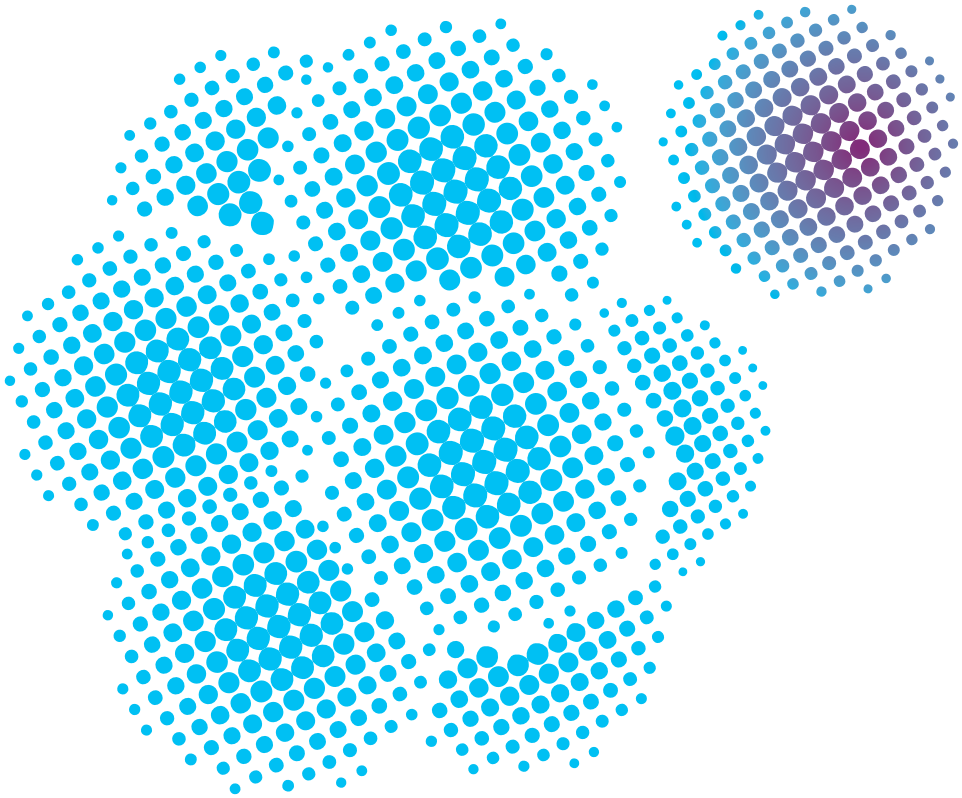
Claria
a new life. well planned.

MEDGENOME

PREIMPLANTATION GENETIC SCREENING/ DIAGNOSIS (PGS/ PGD)



Maximise the success of your IVF procedures.
And help transform your patients' life.

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

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).

We understand your time is valuable, and that’s why Claria has a team of in-house genetic counsellors to help you interpret and explain reports.

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

Why is screening an embryo before implantation critical?

1. One-in-two human preimplantation embryos from IVF (in vitro fertilized) are chromosomally abnormal[#]
2. Even up to 40% of morphologically normal embryos harbour aneuploidies*
3. 73% pregnancy rate with PGS vs 36% without[$]
4. Reduces number of IVF cycles the patient has to undergo
5. Improves the overall success rate of the IVF Center

What is Preimplantation Genetic Screening (PGS)?

Preimplantation Genetic Screening (PGS) is a test that examines the chromosomal material of an IVF embryo before implanation. It involves removing one or more cells from an IVF embryo to test for chromosome number and check for any numerical chromosomal abnormalities (Aneuploidy). This screening method facilitates the selective implantation of embryos that have the normal number of chromosomes (Euploid Embryos).

Why PGS?

1. Leads to greater implantation rates and improved IVF outcomes
2. Reduces the number of IVF cycles required to achieve a successful pregnancy
3. Increases success rate for single embryo transfer
4. Reduces the likelihood of miscarriage due to Aneuploidies
5. Increases reproductive success rates in women above 35 years

[#] *McCoy RC. Mosaicism in Preimplantation Human Embryos: When chromosomal abnormalities are the norm. Trends Genet. 33(7): 448–463 (2017).*

* *Harton GL, Munne S, Surrey M, et al. Diminished effect of maternal age on implantation after preimplantation genetic diagnosis with array comparative genomic hybridization. Fertil Steril. 2013;100(6):1695–1703.*

[$] *Majumdar G, Majumdar A, Lall M, Verma IC, Upadhyaya KC. Preimplantation genetic screening for all 24 chromosomes by microarray comparative genomic hybridization significantly increases implantation rates and clinical pregnancy rates in patients undergoing in vitro fertilization with poor prognosis. J Hum Reprod Sci 2016;9:94-100*

Who should be offered PGS?

- Couples undergoing IVF
- Patients at any age that have repeated implantation failure or recurrent pregnancy loss while undergoing IVF
- Women over 35 years old undergoing IVF
- Couples with recurrent miscarriages
- Positive history of chromosomal abnormalities in the family
- Diagnosed carriers of chromosomal aberrations

When should a biopsy be done?

A biopsy can be done on Day 3 (Blastomere) or Day 5 (Trophectoderm).

On Day 3, a fresh embryo transfer is possible. However, on Day 5, a frozen embryo transfer is possible, which is why Day 5 biopsy is recommended.

Why is Day 5 biopsy preferred for PGS?*

- At this stage, there are sufficient number of cells from which DNA can be isolated, thus ensuring success of the test
- Mosaicism of Aneuploidies can be detected at this stage
- Vitrification (rapid-freezing) of embryos after biopsy also allows the clinician to determine the optimum conditions for implantation

** Wang AY, Sullivan EA, Li Z, FarquharC. Day 5 versus day 3 embryo biopsy for preimplantation genetic testing for monogenic/single gene defects. Cochrane Gynaecology and Fertility Group. 2018*

Day 3 (Blastomere)	Day 5 (Blastocyst Biopsy)
Single cell = Less DNA	More cells (8-10 cells) = More DNA
Poorer representation of embryo's cells (1 cell only)	Better representation of embryo's cells (few cells)
Higher Test Failure Rate, as only one/ two cell(s) is available for analysis	Lower Test Failure Rate, as more number of cells are available for analysis
Cannot detect Mosaicism	Can detect Mosaicism

Why Claria PGS is better?

Sequencing based PGS lead to higher resolution and detects segmental deletions and duplications

CAP proficiency testing passed

Inherent flexibility to suit your needs without any compromise on quality.

We provide end-to-end support: From site validation and embryo biopsy training, to result data interpretation, phenotype correlation and genetic counselling.

Robust sequencing technology that provides sensitive and replicable results.

Technology

Claria PGS is carried out using advanced Next-Generation Sequencing (NGS) technology

What are the advantages of NGS based techniques?

- Rapid and convenient
- Screening of all 23 pairs of chromosomes for abnormalities in one test
- Able to detect greater than 20 Mb gains and losses in chromosomes
- Higher resolution - 1Mb areas are analysed to provide data with high confidence
- High sensitivity in detecting Aneuploidy (100 % sensitivity)
- High specificity and accuracy (99.98% specificity)
- Lower chances of test failure with NGS

Externally validated results

MedGenome's PGS test has shown 100% accuracy in Aneuploidy detection, when external validation was done using Proficiency Testing (PT) samples by the American Association of Bioanalysts.

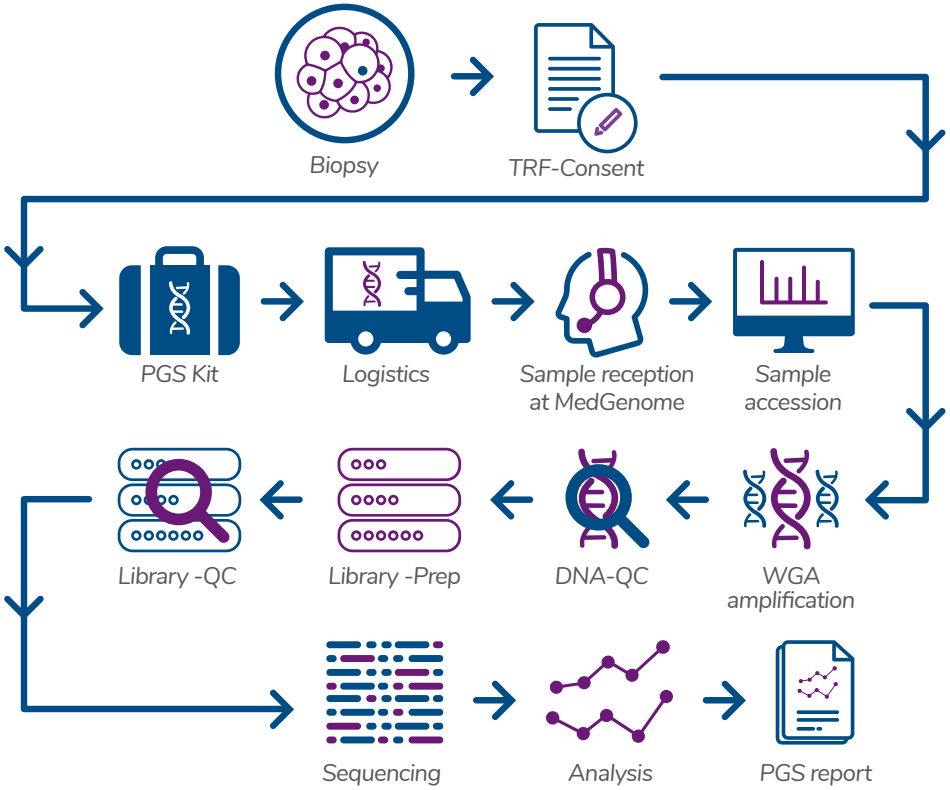
Advantages of PGS by NGS vs. other screening approaches

Fluorescent In Situ Hybridisation (FISH)	*Array Comparative Genomic Hybridisation (aCGH)*	*Single Nucleotide Polymorphism (SNP) Microarray*	NGS
A largely manual process, highly skill/ operator dependant.	Requires control DNA for each sample to provide a comparison. A prolonged hybridisation step.	SNP array analysis of DNA, extracted from a cell population, cannot indicate the mosaicism within the sample.	NGS detects partial chromosomal gains and losses more precisely. NGS detects Aneuploidy and segmental imbalances at the same time.
Screening all 24 chromosomes at once requires a special probes set, requiring separate software at higher cost per sample.	Levels of mosaicism of 20% or less will not be detected.	Longer time needed to complete intended test.	NGS provides more accurate detection of mosaicism of the Trophectoderm cells from blastocyst biopsy.
Difficult to resolve chromosomal overlaps/ split signals.	Relatively expensive.	Relatively expensive.	NGS offers reduced costs and enhanced precision. It allows parallel analysis for multiple embryos for a single patient.

What can Claria PGS detect?

- Turner Syndrome
- Klinefelter Syndrome
- Down Syndrome
- Edwards Syndrome
- Patau Syndrome
- Other trisomies and monosomies which could increase the risk of implantation failure and miscarriage
- Segmental Gain and Losses (>20Mb) in chromosomes which can lead to abnormalities in the embryo

Claria PGS workflow



Case study

36 years old woman realizes dream of motherhood through PGS technology

Patient information

Mrs Swamy (36), (name changed) a house wife and her husband have been wanting a baby since they got married in 2006. Unfortunately, each time she got pregnant, it wouldn't last more than 6-7 weeks. They tried to conceive through Intra Uterine Insemination (IUI) process 7 times and once through In Vitro Fertilisation (IVF) in UK and India respectively.

Previous genetic testing

On investigation it was found that the miscarriages occurred due to aneuploidies in the foetus. While there was no family history of chromosomal abnormalities, advanced maternal age was considered as one of the contributing factors.

Doctor Recommendation

She was recommended Intra Cytoplasmic Sperm Injection (ICSI) along with Pre-implantation Genetic Screening (PGS) for the Embryos that developed.

Genetic testing at MedGenome

In the next IVF cycle 11 embryos were screened using PGS at MedGenome Labs. The report provided by the company recommended the best embryos for transfer.

Implications of the test

After a 12 year long struggle the couples dream of becoming parents became a reality as they were blessed with a baby.

Summary

PGS is an advanced genetic testing technique, which screens IVF embryos for numerical chromosomal defects (known as Aneuploidies) prior to implantation. This allowed the clinician to choose normal (known as Euploid) embryos for transfer. By using PGS the chances of having a successful IVF pregnancy increases from 40% to 70%.

Preimplantation Genetic Diagnosis.

What is PGD?

PGD is a diagnostic procedure to test the material collected from an embryo for the presence of mutations carried by one or both parents. This is carried out when one or both genetic parents has a known genetic abnormality. In PGD every test is prepared on a case-by-case basis.

Possible candidates for PGD

- Carriers of X-linked genetic disorders
- Carriers of single gene disorders
- Couples who have a child/ children affected by a single gene disorder
- Couples who have a family history of a single gene disorder

What are the benefits of PGD?

PGD can test for most single gene disorders

PGD allows the clinician to select embryos that do not carry the single gene disorder being tested for the implantation

By using PGD, the single gene disorder can be prevented from being passed on from one generation to the next

How to order the Embryo Biopsy Kit

Contact Customer Support
MedGenome Labs Pvt. Ltd., Bangalore
Ph: 91-80-67154990/91
(At least 2 days in advance)

▼

Clearly indicate number of kits required

▼

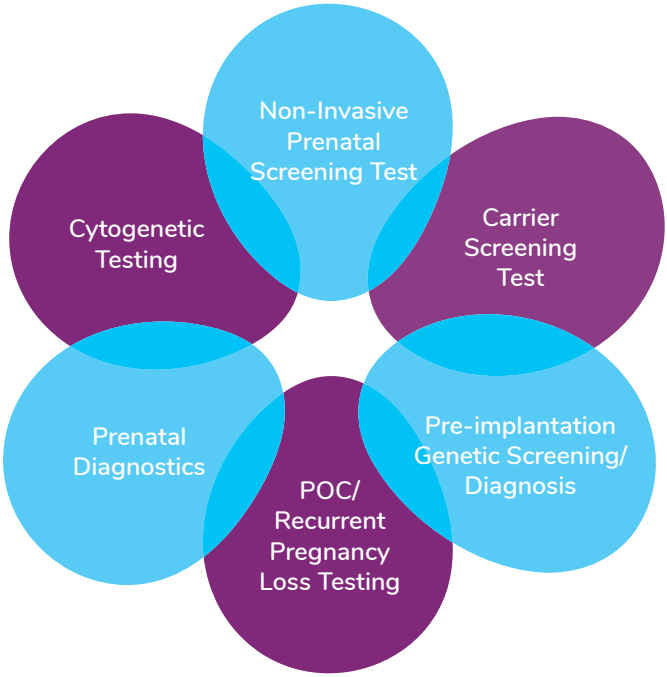
Kits will be transported to the provided address at room temperature

▼

Ensure the contents of the kit are intact before proceeding with the biopsy. Refer to the instructions on the kit.

For further queries or clarification, contact customer care

Claria from MedGenome offers the complete range of Reproductive Testing solutions



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