GeNeCaRe
Diagnostics & Research Centre
WE CARE FOR YOUR GENES

Non-Invasive Prenatal Screening Test (NIPT)

Test Requisition Form

Please Fill In English And In BLOCK LETTERS.

Patient Details

First Name*

Surname _____ DD / MM / YY
Date of Birth*

Email ID

Phone No

Clinician Details

Clinician Name*

Hospital Name

Email ID

Phone No

Clinical Indications & Obstetrics Resume

Gestational Age* (on collection date) ☐☐ Wks ☐ Days

GA Calculated by
☐ LMP ☐ Ultrasound ☐ IVF

LMP * DD / MM / YY

EDD * DD / MM / YY

Maternal Weight* ☐☐☐ Kgs

Maternal Height* ☐☐☐☐ ☐ Ft In ☐ CM

Gravida ☐ Para ☐ Abortions ☐

Still Birth ☐ Live Issue ☐

Consanguineous Marriage ☐ Yes ☐ No

If yes, ☐ Uncle-niece/ First Cousins
☐ More Distant

History of Infertility ☐ Yes ☐ No

☐ Singleton*

☐ Twins ☐ Monochorionic ☐ Dichorionic ☐ Don't Know

☐ Multiple/Vanishing twins

☐ Spontaneous conception *

☐ IVF conception ☐ Self egg ☐ Donor egg ☐ Surrogate

If IVF conceived pregnancy: Age of mother at egg retrieval _____ if donor egg; mention age of mother _____

We do NOT accept vanished twin, multiple gestation with more than 2 fetuses

Ultrasound abnormalities ☐ Yes ☐ No

Clinical History _____

Family history of chromosomal / Genetic abnormality _____

Screening test

First trimester / Combined / Screening (Risk score)

Nuchal Translucency: NT Measurement (mm) _____ (mm)

CRL _____

Bichemical Screening Risk _____

Quadruple screening (Risk score) _____

Sample Information*
Date & Time of blood collection DD / MM / YY
(10ml Streck tubes) HH / MM

Clinician Statement*

I attest that this patient has been informed about details of the test, its capabilities and limitations, and has given consent for this test.

Date DD / MM / YY **Clinician signature***

*Indicates mandatory fields Please fill in fields marked in

Test request for*

☐ **NIPT** all chromosome

☐ **NIPT with Microdeletion** (all chromosome and covers microdeletions :22q11.2 deletion,1p36 deletion, Cri-du-chat syndrome, Angelman syndrome & Prader-Willi syndrome, Digeorage Syndrome)

Check list*

☐ 10ml Streck tubes of blood sample
☐ Tubes Labelled
☐ D.O.B of pregnant women
☐ Gestational age mentioned
☐ Maternal weight
☐ Date of collection
☐ Consent and T&C signatures
☐ Signature of clinician
☐ Test code
☐ Other report _____

Signature of husband

Signature of the expectant mother*

Sample Collection is available Pan India

D-202-203, Second Floor, Shreepad World, Beside Nayara Petrol Pump, PAL Adajan, PAL, SURAT - 395009, Gujarat, INDIA.
Front Desk : 94261 72023 Technical Queries : 99746 42024 Logistics : 99746 52025 / Email : info@genecare.in

PATIENT CONSENT FORM

Purpose of the test: The purpose of Non-Invasive Prenatal Screening Test (NIPT) is to screen the fetus for chromosome aneuploidies, including the specific whole extra or missing chromosomes, and if opted for five microdeletions. which are caused when a small piece of chromosome is missing. The conditions are listed below.

NIPT is performed on a maternal blood sample which contains DNA (genetic material) from both the mother and fetus. The fetal DNA which is tested comes from the placenta; this DNA is identical to the DNA found in the actual cells of the fetus in about 98% of all pregnancies. This is available for women who are at least 10 to 12 weeks pregnant.

Aneuploidy Screened:

Trisomy 21 (Down Syndrome) caused by an extra copy of chromosome 21 is the most common genetic cause of intellectual disability. It occurs in about 1:800 births . The affected individuals have some degree of intellectual disability, some have heart and/or other organ defects that require surgery or medical treatment.

Trisomy 18 (Edward Syndrome) is known to occur in 1:7500 liveborns and causes severe intellectual disability . Most babies have multiple severe birth defects. Many fetuses are miscarried or are stillborn. Of those born alive, most die before one year of age. Babies who survive have profound intellectual disabilities and growth and development problems.

Trisomy 13 (Patau Syndrome) is caused by an extra copy of chromosome 13 and occurs in about 1 in every 22,700 live born babies and causes severe intellectual disability . Most babies with trisomy 13 have multiple severe birth defects of the brain and other organs. Many babies are miscarried or stillborn. Of those babies born alive, most die before one year of age.

Monosomy X (Turner Syndrome) is caused by a missing copy of the X chromosome This only affects girls and is found in about 1 in every 5000 liveborn babies. Affected girls are shorter and some have heart or kidney defects, hearing problems, and some have minor learning disabilities. Girls with Monosomy X may need1,2 hormone treatments in early childhood and usually during puberty. As adults, most are infertile. At GeNe Care Diagnostics & Research Centre we don't determine the gender of the fetus.

Other Sex Chromosomal abnormalities (SCA) is caused by extra copy of chromosome X and/or Y.

The overall incidence of SCA is 1 in every 400 live births . Affected individuals have less severe phenotypes and usually gets diagnosed at the time of puberty. The indications for SCA are delayed puberty, primary or secondary amenorrhea, ambiguous genitalia and infertility .

Rare Autosomal Aneuploidies (RAAs) occurs when there is an extra or missing copy of any chromosome. These aneuploidies are rare but are often associated with miscarriage, still birth and early neonatal deaths. RAAs might be restricted to placental cells, this is known as confined placental mosaicism (CPM). CPM can cause implications to the pregnancy such as intrauterine growth retardation. The outcome varies depending on the chromosome involved.

Triploidy is caused by an extra copy of all chromosomes. Abnormalities are often present in both the placenta and the fetus. It is found in about 1 in 1000 first trimester pregnancies ; most babies with triploidy are miscarried or stillborn. Of those rare babies born alive, most die before one year of age. Mothers carrying triploidy fetuses may also experience pregnancy complications such as pre-eclampsia, severe nausea, excessive bleeding, and placental disease.

not (late gestational age) be requested as low fetal fraction is mostly a biological issue. In rare cases, GeNe Care Diagnostics & Research Centre may not be able to return results on a subsequent sample.

Limitations and risk

1. This is a screening test and Although this screening test will detect the majority of pregnancies in which the fetus has one of the above listed chromosome abnormalities, it cannot detect 100% of pregnancies with these conditions. The results of this test do not eliminate the possibility of other abnormalities of the tested chromosomes, and it does not detect abnormalities of untested chromosomes, other microdeletions, genetic disorders, Single gene Mutation, birth defects, or other complications in your fetus.

2. Inaccurate test results or a failure to obtain test results may occur due to one or more of the following rare occurrences: courier/shipping delay; sample mix-up; laboratory failure or error; biological factors such as but not limited to: sample contamination or degradation, too little DNA from the fetus in the maternal blood sample (Low Fetal DNA), mosaicism (a mixture of cells with normal and abnormal chromosomes) in the fetus, placenta or mother, other genetic variants in the mother or fetus, or an unrecognized twin or vanishing pregnancy; other circumstances beyond our control; or unforeseen problems that may arise. About 1 to 2%of all pregnancies have confined placental mosaicism, a situation in which the placenta has cells with a chromosome abnormality while the fetus has normal chromosomes or vice versa. This means that there is a chance that the chromosomes in the fetus may not match the chromosomes in the DNA screened.

3. If you (mother of pregnancy) and your partner are related by blood (e.g. cousins), or if the mother of the pregnancy has parents who are related to each other by blood (e.g.,first cousins), there is a small chance that this test may not be able to return results on your pregnancy.

4. If you, (mother of the pregnancy) are found to be a carrier of one of the microdeletions on this panel, this screen will not be able to return results on the fetus. Finding out you carry a microdeletion may cause feelings of anxiety or concern about your own health and well-being as well as concerns about your pregnancy. If you know you carry one of the microdeletions on this screen, it is recommended that you use another form of testing to detect the presence or absence of that . microdeletion in your fetus and not NIPT with Microdeletion.

5. This test is not intended to identify pregnancies at risk for open neural tube defects.

Microdeletions Screened : (Only in NIPT with microdeletion)

22q11.2 deletion syndrome is caused by a small missing piece of chromosome 22. It is found in about 1:2000 liveborn babies. Children with 22q11.2 deletion syndrome have mild-to-moderate intellectual disability and delayed speech and language. Many have heart defects, immune system problems, and other health problems. Some people with 22q11.2 deletion syndrome have autism spectrum disorder and some later develop psychiatric illnesses such as schizophrenia.

1p36 deletion syndrome is caused by a small missing piece of chromosome 1 and is also called Monosomy 1p36. About 1:5000 live born babies has this condition3 . Children with Monosomy 1p36 have moderate-to-severe intellectual disability. Most children have heart defects that may require surgery or medical treatment. Some children may need special physical and occupational therapies to help with weak muscle tone. About half of children with Monosomy 1p36 have seizures and/or behavioral problems; some have hearing and/or vision loss.

Angelman syndrome (15q11.2 deletion maternal) Angelman syndrome (AS) is caused either by a small missing piece of chromosome number 15 or from inheriting two copies of chromosomes 15 from one parent and none from the other. There are other rare cases as well. About 1 in 12000 live born babies has this condition. Babies often have feeding difficulties and weak muscle tone. Children have severe intellectual disability and motor problems; most have a small brain and head size and some have seizures. Most children do not develop speech.

Prader-Willi syndrome (15q11.2 deletion paternal) is caused either by a small missing piece of chromosome number 15 or from inheriting two copies of chromosome15 from one parent and none from the other; there are other rare causes as well. About 1 in 10,000 liveborn babies has this condition. Babies have weak muscle tone and feeding problems. Children with PWS typically have intellectual disability, behavior problems, and delayed motor and language development. They also have excessive appetites and may become obese and may develop diabetes.

Results :

LOW RISK result indicates a reduced chance that your fetus has the listed chromosome abnormalities but it cannot guarantee normal chromosomes or a healthy baby.

NIPT HIGH RISK result indicates an increased likelihood your fetus has one of the chromosome abnormalities tested but does not confirm that the fetus has that abnormality. The recommended follow-up is a prenatal diagnostic test such as FISH, Karyotype and Microarray. Your clinician will explain the test results and recommend follow-up steps to you, which may include a referral to a genetic counsellor and/or to prenatal diagnostic testing.

NIPT is not a diagnostic test –it will not confirm any of these chromosome abnormalities. It will only provide the risk for each of these in your current pregnancy. Therefore, DECISIONS ABOUT YOUR PREGNANCY SHOULD NEVER BE MADE BASED ON THESE SCREENING RESULTS ALONE AS THEY NEITHER CONFIRM NOR RULE OUT THE PRESENCE OF A CHROMOSOME ABNORMALITY IN THE FETUS. Follow-up diagnostic testing should always be performed during pregnancy or at birth to confirm or rule out a chromosome abnormality or microdeletion. There is a chance that the sample(s) submitted will not return results; in this case, a second sample from the mother may be requested to repeat the test at no charge or a refund maybe provided. In cases where low fetal fraction (fetal fraction less than 3.5%) is observed a repeat sample may (charged separately) or may not be.

I have read or have had read to me the above informed consent information about the Non-Invasive Prenatal Screening test (NIPT) performed GeNe Care Diagnostics & Research Centre. I have had the opportunity to ask questions to my Clinician regarding this test, including the reliability of test results, the risks, and the alternatives prior to my informed consent. I request and authorize GeNe Care - Diagnostics & Research Centre to test my sample for the chromosome abnormalities listed above. I also understand that while the laboratory takes atmost care to report results within the turn around time, there maybe unforeseen circumstances when the turn around time is exceeded. In such circumstances, GeNe Care Diagnostics & Research Centre will not be liable. GeNe Care Diagnostics & Research Centre is not liable for any sample damage that may occur during collection and transport from the collection center/hospital to GeNe Care Diagnostics & Research Centre facility. I acknowledge that I must sign the consent statement located on the test requisition form that will be sent with my sample to GeNe Care Diagnostics & Research Centre. I fully understand that the gender of my fetus will not be reported.

Patient Sign Date:

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FORM G
[See rule 10]
FORM OF CONSENT
(for invasive techniques)

I, _____ wife / daughter of _____ age ___ years, residing at _____ hereby state that I have been explained fully the probable side Effects and after effects of the pre-natal diagnostic procedures.

I wish to undergo the preimplantation / pre-natal diagnostic technique / test / procedures in my own interest to find out the possibility of any abnormality (i.e. disease / deformity / disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure / technique / test conducted show the absence of disease / deformity / disorder.

I understand that the sex of the foetus will not be disclosed to me.

I understand the breach of this understanding will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and rules framed thereunder.

Date:
Place: SURAT

Signature of the pregnant woman.

X

I have explained the contents of the above to the patient and her companion (Name _____ _____Address_____ Relationship _____) in a language she / they understand.

Name, signature and registration number of Gynecologist / Medical Geneticist / Radiologist / Pediatrician / Director of the clinic / Centre / Laboratory

Date:

Name, address and registration number of Genetic Clinic / Institute.
GENECARE DIAGNOSTICS & RESEARCH CENTER
D-202/203,2ND Floor, Shreepad World, Beside Nayara Petrol Pump, Pal, Adajan, Surat-395009
Registration No.: GJ-05/SUR/PCPNDT/1476/2025

SEAL

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FORM E
[See Rule 9(3)]
FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY

1. Name and address of Genetic Laboratory: **GENECARE DIAGNOSTICS & RESEARCH CENTER**
D-202/203,2ND Floor, Shreepad World, Beside Nayara Petrol Pump, Pal, Adajan, Surat-395009
2. Registration No.: **GJ-05/SUR/PCPNDT/1476/2025**
3. Patient's name:
4. Age: years
5. Husband's / Father's name:
6. Full address with Tel. No., if any:
7. Referred by / sample sent by:
(full name and address of Clinic)
(referral note to be preserved
carefully with case papers)
8. Type of sample:
(Maternal blood / Chorionic Villi
Sample / Amniotic fluid / Foetal
Blood or other foetal tissue (specify)

9. Specify indication for pre-natal diagnosis:
    a. Previous child / children with
    i. Chromosomal disorders
    ii. Metabolic Disorders
    iii. Malformations
    iv. Mental Retardation
    v. Hereditary hemolytic anemia
    vi. Sex-linked disorders
    vii. Single gene disorder
    viii. Any other (specify)

b. Advanced maternal age (35 years or above)
c. Mother / Father / Sibling having genetic disease (specify)
d. Other (specify)
10. Laboratory tests carried out (give details):
    i. Chromosomal studies
    ii. Biochemical studies
    iii. Molecular studies
    iv. Preimplantation genetic diagnosis
11. Result of diagnosis (if abnormal, give details): Normal / Abnormal
12. Date(s) on which tests carried out:
The results of the pre-natal diagnostic tests were conveyed to _____on _____

Place: SURAT
Date:

Name, signature and Registration No. of the
Medical Geneticist / Director of the Institute.