, Mazey R, Mousa HA, Johnstone ED, McKelvey A, Cohen KE, Risley M, Denman W, Kelly B. Ultrasound Obstet Gynecol.2016, 47(2), 188-193. Published online at www.wileyonlinelibrary.com. Doi: 10.1002/uog.15791.

2. IONA test for first-trimester detection of trisomy 21, 18 and 13. L. Poon LC, Dumidrascu-diris D, Francesco C, Fantasia I, Nicolaides KH. Ultrasound, Obstet Gynecol, 2016, 47 (2), 184-187. Published online at www.wileyonlinelibrary.com. Doi: 10.1002/uog.15749.

Fetal sex determination has a detection rate of >99% and is available for singleton pregnancies and monochorionic twin pregnancies.

Example contingent prenatal screening pathway



This contingent pathway outline is a guide, the risk cut-off's will vary across different territories with differing public screening policies.

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Benefits of the IONA® test

Due to its fast turnaround time and high detection rate, the IONA® test can be an ideal companion in a contingent screening programme. Enabling a higher overall detection rate while keeping the false positive rate low. For many women with an initial high-risk result from first trimester screening, this means they will not need to undergo a follow up invasive procedure such as an amniocentesis which carries a small risk of miscarriage.

The IONA® test is a regulated, CE-IVD screening test that enables clinical laboratories to offer NIPT testing locally with a rapid turnaround. This allows pregnant women and their families to receive the information they need to make an informed choice safely and quickly, reducing anxiety and giving peace of mind.

Responsible Screening

Premaitha work closely with healthcare providers to ensure that all users of the IONA® test are sufficiently trained to offer the test to pregnant mothers. The complexity of prenatal screening, understanding when it is appropriate to offer the IONA® test and fitting it into to the existing care pathway is often not so simple. At Premaitha we work in close collaboration with our labs, hospitals and clinics to ensure the IONA® test becomes an integral part of prenatal screening. We can highlight best practice in terms of clinical implementation and the importance of genetic counselling, before and after the test.

Next steps

Please call or email to find out more about offering the IONA® test for the pregnant women in your area.

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About Premaitha Health

Premaitha Health (AIM:NIPT) is a leading international molecular diagnostics group, including Yourgene Biosciences, Inc. The Group's aim is on utilising the latest advances in DNA analysis technology to develop safer, faster and regulatory approved genetic screening tests. Currently, the Group's primary focus is non-invasive prenatal tests (NIPT) for pregnant women and the IONA® test, a leading quality driven regulated CE-IVD product for establishing NIPT in-house within clinical laboratories.

Premaitha is headquartered in Manchester, UK, with Yourgene offices in Taipei and Singapore. Shares trade on the AIM market of the London Stock Exchange (AIM: NIPT).

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For further information, please visit

www.premaitha.com

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