Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

TEST REQUISITION FORM

CHROME NON - INVASIVE PRENATAL TESTING

The most preferred non-invasive prenatal test

Patient Details:

Patient's Name: _____ DOB: _____ Age: _____

Gender : ☐ Male ☐ Female ☐ Others Ethnicity _____

E-mail ID : _____ Contact No. _____

Address : _____

_____

Height : _____ Weight : _____ Blood Type: _____ LMP/EDC Date DD/MM/YYYY

Gestation Age : As per LMP _____ wks _____ days. As per USG _____wks _____days

Sample Collection Date _____ Sample Collection Time _____

Reason For Referral :

(Please mention details wherever available)

☐ Abnormal Biochemical Screening ☐ Abnormal Ultrasound Screening ☐ Advanced Maternal Age

☐ Twins ☐ Screening Purpose ☐ Others : _____

Pregnancy Type: ☐ Singleton ☐ Multiple # (If multiple, mention number of fetuses) _____

Undergone IVF : ☐ Yes ☐ No Donor Gamete : ☐ Yes ☐ No Undergone Fetal Reduction: ☐ Yes ☐ No

Vanishing twin* : ☐ Yes ☐ No

(#Validated only for singleton and twin pregnancies)

(If yes, it is recommended that mother's blood to be collected after 8 weeks of the event. In such cases, there is significant risk of false positive test results)

Past Obstetric History:

☐ Recurrent Pregnancy Loss ☐ Still Birth ☐ Abortion ☐ IUFD ☐ Others: _____

Known parental chromosomal abnormality : ☐ Yes ☐ No

Known family or personal history of Genetic Disorders or Cancer : ☐ Yes ☐ No

Please mention details/attach report _____

Test Requested

☐ **NIPT Focus**
(Analysis & reporting of aneuploidies in 5 common chromosomes (13,18,21,X & Y)

☐ **NIPT Comprehensive**
(Analysis and reporting of aneuploidies in all 23 Chromosomes)

☐ **NIPT Plus**
(Analysis and reporting of aneuploidies in all 23 Chromosomes + 6 common microdeletions)

*DiGeorge (22q11.2), Angleman (15q11.2), Prader-willi (15q11.2), Cri-du-chat(5p), Wolf-Hirschhorn syndrome (4p), 1p36 deletion
*ACOG guidelines for screening of Fetal Chromosomal Abnormalities recommends screening only for common chromosomal aneuploidies (Trisomy 13, 18, 21 and sex chromosome aneuploidies)

Clinician Information

Doctor's Name: _____ Hospital's Name _____

Email ID : _____ Contact No. _____

DD/MM/YYYY _____ Doctor's Signature _____

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Please Note:

In accordance with the PCPNDT act, fetal gender is not disclosed in any of the above modules.

- Sex chromosomal anomalies when detected are reported.
- Samples for the above tests can be collected from 9 weeks of gestation onwards.
- Information regarding maternal age, weight, number of fetus, fetal gestation as well as fetal ultrasound reports are required for accurate interpretation of test results.
- The CHROME-NIPT has been validated for singleton, twin and donor oocyte pregnancies.
- ACOG guidelines for screening of Fetal Chromosomal Abnormalities recommends screening only for common chromosomal aneuploidies (Trisomy 13,18, 21 and sex chromosome aneuploidies)

Information About & CHROME-NIPT:

The Chrome NIPT is a screening test which analyzes cell free fetal DNA for fetal aneuploidies from maternal blood. The test is performed on maternal blood sample (approx 10ml) which contains both maternal as well as fetal DNA (genetic material). The cell free fetal DNA comes from the placenta, which is identical to the DNA found in the cells of the fetus in ~98% of all pregnancies. The technology used for this assay is Next Generation Sequencing (NGS). The test is usually recommended by your treating clinician in the following scenarios:

- The couple is concerned about the risk of chromosomal aneuploidies in the fetus
- Has an abnormal maternal serum screening test
- There is advanced maternal age (>35 years)
- Previous child with a chromosomal abnormality similar to that evaluated by the CHROME-NIPT

The CHROME -NIPT Is Not Suitable For :

- Pregnant women with < 9 weeks gestation.
- Pregnant women who have recently (upto the 3 months ago) received blood transfusion, stem cell therapy, immune therapy or organ transplantation.
- Multiple gestations other than twins. Please note that the test performance may be affected in the presence of a vanishing twin.

Test Results

One can expect any of the following test results on opting for either of the above modules:

- ANEUPLOIDY NOT DETECTED (Low Risk) – Indicates that the chance that the fetus has any of the tested conditions is low. However, it does not guarantee normal chromosomes or a healthy baby.
- ANEUPLOIDY DETECTED (High Risk)- It indicates that there is an increased chance of the fetus to be affected with one of the chromosome abnormalities listed but does not confirm that the fetus has that abnormality. The result should be confirmed by diagnostic prenatal testing such as chorionic villus sampling (CVS) or amniocentesis. False positive results are known and arise due to confined fetal/placental mosaicism, low-level maternal mosaicism or rarely due to presence of maternal malignancy.
- NO RESULT - In some cases, no result is obtained. If this occurs, the laboratory will request a repeat specimen for testing at no additional charges. However an invasive testing is recommended if the repeat testing fails again to provide an answer.

Test Limitations

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, birth defects, or other complications in your fetus.

- 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; other circumstances beyond our control; or unforeseen problems that may arise. The laboratory cannot be held liable for any of the above.
- Biological factors affecting test performance can include, but are not limited to: sample contamination or degradation; too little DNA from the fetus in the maternal blood sample (low fetal fraction); other genetic variants in the mother or fetus; an unrecognized twin pregnancy; or mosaicism (a mixture of cells with normal and abnormal chromosomes) in the fetus, placenta, or mother & unbalanced translocation. 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.

As CHROME- NIPT is a SCREENING TEST, 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.

- Test results are expected within 7-10 working days. The laboratory usually ensures timely dispatch of reports, however certain un-anticipated delays may occur for which the laboratory cannot be held liable.
- The reports are released to your referring clinician as well as the patient/guardian (in case of minor). Since genetic test results are confidential, reports / information regarding the results will not be released to any other person/clinician unless consent is provided by the patient.

Patient Consent

I have had the opportunity to ask questions to my healthcare provider regarding this test, including the reliability of test results, the risks and the alternatives prior to giving my informed consent.

- ☐ I have read and understood/have been explained the above in a language of my understanding and permit NCGM to perform the recommended genetic analysis.
- ☐ I understand that the data derived from my genetic testing may be stored indefinitely as a part of the laboratory database. This data is always stored in de-identified form. I understand my de-identified data/sample may be used for research collaborations as well as scientific presentations and publications.

Name: **Signature:**

Relationship to Patient: **Date, Time and Place:**

Clinician Name & Signature:

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FORM-G
[See Rule 10]
FORM OF CONSENT
(For Non-invasive / invasive techniques)

I, _____age _____yrs, wife/daughter of _____residing at (address) _____ _____, hereby state that I have been explained fully the probable side effects and after-effects of the prenatal diagnostic procedures. I wish to undergo the pre-natal diagnostic procedures in my interest, to find out the possibility and abnormality (i.e. deformity/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 fetus will not be disclosed to me.
I understand that breach of this undertaking will make me liable to penalty as prescribed in the Prenatal Diagnostic Technique (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994).

Date : _____

Place : _____ **Signature of Patient**

I have explained the contents of the above consent form to the patient and/or her companion (Name_____Address _____ _____Relationship_____) in a language she/they understand.

Date : _____

Place : _____ **Signature of Clinician**

Name, Signature & Registration No.
of Gynaecologist/Medical Geneticist / Radiologist/
Pediatrician / Director of the Clinic / Center / Laboratory

Name, Address & Registration No.
of Genetic Clinic / Institute [Seal]