Claria
a new life. well planned.

non-invasive prenatal test

Provide the best clarity and reassurance to your patients.

Validated on Indian patients
Claria
From MedGenome

MedGenome is driven to enable clinicians to deliver the best outcomes to their patients. Our passion to deliver actionable insights to clinicians has resulted in the development of “Claria” - a suite of NGS (Next-Generation Sequencing) technology-based solutions for reproductive testing.

Claria offers the most accurate Non-Invasive Prenatal Screening Test (NIPT), the Genetic Carrier Screening Test and the Preimplantation Genetic Screening/Diagnosis (PGS/PGD).

Additionally, Claria offers an absolutely free, on-demand pre and post-test genetic counselling to all your patients.

Chromosomal abnormalities in India

A woman’s risk of having a pregnancy with certain chromosomal abnormalities increase with age.

The risk of having a baby with Down Syndrome

<table>
<thead>
<tr>
<th>Age of woman</th>
<th>Risk</th>
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<tbody>
<tr>
<td>26 years</td>
<td>1 in 1300</td>
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<tr>
<td>36 years</td>
<td>1 in 270</td>
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</table>

However, the incidence of microdeletions is independent of maternal age. In younger women, the risk for a clinically significant microdeletion exceeds the risk for Down Syndrome.

Incidence of microdeletions at birth

3. Combined prevalence using higher end of published ranges from Gross et al. Prenatal Diagnosis 2011; 39, 259-266.
Claria NIPT

MedGenome Claria NIPT is a simple, safe and non-invasive prenatal screening test that provides assurance to expectant parents with accurate genetic information about their baby.

- Claria NIPT is the only test to be validated on the Indian population
- This screening test can be performed from as early as the 9th week of a pregnancy
- Compared to first trimester screenings, Claria NIPT screens for more chromosomal abnormalities
- Has a higher sensitivity and lower false positive rate for the conditions screened

NIPT has revolutionized prenatal screening for chromosomal aneuploidies around the world. Given the population variation as well as ethnic differences in India compared to the rest of the world, we evaluated the performance of this test in India. Below is a summary of our findings:

**Results of MedGenome Study**

- 480 Low risk
- 19 High risk

**Sensitivity & Specificity**

- >99%
- >86%

In this study, 96.6% potentially intermediate to high risk on conventional screening patient tested as low risk on NIPT thus avoiding invasive procedures for aneuploidy confirmation. The high negative predictive value provides significant reassurance to pregnant women.

Unlike other tests, Claria NIPT also tests for triploidy and vanishing twin. It is the only test that differentiates between maternal and fetal DNA, which helps minimise false positives.

Claria NIPT does not test for the gender of the foetus. MedGenome is a PC & PNDT certified company.

Chromosomal Anomalies that are detected:

Common aneuploidies T21, T18, T13, Sex Chromosomes abnormalities, Triploidy

Aneuploidy
- Trisomy 21 (Down Syndrome)
- Trisomy 18 (Edwards’ Syndrome)
- Trisomy 13 (Patau syndrome)
- Triploidy
- Monosomy X (Turner Syndrome)
- Klinefelter Syndrome, Triple X Syndrome, Jacob’s Syndrome

Microdeletions
Microdeletions occur in 1-7% of all structurally normal pregnancies. They cause severe physical and/or intellectual impairments.

- 22q11.2 Deletion Syndrome
- 1p36 Deletion Syndrome
- Prader-Willi Syndrome
- Angelman Syndrome
- Cri-du-chat Syndrome

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Claria NIPT now offers screening for twin, egg donor, and surrogate pregnancies
To determine:

- Zygosity information
- Individual fetal fractions for dizygotic twins
- Monosomy X, other sex chromosome abnormalities and 22q11.2 deletion syndrome
- Screens for Trisomy 21, 18 and 13 in Twin pregnancies with >99% sensitivity and specificity
- Helps clinicians effectively triage twin pregnancies

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Why Claria NIPT?

- Only test with SNP based approach - High sensitivity/specificity for low false positive and negative rates

Accuracy: Over 99.9%

- Only NIPT to be validated in the Indian patient group

- Reports fetal fraction in each case, providing greater confidence in the results of the test

FREE pre & post test genetic counselling for all patients

- Only NIPT to process all samples at our CAP* accredited lab in India, enabling accurate and faster reporting

* College of American Pathologist- This is the highest standard of quality accreditation that is given to a diagnostic lab
Who is Claria NIPT for?

All pregnant women who need insight into their baby’s development can avail the test, regardless of their age. Claria NIPT is recommended for all types of pregnancies.

Medical societies today support the use of NIPT as the first line of screening for all pregnancies, irrespective of the risk. For physicians, it is important to recommend this test for pregnancies where:

- The woman is above 30 years of age
- An abnormal ultrasound is reported
- There is a family history of chromosomal conditions or birth defects
- Couples have had a child with a chromosomal disorder
- A couple has a history of infertility or pregnancy loss (miscarriages or stillbirths)

Why screening is important

- Reassurance for expecting parents
- Early information for better management
- Preparation for the birth and early intervention wherever possible

Traditional screening test vs. Claria NIPT

<table>
<thead>
<tr>
<th></th>
<th>Traditional screening test</th>
<th>Claria NIPT</th>
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</thead>
<tbody>
<tr>
<td>Test accuracy</td>
<td>75-90%</td>
<td>&gt;99.9%</td>
</tr>
<tr>
<td>False positives</td>
<td>5%</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Affected, undetected cases</td>
<td>10-15%</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Test applicability</td>
<td>Can only be done from the 11th week onwards and within certain gestational time frames</td>
<td>Can be done from as early as the 9th week of pregnancy and anytime after that during gestation</td>
</tr>
</tbody>
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Claria NIPT in 4 simple steps

1. To book the test, talk to our local representative or dial 1800 103 3691 or visit www.medgenome.com

2. Quick and simple blood draw from the mother’s arm, posing no risk to the baby

3. Receive highly accurate reports from our CAP accredited lab based in India

4. Review the test results. Our Genetic Counsellors and Scientific Advisors are always available to help you in interpreting and understanding the report

Assistance beyond screening tests. Free Genetic Counselling to all your patients

Free on-demand pre & post test genetic counselling to all patients. An information, education & service hub for patients & doctors.

Objective

Benefits to Doctors
- Support to prescribe genetic tests
- Inform about newer tests & technology

Benefits to Patients
- Education on genetic testing & our offerings
- Counseled about Pre-test & Post-test

Patient experience

How to avail of our Free Genetic Counselling services

Doctor

MoU
Sign a memorandum of understanding (MoU) with us to enroll for genetic counselling

Customized service
Sign up for daily/fortnightly/monthly service depending on the patient volume

Contact
Contact a MedGene sales representative for genetic counselling sessions for your patient

Phone
1800 103 3691

Email
gcc.india@medgenome.com
Claria from MedGenome offers the complete range of Reproductive Testing solutions

- Non-Invasive Prenatal Test
- Carrier Screening Test
- Pre-implantation Genetic Screening/Diagnosis
- Product of Conception
- Fluorescence In Situ Hybridisation & Karyotyping

Call: 1800 103 3691 to learn more
www.medgenome.com | Email: diagnostics@medgenome.com

MedGenome Labs Ltd.
3rd Floor, Narayana Netralaya Building,
Narayana Health City, #258/A,
Bommasandra, Hosur Road,
Bangalore – 560099