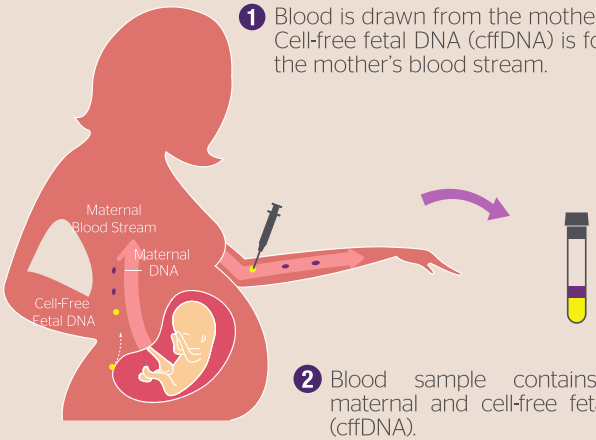
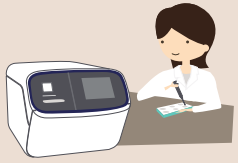
How does iGene® NIPT work?



1. Blood is drawn from the mother's arm. Cell-free fetal DNA (cffDNA) is found in the mother's blood stream.

2. Blood sample contains both maternal and cell-free fetal DNA (cffDNA).

3. Blood sample is analysed using a Whole Genome Sequencing approach.



This sequencing technology reads millions of sequences, allowing detection of certain chromosomal and genetic abnormalities.

4. Your doctor will receive your report with a result of *"Screen Positive"* or *"Screen Negative"* between 7 - 10 working days and advise you on the next step.

- Down Syndrome (T21)
- Edwards Syndrome (T18)
- Patau Syndrome (T13)

For further information,
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iGene Laboratory is a wholly owned subsidiary of INEX Innovate Private Limited, a healthcare and molecular diagnostics company focused on creating and developing products in the maternal and fetal healthcare space.

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Ask your provider

*Clinic/Practice Stamp

iGene Laboratory Pte Ltd is licensed by the Ministry of Health of Singapore as a Clinical Laboratory (HCI Licence Number: 17I0382/02/192) to provide services in Molecular Pathology (Non-Invasive Prenatal Testing).

iGene® NIPT is powered by BGI technology

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iGene

Non-Invasive Prenatal Test

Knowing early, safely.

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What is iGene® Non-Invasive Prenatal Test?

Studies show that pregnant women carry both cell-free maternal and cell-free fetal DNA (cffDNA) from 10 weeks of pregnancy[1,2]. These fetal DNA molecules can be examined for evidence of fetal chromosomal abnormalities by taking a blood sample from the expectant mother. iGene® Non-Invasive Prenatal Test (NIPT) can screen for the possibility of fetal chromosomal abnormalities such as Down Syndrome and other genetic disorders.

NIPT is recommended by the American College of Medical Genetics and Genomics (ACMG) as a screening option for Trisomy 21 (Down Syndrome), Trisomy 18 (Edwards Syndrome) and Trisomy 13 (Patau Syndrome)[3].

Simple

iGene® NIPT is suitable for pregnant mothers who are at 10 weeks of gestation or above.

Non-Invasive

iGene® NIPT requires a minimum of 10 ml of blood drawn from the mother's arm.

Detects T21, T18, T13

iGene® NIPT detects Down Syndrome (T21), Edwards Syndrome (T18) and Patau Syndrome (T13).

Am I eligible?

iGene® NIPT can be done from 10 weeks of pregnancy onwards. Women with associated risks such as the following may consider the test[4] :

- Increased maternal age (>35 years old)
- Deemed high-risk after screening tests such as nuchal translucency and first trimester screen
- A family history with inherited conditions
- A previous pregnancy with a fetal chromosomal abnormality

Please speak to your doctor to find out if iGene® NIPT is suitable for you.

Please Note: Ordering the test can only be rendered after adequate assessment of your condition after discussion with your doctor. You should not rely on the information provided herein.

What does iGene® NIPT detect?

iGene® NIPT detects the following conditions:

Trisomy Aneuploidies	• Trisomy 21 (Down Syndrome) • Trisomy 18 (Edwards Syndrome) • Trisomy 13 (Patau Syndrome)
Sex Chromosome Aneuploidies[a]	• Trisomy X (Triple X Syndrome) • Monosomy X (Turner Syndrome) • XXY (Klinefelter Syndrome) • XYY (Jacob's Syndrome)
Deletion Syndromes[a,b]	iGene® NIPT can detect 84 Deletion Syndromes including: • 22q11.2 Deletion Syndrome (DiGeorge Syndrome) • 5p-Deletion Syndrome (Cri du Chat Syndrome) • 1p36 Deletion Syndrome • 16p12.2 Deletion Syndrome • 2q33.1 Microdeletion Syndrome • 11q23 Microdeletion Syndrome (Jacobsen Syndrome) • 15q11.2 Microdeletion Syndrome (Prader-Willi/Angelman Syndrome)
Additional Trisomies[a]	• Trisomy 9 • Trisomy 16 • Trisomy 22
Fetal Sex	• Information on Fetal Sex will be reported if requested

[a] *Sex Chromosome Aneuploidies, Deletion Syndromes and Additional Trisomies testing are available for singleton pregnancies only*

[b] *Based on in-silico / internal validation data[5]*

When can I take the test ?

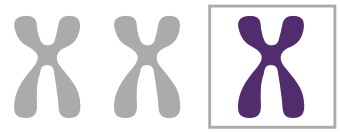
iGene® NIPT can be done from 10 weeks of pregnancy to facilitate informed decisions and any further testing, if necessary.

After approximately 7 - 10 working days, the report is sent to your doctor. Your doctor will discuss the results with you.

Please Note: that the contents of this flyer are provided on the understanding that no medical advice or recommendation is being rendered.

What is a Trisomy ?

A Trisomy is used to describe the presence of an extra chromosome – three instead of the usual two. For example, Trisomy 21 or Down Syndrome occurs when a baby is born with three copies of chromosome 21, instead of two. iGene® NIPT can screen for Trisomy 21 (Down Syndrome), Trisomy 18 (Edwards Syndrome) and Trisomy 13 (Patau Syndrome).



An extra copy of chromosome, Trisomy

Trisomy 21 - Down Syndrome

Down Syndrome occurs in about 1 in every 700 pregnancies[6]. Babies born with Down Syndrome may be associated with physical growth delays and intellectual disabilities[6]. The chances of having a baby with Down Syndrome increases as a woman gets older[4].

Trisomy 18 - Edwards Syndrome

Babies born with Edwards Syndrome have developmental disabilities, causing slow growth before birth and a low birth weight. Heart defects and abnormalities of other organs may also develop before birth[7].

Trisomy 13 - Patau Syndrome

Babies with Patau Syndrome are at risk of infant mortality. Features include slow growth before birth, low birth weight, heart defects, organ malformation, brain and central nervous system abnormalities and craniofacial abnormalities[8].

Source:
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3. Gregg, A. R., et al. (2016). Noninvasive prenatal screening for fetal aneuploidy, 2016 update: A position statement of the American College of Medical Genetics and Genomics. Genetics in Medicine. doi:10.1038/gim.2016.97
4. The American College of Obstertricians and Gynecologists Committee Opinion number 545 (2012)
5. Liu et al., PLoS One 2016
6.Tsaliki, Evdokia, et al. Prenatal diagnosis 32.10 (2012): 996-1001.
7. Cereda, Anna, and John C. Carey. Orphanet journal of rare diseases 7.1 (2012): 81.
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