International quality certification

Certified by Fair and Professional Third-party Organization

- Certified by College of American Pathologists (CAP) and comply with standards for medical Laboratories.
- Our laboratories are accredited by the Taiwan Accreditation Foundation (TAF) in accordance with ISO 15189 specifications.

National Quality Awards

SOFIVA NIPS received the「National Biotechnology & Medical Care Quality Award」and the 「Symbol of National Quality (SNQ)」.

Technical Collaboration with Illumina

As the only NIPS partner of global Testing giant illumina in Taiwan.

First to use TFDA-certified tubes for NIPS sample collection

SOFIVA is the first one in Taiwan to discontinue the use of research-use-only (RUO) blood collection tubes and insist on using cell-free blood collection vacuum tubes that meet In Vitro Diagnostic (IVD) medical devices specifications.

Terms and Conditions:

1. Revealing the gender of the fetus is prohibited in the NIPS report according to regulations by the Ministry of Health and Welfare.
2. SOFIVA NIPS focuses on abnormal numbers of chromosomes as well as the microdeletions and single-gene pathogenic loci listed in the table. Not all numerical and structural abnormalities can be detected. Microdeletions less than 2 Mb in size as well as highly repeat regions are not included in NIPS v2.0 and v3.0.
3. The result of SOFIVA NIPS may be affected if the mother has chromosome abnormalities, specific microdeletions, specific genetic mutations, or a blighted ovum.
4. For details regarding free confirmation, please refer to the terms and conditions on the consent form.
5. Approximately 70% of cases of Prader-Willi Syndrome or Angelman Syndrome are caused by microdeletions, while the remaining 30% are caused by uniparental chromosomes and specific gene mutations.

I Choose SOFIVA GENOMICS

Monitoring of Cell-free Fetal DNA Concentrations

If the fetal DNA concentration in the sample is too low or the sample quality does not meet requirements, another sample for retesting will be requested to ensure accuracy.

The Leading Database of NIPS Cases for Both Singleton and Twins

More than a million clinical NIPS results have been reported and the twin databases are verified by cooperating with global testing giant illumina®.

NGS technology
A complete testing for genetic abnormalities

Through the Next Generation Sequencing (NGS) technology, it is possible to fully detect newborn genetic abnormalities by designing probes for specific positions.

Free Confirmatory Testing by Amniocentesis

Free amniocentesis confirmation services are offered to all the women whose result indicates abnormalities.

Details Make Differences

The entire testing process is carried out in Taiwan and documented with a barcode scan. The reports, on the other hand, are available for online inquiry upon approval of a professional physician.

SOFIVA GENOMICS Medical Laboratory
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Website Product Information

SOFIVA NIPS
(Non-Invasive Prenatal Screening)
v1.0 / v2.0 / v3.0

Most mothers' first choice for safe screening during pregnancy

- Founded by Authorities in Genomic Medicine
- Laboratories Superior to those in Medical Centers
- Leading Genetic Testing Brand in Taiwan
- Guard the health of your baby in advance
- Safe and Reliable Blood Test

SOFIVA GENOMICS

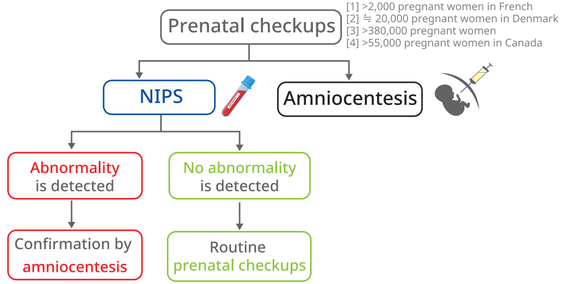
Recommended by International Societies

American College of Medical Genetics (ACMG) recommends NIPS as the preliminary prenatal genetic testing

- Safer and avoid miscarriage caused by invasive testing
- Early testing and quickly obtain test results

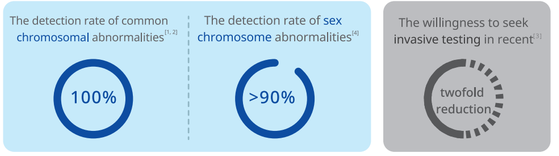
Genet. Med. 2013; 16(19): 1-

Scientific evidence



[1] >2,000 pregnant women in French
[2] ≒ 20,000 pregnant women in Denmark
[3] >380,000 pregnant women
[4] >55,000 pregnant women in Canada

In recent year, worldwide medical care organizations have successively published NIPS journal articles and the results indicate:

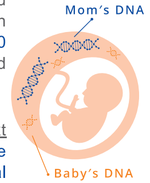


[1] JAMA, 2018; 320(6):557-565. [2] Acta Obstet Gynecol Scand, 2021;100:884–892. [3] CMAJ, 2021; 193(30): 1156–1163. [4] Genet. Med,2021; 23: 1349–1355.

An Innovative Test ! SOFIVA NIPS More Comprehensive, Safer, and Better

High detection rate and zero miscarriage prenatal screening

According to the statistics of the Ministry of Health and Welfare, over 40,000 mothers choose amniocentesis in Taiwan each year, but in average around 40 to 120 babies suffer from unnecessary complications and some mothers even die from infection-induced sepsis.



Through blood testing and the combination with Next Generation Sequencing (NGS) technology, NonInvasive Prenatal Screening (NIPS) can sequence the fetal cell-free DNA to precisely and quickly confirm chromosomal and/or genetic abnormalities.

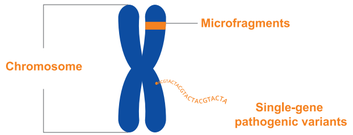
Chromosomal abnormalities are not the only cause of newborn disease

Apart from karyotyping, microfragments and single gene pathogenic variants are hardly detected using ultrasound. According to clinical statistics, these genetic abnormalities can easily result in developmental retardation, aplasia, mental retardation and other severe diseases.

→ NIPS plus the testing of microfragments and single-gene pathogenic variants can fully check the health of fetus in advance.

Common chromosome aneuploidy abnormalities

- Down syndrome T21 (53%)
- Edwards syndrome T18 (13%)
- Patau syndrome T13 (5%)



◆ Chromosomes (Common disease-Down Syndrome, the incidence rate is 1/800.)
◆ Microfragments (Common microfragment abnormalities, the incidence rate is 1/1,000.)
◆ Single-gene pathogenic variants (Skeletal Dysplasia Mutations, the incidence rate is 1/1,250.)

SOFIVA Product	NIPS v1.0	NIPS v2.0	NIPS v3.0
Suitable Subjects	Expectant mothers at over 10 weeks of pregnancy		
Test Items	**7-in-1** 3 Somatic Chromosome Abnormalities Down Syndrome Edwards Syndrome Patau Syndrome 4 Sex Chromosome Abnormalities Turner Syndrome Klinefelter Syndrome Triple X Syndrome XYY Syndrome	**31-in-1** 22 Somatic Chromosome Abnormalities Down Syndrome Edwards Syndrome Patau Syndrome 4 Sex Chromosome Abnormalities Turner Syndrome Klinefelter Syndrome Triple X Syndrome XYY Syndrome 5 Microdeletions Syndromes Prader-Willi Syndrome (70%) Angelman Syndrome (70%) DiGeorge Syndrome 1p36 Deletion Syndrome Cri-du-chat Syndrome	**66-in-1** 22 Somatic Chromosome Abnormalities Down Syndrome Edwards Syndrome Patau Syndrome 4 Sex Chromosome Abnormalities Turner Syndrome Klinefelter Syndrome Triple X Syndrome XYY Syndrome 20 Skeletal Dysplasia Mutations Crouzon Syndrome Pfeiffer Syndrome Apert Syndrome Achondroplasia Hypochondroplasia Thanatophoric Dysplasia Type 1 Thanatophoric Dysplasia Type 2 Muenke Syndrome 20 Microdeletions Syndromes Prader-Willi Syndrome (70%) Angelman Syndrome (70%) DiGeorge Syndrome 1p36 Deletion Syndrome Williams Syndrome Smith-Magenis Syndrome Koolen-de Vries Syndrome 18q Deletion Syndrome Wolf–Hirschhorn Syndrome Alagille Syndrome Jacobsen Syndrome Hereditary Neuropathy with Liability to Pressure Palsy Rubinstein-Taybi Syndrome WAGR Syndrome Potocki-Shaffer Syndrome Miller Dieker Syndrome 1q21.1 Deletion Syndrome Kleefstra Syndrome Phelan-Mcdermid Syndrome Cri-du-chat Syndrome
Detection Rates	• Chromosomes abnormalities of T21/T18/T13 > 99.5% • Other chromosome abnormalities> 90% • Sex chromosome abnormalities> 90% • Microdeletions syndrome >99% • Skeletal Dysplasia Mutations > 99%		
Free Confirmation for Positive Results	• Karyotyping for chromosome abnormalities	• Karyotyping for chromosome abnormalities • Chromosomal microarray analysis	• Karyotyping for chromosome abnormalities • Chromosomal microarray analysis • Point mutation detection

Test Procedure

After the health education and counseling sessions, fill in the consent form

Collect 10 c.c. of the pregnant woman's blood

Send the sample to SOFIVA GENOMICS Medical Laboratory for testing

Report is produced in 8 working days

Q & A

Q If I am not at advanced maternal age, do I have to do SOFIVA NIPS as well?

Although pregnant women at advanced maternal age are more likely to have a baby with abnormalities, the statistics of international associations indicate that the **incidence rate of microfragment and single-gene abnormalities** does not related to maternal age as most of them are resulted from somatic mutation.

Therefore, it is suggested that pregnant women should, **regardless of their age and parity in pregnancy, do non-invasive prenatal screening during each pregnancy.**

Q What should I do upon receipt of the testing report?

✓ If the report reveals abnormalities, a free amniotic fluid chromosome or array testing is suggested to **confirm the screening results**.

→A further discussion through genetic counseling or with a specialist physician is suggested.

✓ If the report reveals no abnormality, it is still a must to **take routine prenatal check-ups** to track the conditions of the fetus and let the obstetrician focus on your overall well-being throughout your pregnancy.

Q Can SOFIVA NIPS result in any influence on the fetus?

Absolutely not! As NIPS requires only blood testing to obtain the fetus' DNA without using invasive amniocentesis it is a zero-miscarriage safe screening method.