

CONCEPTO NIPT

Concepto NIPT is a non-invasive prenatal test, which is a genetic screening test pregnant women can take from week 10 of their pregnancy. The Concepto NIPT test determines the risk of the baby having the most common chromosome abnormalities.

INTRODUCTION

Concepto NIPT is a simple, safe, and non-invasive screening test that uses cell free DNA (cfDNA) found in maternal blood to detect prenatal chromosomal anomalies accurately, starting from week 10 of pregnancy

Non-invasive prenatal testing (NIPT) analyses cell-free DNA circulating in the pregnant mother's blood. With a simple blood test, drawn from the mother's arm, this test identifies the risk of

- Common trisomies - Down syndrome (T21), Edward Syndrome (T18), Patau Syndrome (T13) with over 99% sensitivity and specificity.
- Optional gender detection (X and Y chromosome).
- Sex chromosome anomalies.
- High Demand 60 Microdeletions.

Test results are made available in 5 working days, once the samples reach our lab.

	NIPT Standard	NIPT Advance	NIPT Absolute
Down's Syndrome (Trisomy 21)	✓	✓	✓
Edward's Syndrome (Trisomy 18)	✓	✓	✓
Patau's Syndrome (Trisomy 13)	✓	✓	✓
Gender- Male (XY) Female (XX) - (Optional)	✓	✓	✓
Sex chromosome anomalies:			
Turners Syndrome X(O)		✓	✓
Klinefelter's syndrome (XXY)		✓	✓
Jacob's syndrome (XYY)		✓	✓
Triple X syndrome(XXX)		✓	✓
High Demand 60 Microdeletions			✓

HOW DOES IT WORK?

The test requires a 10 ml blood sample drawn from the mother's arm. Maternal blood contains DNA from the mother and the fetus.

Using massively parallel sequencing technology (MPS), Concepto NIPT sequences millions of fragments of both fetal and maternal DNA from each sample. With whole-genome sequencing technology and four different bioinformatic analysis pipelines, Concepto NIPT test analyses data across the entire genome and compares chromosomes in the tested sample to the optimal reference chromosomes to accurately determine the presence of a genetic abnormality.

WHO SHOULD TAKE THIS TEST?

NIPT is recommended for all pregnancies regardless of age, risk, or family history. The test is also suitable for:

- twin pregnancies (NIPT standard only)
- IVF (in vitro fertilisation) cases
- pregnancies with a donated egg cell

The International Society for Prenatal Diagnosis, the American College of Obstetricians and Gynaecologists (ACOG) /Society for Maternal Fetal Medicine (SMFM), the American College of Medical Genetics and Genomics (ACMG), and the European Society of Human Genetics/American Society of Human Genetics support this.

6 REASONS TO CHOOSE CONCEPTO-NIPT

- Accuracy - more than 99% sensitivity and specificity for common trisomies
- No risk
- Lower failure rate
- Quick results

STATISTICALLY PROVEN

Performance statistics:

SYNDROME		SENSITIVITY	SPECIFICITY
Trisomy 21		99.17%	99.95%
Trisomy 18		98.24%	99.95%
Trisomy 13		>99.9%	99.96%
CNV	≥10 Mb	>99.9%	99.97%
CNV	<10 Mb	>99.9%	99.86%
Fetal sex		99.53%	99.20%

Sex Chromosome Aneuploidies	SENSITIVITY	SPECIFICITY
XYY	>99.9%	99.6%
XXY	>99.9%	99.6%
XXX	>99.9%	99.6%
XO	>99.9%	99.6%

Generally, resample rates are 2.18%, and no-call rate 0.069%.

THE BEST STATISTICS:

	Concepto NIPT	Competitor 1	Competitor 2	Competitor 3
Resample rate	2.18%	3.4%	4.1%	5%
NoCall rate	0.069%	1.61%	0.10%	2.25%
Population size of validation study*	146,958	20,194	86,658	18,955
PPV for T21	92.19%	> 90%	85.50%	80.90%
Analysis of all chromosomes	YES	NO	YES	NO
T21, T18, T13	YES	YES	YES	YES
Sex chromosome aneuploidies (XO, XXX, XYY, XYY)	YES	YES	YES	YES
Deletions, duplications	> 5 Mbp	LIMITED	> 7 Mbp	LIMITED
Number of reported abnormalities	More than 200	12	151	8

**Based on prospectively collected data.*

THE BEST NUMBERS:



More than 10,000,000 tests with the same technology as Concepto NIPT have been performed worldwide



More than 100,000 Concepto NIPT tests have been processed in the UK region

ABOUT CONCEPTO NIPT

Developments in the science field of genetics and enormous advances in genetic technologies in the last decade have expanded our capability to understand diseases, and provide effective treatments. Transforming the world of prenatal testing, the advent of new **DNA-based non-invasive prenatal testing (NIPT)** has introduced **a highly accurate screening strategy for fetal aneuploidies**. The first clinical test of NIPT was performed in 2010 and in the first quarter of 2013 the test was launched in Europe.

Providing screening for the **most common trisomies present at birth (21, 18, 13)**, as well as testing options for **sex chromosome aneuploidies, high demand 60 microdeletions, and for gender**, the NIPT provides a significantly stronger risk indication than traditional screening procedures.

As of 2022, over **10,000,000 tests with the same technology as Concepto NIPT** have been performed worldwide.

1866 – Discovery of the Down syndrome

1879 – Discovery of chromosomes

1928 – Discovery that chromosomes carry genes

1947 – Discovery of circulating DNA in peripheral blood

1953 – Determination of the double-helix structure of DNA

1959 – Discovery of T21 as the cause of Down syndrome

1977 – Introduction of the first generation sequencing technology

1986 – First automatic sequencer

1997 – Discovery of fetal DNA circulating in maternal bloodstream

2005 – Introduction of the next generation sequencing technologies

2008 – First use of NIPT methodology

2010 – The start of the NIPT clinical testing

2013 – Test package for deletions added

2015 – Concepto NIPT technology validated by a study of nearly 147,000 pregnancies

2018 – Technology transfer

2022 – 10,000,000 NIPT tests with Concepto NIPT technology performed

LIST OF 60 MICRODELETIONS COVERED

- Androgen insensitivity syndrome (AIS)
- Angelman syndrome/Prader-Willi syndrome
- Bannayan-Riley-Ruvalcaba syndrome (BRRS)
- Branchiootorenal dysplasia syndrome (BOR)/ Melnick-Fraser syndrome
- Cat eye syndrome (CES)
- Chromosome 10q deletion syndrome
- Chromosome 10q22.3–q23.31 microdeletion syndrome
- Chromosome 18p deletion syndrome
- Chromosome 18q deletion syndrome
- Cornelia de Lange syndrome (CDLS)
- Cowden syndrome (CD)
- Cri du Chat (5p deletion) syndrome
- Dandy-Walker syndrome (DWS)
- DiGeorge syndrome type 2 (DGS2)
- Distal arthrogryposis type 2B (DA2B)
- Duchenne and Becker muscular dystrophy (DMD/BMD)
- Dyggve-Melchior-Clausen syndrome (DMC)
- Feingold syndrome
- Holoprosencephaly type 1 (HPE1)
- Holoprosencephaly type 4 (HPE4)
- Holoprosencephaly type 6 (HPE6)
- Jacobsen syndrome
- Langer-Giedion syndrome (LGS)
- Leukodystrophy with 11q14.2–q14.3
- Mental retardation, X-linked growth hormone deficiency (MRGH)
- Microphthalmia, syndromic type 6, pituitary hypoplasia
- Microphthalmia with linear skin defects
- Monosomy 9p syndrome
- Orofaciodigital syndrome
- Panhypopituitarism, X-linked
- Potocki-Lupski syndrome (17p11.2 duplication syndrome)
- Prader-Willi-like syndrome (SIM1 syndrome)
- Rieger syndrome type 1 (RIEG1)
- Saethre-Chotzen syndrome (SCS)
- Sensorineural deafness and male infertility
- Smith-Magenis syndrome
- Split-hand/foot malformation type 3 (SHFM3)
- Split-hand/foot malformation type 5 (SHFM5)
- Syndrome diaphragmatic hernia, congenital (HCD/DIH)
- Trichorhinophalangeal syndrome type I (TRPS1)

LIST OF 60 MICRODELETIONS COVERED

- Van der Woude syndrome (VWS)
- WAGR syndrome and aniridia II
- Wilms tumor 1 (WT1)
- X-linked lymphoproliferative syndrome (XLP)
- Xp11.22–p11.23 microduplication syndrome
- 1p36 microdeletion syndrome
- 1q41–q42 microdeletion syndrome
- 2q33.1 deletion syndrome/Glass syndrome
- 5q21.1–q31.2 deletion syndrome
- 8p23.1 deletion syndrome
- 8p23.1 duplication syndrome
- 11q11–q13.3 duplication syndrome
- 12q14 microdeletion syndrome
- 14q11–q22 deletion syndrome
- 15q26 overgrowth syndrome
- 16p11.2–p12.2 microdeletion syndrome
- 16p11.2–p12.2 microduplication syndrome
- 17q21.31 deletion syndrome
- 17q21.31 duplication syndrome

WHY NIPT

To undergo the Concepto NIPT test, a pregnant woman should receive comprehensive information regarding non-invasive prenatal testing and objective advice on human genetics from a qualified health professional. The Concepto NIPT is available from week 10 of pregnancy.

The Concepto NIPT test is suitable for any woman upon her own request, regardless of age or the predetermined genetic risk. NIPT may be the test of choice due to:

- It has higher detection rate and lower false positive rate than current screening methods available in the UK.
- The maternal age upon delivery is 35 years or older.
- There are contraindications for invasive prenatal testing, such as placenta praevia, risk of miscarriage, etc.
- The history of any previous pregnancies with a chromosomal abnormality.
- Fetal ultrasonographic findings indicating an increased risk of T21, T18 or T13.
- Requires reassurance about a previous screening result.
- Received IVF treatment or had a history of recurrent miscarriage.

TEST LIMITATIONS

Although Concepto NIPT is appropriate for almost all women, there are a few limitations in specific cases.

They are summarised in the table below.

SAMPLE TYPE	ADDITIONAL INFORMATION	SAMPLE ACCEPTABILITY
Gestational age at draw	Gestational age must be 10 weeks or more	Accepted
	Gestational age less than 10 weeks	Rejected
Number of fetuses	Singleton and twins pregnancies (For twin pregnancy only NIPT Standard)	Accepted
	Triplets	Rejected
Vanishing twin syndrome	The developmental arrest must have finished within 8 weeks of pregnancy. Over 8 weeks have passed between the end of the developmental arrest and Concepto NIPT sampling.	Accepted
	Less than 8 weeks have passed between the end of the developmental arrest and Concepto NIPT sampling.	Rejected
	The developmental arrest occurred after week 8 of pregnancy.	Rejected
Therapy with heparin or its analogues	At least 24-hour pause before collecting the blood sample	Accepted
	Less than 24-hour pause before collecting the blood sample	Rejected
Pregnant woman has a history of a benign or malignant tumor	When there is no more tumor DNA in maternal blood	Accepted
	The patient is currently affected	Rejected
Cellular immunotherapy with exogenous DNA	At least 4-week gap between the last therapy and Concepto NIPT sampling	Accepted
	Less than 4-week gap between the last therapy and Concepto NIPT sampling	Rejected
Human serum albumin therapy	At least 4-week gap between the last therapy and Concepto NIPT sampling	Accepted
	Less than 4-week gap between the last therapy and Concepto NIPT sampling	Rejected

TEST LIMITATIONS

SAMPLE TYPE	ADDITIONAL INFORMATION	SAMPLE ACCEPTABILITY
Blood transfusion	At least 1-year gap between the last therapy and Concepto NIPT sampling	Accepted
	Less than 1-year gap between the last therapy and Concepto NIPT sampling	Rejected
Stem cell therapy		Rejected
Organ transplant (maternal)		Rejected
Abnormal maternal karyotype (pre-test consultation for each individual case)	Inversion, translocation, deletion, duplication, and maternal mosaicism	Rejected

ABOUT CONCEPTO NIPT LTD

10+ years of experience

100,000+ customers served

200+ partner clinics

1 mission: Advanced and affordable prenatal tests for all women

WHY CHOOSE US?

Concepto is proud to be UK's leading provider of prenatal tests including – NIPT, Early gender and a range of fertility tests. If you are a maternity/fertility/scan clinic with the same values and ethics that we have towards our business and patients, join us in our endeavour to provide fast and accurate prenatal tests across UK. Our guiding principles:



TRUST

A decade of providing tests to customers in the UK



RELIABILITY

On-time, supportive and collaborative towards partners



AFFORDABILITY

Conscious pricing, without compromising on quality

OUR MILESTONES

Catering to over 200 Clinics

More than 7000 test prenatal tests completed

Personalised and comprehensive support

Chosen test provider to leading private clinic chains of UK

Operations across UK & Ireland Territories, expansion to Wales upcoming

Our partners generate over 50% of revenue just through our blood tests

THE OFFERING

Concepto NIPT leads with advanced technology, strong, clinical partnerships, and superior customer service.

Fast Results: Quick, accurate results for all tests.

Hassle-Free Operations: All-you-need pre-packaged kits for collecting samples, including pre-paid Royal Mail envelopes for sample submission.

Transparent Pricing: Zero upfront costs for kits, billing only after the diagnosis is completed.

Expert Support: Get access to NHS antenatal screening experts and genetic counsellors.

Phlebotomy Support: Unlock our list of mobile phlebotomists across the UK to assist with blood sample collection

Marketing Assistance: Weekly social media content and promotional materials to boost sales



CONCEPTO NIPT

For any queries, write to us at

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