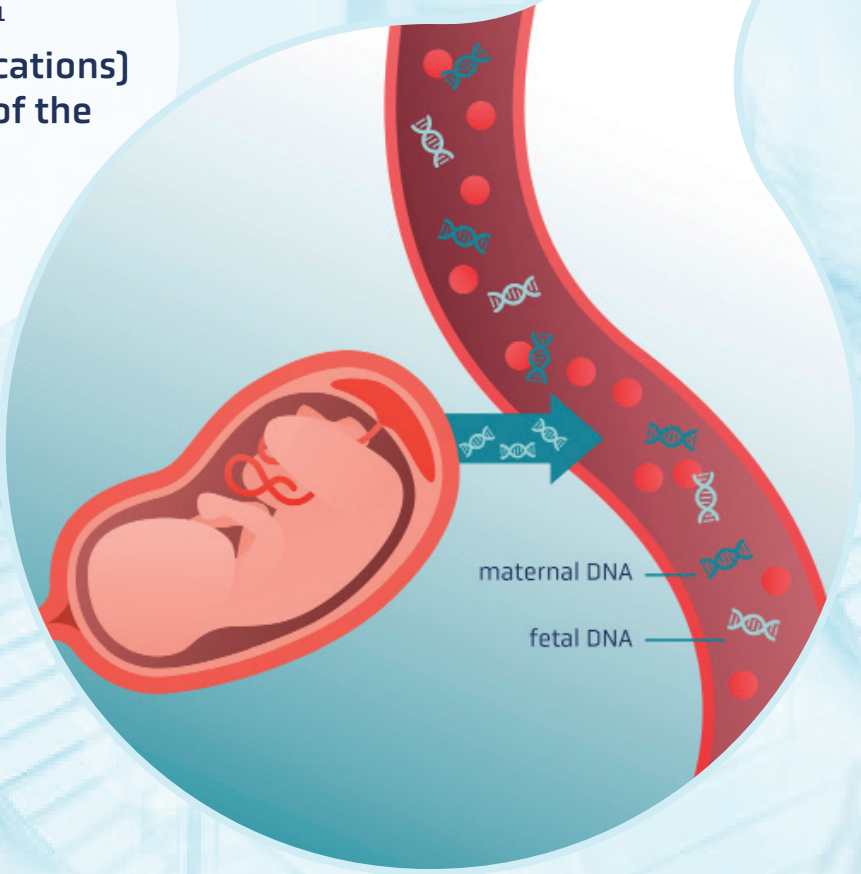
SafeBaby®
NON INVASIVE PRENATAL TEST

Prenatal genetic testing non-invasive

igls
Integrated Genetic Laboratory Services

Detection in maternal blood of complete chromosomal alterations, and CNV[1] (deletions and duplications) in all chromosomes of the future baby.



SafeBaby®

Detection of aneuploidy in chromosomes 13, 18, 21, X and Y

SafeBaby® Gold

Detection of aneuploidies, deletions and duplications in all chromosomes

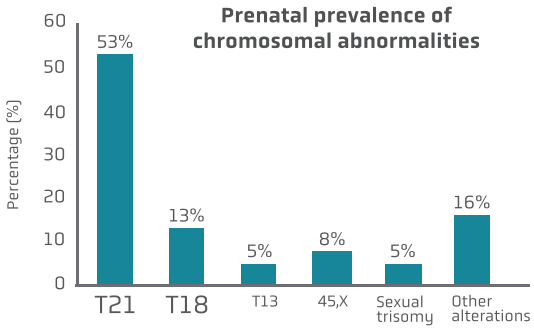
SafeBaby® is a highly accurate non-invasive prenatal test (NIPT) that detects the risk of aneuploidy in fetal chromosomes 13, 18, 21, X and Y by studying the fetal DNA present in maternal blood. SafeBaby® also provides information on foetal sex.

SafeBaby® Gold detects aneuploidy and CNV1 in all fetal chromosomes. Furthermore, by extending the study of chromosomal alterations to all chromosomes, SafeBaby® Gold is a simple alternative for the study of possible reasons for gestational losses.

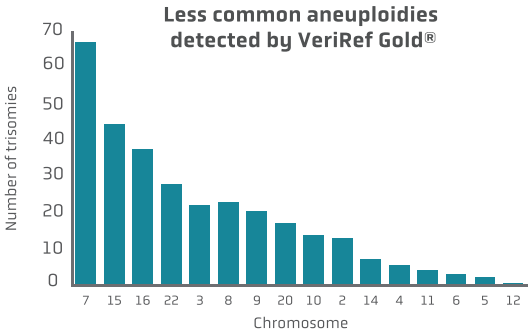
Non-invasive prenatal testing

SafeBaby® Gold

Detection of less common chromosomal alterations Aneuploidies and CNVs (deletions and duplications) in all chromosomes.



16% of the chromosomal alterations are not on chromosomes 21, 18, 13, X and Y.



It also detects less common chromosomal abnormalities not covered by other NIPT technologies.

SafeBaby® Gold detects and reports trisomies on all 24 chromosomes

	Chromosome	Sensitivity (%)	Specificity (%)
SafeBaby®	Down's Syndrome (21)	>99,9	99,9
	Edward's syndrome (18)	>99,9	99,9
	Patau syndrome (13)	>99,9	99,9
	Monosomy X	95,0	99,9
	XX	>99,9	99,8
	XY	>99,9	>99,9
SafeBaby® Gold	Resto de cromosomas (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 19, 20 y 22)	96,4	99,8
	Deletions and duplications	**Sensitivity (%)**	**Specificity (%)**
	CNV[1]	74,1	99,8

SafeBaby® and SafeBaby® Gold are the most accurate tests available on the market, with the lowest failure rate (<0.1%) and the lowest false positive rate (<0.1%).

The process

Mother´s blood draw (10ml) at 10 weeks +

Keep the blood sample at room temperature until shipping

Ship at room temperature

Cell-free fetal DNA analysis

Results in 7 working days

1. CNV: Copy Number Variations (CNV) refers to structural variations in certain DNA segments compared to a reference genome.

5-10 mL maternal blood in Streck tube

It is mandatory to send the informed consent with the sample

The non-invasive prenatal test (NIPT) based on the analysis of circulating free fetal DNA is a screening test, not a diagnostic test. The test should not be used in isolation for diagnosis. Additional tests are necessary before making an irreversible decision about pregnancy.

POWERED BY illumina®

In which cases are SafeBaby® and/or SafeBaby® Gold indicated?

All pregnant women can benefit from the Safebaby advanced prenatal test.
This test is especially indicated:

- Advanced maternal age
- Ultrasound findings suggestive of chromosomal abnormalities
- Previous history of pregnancy with chromosomal abnormality
- High-risk biochemical screening result
- Couples wishing to rule out chromosomal abnormalities
- As a first-level approach to assessing early pregnancy losses
- Couples who have experienced recurrent miscarriages

Why choose SafeBaby® and/or SafeBaby® Gold?

- It allows the **study of possible gestational losses and a better follow-up of the pregnancy.**
- It has the **lowest rate of not obtaining results: <0.1%.**
- **Fast**, results in the shortest period of time.
- It **quantifies** in a detailed and very sensitive way the **foetal fraction** of each sample.
- For **high-risk results**, immediate notification and **FREE CONFIRMATION by QF-PCR or CGH Array** from an amniotic fluid sample.
- **Suitable for any BMI, ethnicity, IVF and egg donation.**
- **Test with the highest number of publications that endorse it** (SafeBaby® and SafeBaby® Gold by ILLUMINA).
- **All equipment:** platform, software and consumables **with CE-IVD marking.**
- **Technology: MPS-Massive Parallel Sequencing** (whole genome sequencing). It will allow new developments to be incorporated in the future.
- **Made entirely in Spain.**
- **SafeBaby® Gold** also detects **aneuploidies and CNV[1] (deletions and duplications) in all chromosomes.**

When does it apply?

It can be performed on patients as early as the **10th week** of pregnancy.

Technical sheet SafeBaby® - EN - V1 May 2023 - 3/3

igls
Integrated Genetic Laboratory Services
+34 965 118 029 • info@igls.net • www.igls.net