Yourgene Health

the IONA® test

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

- ENHANCED CLINICAL MENU COVERING TRISOMIES AND SEX CHROMOSOME ANEUPLOIDIES
- LOW RE-DRAW RATES
- TURNAROUND TIME AS LITTLE AS 2 DAYS, WITH SERVICE LAB IN MANCHESTER, UK

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

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.

Why choose the IONA® test?

- CE-IVD NIPT which allows **local** screening for pregnant women, with labs based in Manchester, UK
- Results available in 2-5 days
- Overall accuracy 99% with <1% false positive rate for trisomy 21, 18 and 13
- Low re-draw rate
- Measures fetal fraction, requiring as little as ≥2%
- MyNIPT® portal for safe and secure exchange of results
- Patient-specific risk score: option to incorporate a prior risk from the First Trimester Combined Test (FTCT) or based on maternal age.
- Consent forms and compliant sample packaging kits are available from Yourgene Health for simple and convenient shipping of samples.

2-5

DAYS

TURNAROUND

A comprehensive test panel:

The IONA® test is available as a clinical service at Yourgene Genomic Services, based in Manchester, UK. The IONA® test is a CE-IVD prenatal screening test which is offered to pregnant women to estimate the risk that their fetus may be affected with:

Autosomal Aneuploidies (AAs)

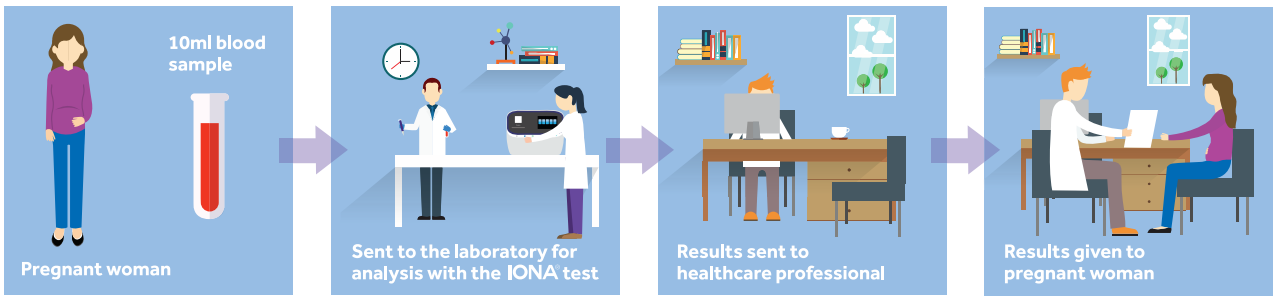
- Trisomy 21 (Down's syndrome)
- Trisomy 18 (Edwards' syndrome)
- Trisomy 13 (Patau's syndrome)
- All additional trisomies (optional)
- All monosomies (optional)

Fetal sex determination (optional)

Sex Chromosome Aneuploidies (SCAs) (optional)

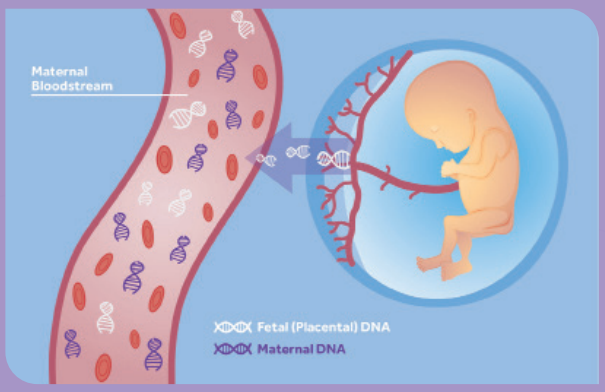
- 45,X (Turner syndrome)
- 47,XXX (Trisomy X)
- 47,XXY (Klinefelter syndrome)
- 47,XYY (Jacob's syndrome)

the IONA® test



How does the IONA® test work?

The IONA® test directly measures chormosomal DNA ratios in maternal plasma to calculate the risks of the fetus being affected with genetic conditions such as trisomy 21, 13 or18. 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 cell free DNA fragments. The IONA® test employs Next Generation Sequencing (NGS) technologies to count the number of fragments of each chromosome and then calculates a patient-specific risk of the pregnancy being affected by a condition. The IONA ® test uses the IONA® Nx NIPT Workflow which runs on the Illumina NGS platform called the NextSeq.

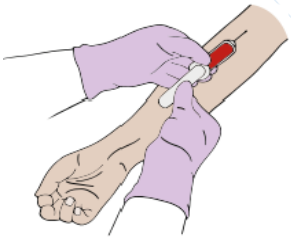


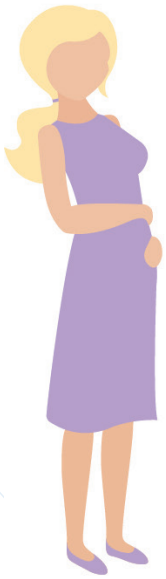
What happens to the sample:

A maternal blood sample is taken from 10 weeks gestation. Yourgene recommend a 10ml blood sample using either 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.





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:

- ✗ Received an organ transplant
- ✗ Cancer
- ✗ Carries a chromosomal imbalance
- ✗ Had a transfusion of heterologous cells in the last year
- ✗ Complete or partial monosomy X (Turner Syndrome)

The IONA® test results

SCREENING TEST RESULTS:			
TRISOMY	BACKGROUND RISK	The IONA® test RISK SCORE	CLINICAL SUMMARY
TRISOMY 21 (Down's Syndrome)	$1:10^{CT}$	Greater than 95%	**HIGH RISK REVIEW with HEALTHCARE PROFESSIONAL RECOMMENDED**
TRISOMY 18 (Edwards' Syndrome)	$1:50{,}000^{CT}$	Less than 1 : 10,000 (<0.01%)	**LOW RISK**
TRISOMY 13 (Patau's Syndrome)	$1:50{,}000^{CT}$	Less than 1 : 10,000 (<0.01%)	**LOW RISK**
Estimated fetal fraction			18.6%

RESULTS AVAILABLE

≥2%

FETAL FRACTION

Less than 1 in 20 test results will be high risk. For every 100 women opting for a NIPT screen, less than 5 will have a high risk result. A high risk result does not mean the baby is definitely affected by Down's, Edwards' or Patau's syndrome.

Risk score

A maternal blood sample is taken from 10 weeks gestation. The IONA® test incorporates the background (prior) risk, using maternal age, of an affected pregnancy into its algorithms to give the most accurate result. Instead of maternal age, the IONA® test is one of the only NIPT solutions with the option to incorporate the prior risk from the First Trimester Combined Test (FTCT) to give the most personalised and comprehensive prenatal screening result.

Reports can be customised with clinic details and translated into 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 discussed with a healthcare professional.

Clinical perfomance

	Sensitivity*	Specificity*
Trisomy 21	>99.99% [92.30 - 99.99%]	>99.99% [99.10 - 99.99%]
Trisomy 18	99.99% [83.20 - 99.99%]	>99.99% [99.20 - 99.99%]
Trisomy 13	>99.99% [69.20 -99.99%]	>99.99% [99.20 -99.99%]

Fetal Sex Determination test performance on singleton and twin pregnancies

99.3%

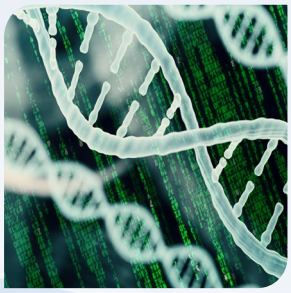
LOW RE-DRAW RATE

>99% Sensitivity and Specificity for SCAs and AAs including Turner Syndrome, Klinefelter Syndrome, XYY Syndrome, Trisomy X and all additional autosomal trisomies and monosomies. For the latest performance data, please visit www.yourgene-health.com

*The Validation performance has been demonstrated by evaluating 472 clinical samples from singleton and twin pregnancy and comparing to a reference result of an amniocentesis or chorionic villus sampling (CVS) sample or a birth outcome. This has been demonstrated using the IONA Nx cfDNA Library Preparation DX kit and the IONA® analysis software version 2.0.2. Data held on file by Yourgene Health Plc.

MyNIPT

MyNIPT™ is a data exchange portal that enables the exchange of patient results easily and securely between the laboratory and the clinic. Healthcare professionals can track the status of the submitted samples, download the test report and communicate with the laboratory. Every IONA® customer has access to the portal enabling them to manage their own clinic users. MyNIPT™ may be used to order stock e.g. sample packaging directly from the laboratory,and to access and download your clinic's customised consent form templates.



Pre- and post- counselling

Yourgene works 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 the existing care pathway is often not so simple. AtYourgene, 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. High risk results should be discussed with a healthcare professional.

We offer accredited in-house training sessions enabling attendees to provide evidence towards revalidation, as well as virtual training sessions. Yourgene provides detailed training materials both digitally and in print and facilitate cascade training. This can cover the sample collection, logistics of sample sending, consent and understanding of the generated results. In addition, we can organise many international educational symposiums and seminars to educate, inform and raise awareness of non-invasive prenatal screening.

How can I send samples for testing?

Sending your NIPT samples is fast, easy and convenient. Yourgene has established a network of IONA® laboratories that will accept blood samples from healthcare professionals for analysis with the CE-IVD IONA® test. Results are available in as little as 2 days from sample receipt. Consent forms and UN3373 compliant sample packaging boxes are also available from Yourgene Health for simple and convenient shipping of samples.

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

About YOURGENE HEALTH

Yourgene Health is an international molecular diagnostics group which develops integrated genomic products and services enabling genomic medicine

For more information, visit our website:

yourgenehealth.com

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