NIPT CLINICAL SERVICE

the IONA® test

non-invasive prenatal screen: safe, fast, accurate

The IONA® test (CE-IVD) is also available through Premaitha's quality assured, registered NIPT clinical service laboratory.

Results are available in as little as 3 days, allowing pregnant women fast, reliable results and reducing the need for invasive tests and the associated stress and anxiety.

The IONA® test is a screening test which estimates the probability that the 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:

- Results available in 3-5 days from sample receipt
- Care Quality Commission (CQC) registered clinical laboratory
- European CE-marked in vitro diagnostic assay
- The only NIPT with the option to incorporate the prior risk from the combined test
- >99% detection rate and <1% false positive rate
- Low re-draw rate of <0.5%
- Measures fetal fraction, requiring as little as ≥2%
- MyNIPT® portal for safe and secure exchange of results

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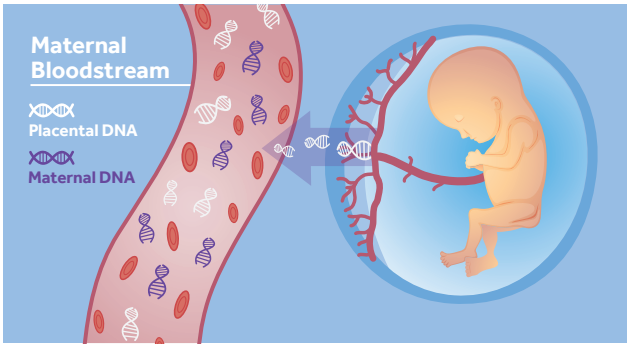
How does the IONA® test work?

The IONA® test directly measures the change of DNA ratio in the maternal plasma when fetal Trisomy 21, 18 or 13 is present. 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.



Sample

A maternal blood sample of 10mL is taken from 10 weeks gestation and is collected using Streck cell-free DNA BCT CE blood collection tubes. Samples are sent via courier or Royal Mail (UK) to the Premaitha NIPT Clinical Laboratory in Manchester, UK.

Premaitha can provide Streck tubes, packaging and pre-paid shipping packs for customers wishing to send their samples to us.

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. You are also able to order supplies, such as sample packaging via the portal.

Quality

The IONA® test is a regulated CE-marked *in vitro* diagnostic test, giving confidence and reliability in the results to clinicians. The Premaitha NIPT clinical service laboratory is registered with the Care Quality Commission (CQC) an independent regulator of health and social care in England.

Premaitha is ISO 13485:2003 certified and operates to a quality management system which is in compliance with the EC In Vitro Diagnostic Medical Device Directive (98/79/EC). Quality is key at Premaitha and pregnant women can be confident they will receive their NIPT results from a regulated and trusted clinical laboratory.

The IONA® test results

The relative amount of chromosomes 21, 18 and 13 are used to calculate a risk score to predict the presence of a trisomy. This is then modified according to the prior risk of the mother such as maternal age or combined test result and an adjusted probability calculated for the fetus being affected.

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 test.

Who can have the IONA® test?

- The IONA® test is available for 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.

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%

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

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.

Next steps

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

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