Neuberg Supratech
REFERENCE LABORATORIES

TRF/CONSENT FORM FOR NON-INVASIVE PRENATAL TESTING

Date:	Test ID:

PATIENT INFORMATION

Patient's Name:	Date of birth:	Contact Number:

Address:

Weight: Blood Type: Inherited Disease: Yes/No: _____
LMP / EDC Date:

Details of any Inherited Disease or cancers (please also state all medications that patient is currently on):

Parental Genotyping:

Gestation Period: _____Weeks	Pregnancy type: Singleton____ Multiple___ (If multiple, then number of fetus_____)	Past History of Gestational Abnormality: Yes/No: _____

To be filled in by Clinical/Medical Institution

PREGNANCY PROFILE/SAMPLE INFO

Doctor:	Undergoing IVF: Yes/No_____ Number of embryos: Implantation _____ Blighted Ovum _____ Fetal Reduction _____

Double Marker/Triple Marker: _____
Notes:

Medical Institution:	Contact Number:	Blood Taken by: Blood Quantity: _____ ml

***This test does not reveal the gender of the fetus.**

Patient's Signature: _____DD/MM/YYYY Patient Email: _____

Doctor's Signature: _____ DD/MM/YYYY Doctor's Email: _____

Please attach an Ultrasound report with this consent form.

CONSENT/ASSENT FORM FOR CHROME-NIPT

Patient Name:_____ Age: _____ Gestation:

CHROME -NIPT evaluation and interpretation is available in the following modules:

- ☐ CHROME-COMPREHENSIVE: analysis and reporting of aneuploidies in all 23 chromosomes
- ☐ CHROME-FOCUS: analysis and reporting limited to aneuploidies involving common chromosomes: 21, 18, 13, X and Y.
- ☐ CHROME-PLUS: analysis and reporting of aneuploidies in all 23 chromosomes + Microdeletions- DiGeorge (22q11.2), Angelman (15q11.2), Prader-willi (15q11.2), Cri-du-chat(5p), Wolf-Hirschhorn syndrome (4p), 1p36 deletion

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. Information regarding maternal age, weight, number of fetus, fetal gestation as well as fetal ultrasound reports is required for accurate interpretation of test results. The CHROME-NIPT has been validated for singleton, twin and as well donor oocyte pregnancies.

Information on CHROME-NIPT:

The Chrome NIPT is a screening test which analyzes cell free fetal DNA for fetal aneuploidies on maternal blood. The test is performed on a maternal blood sample. The collected maternal blood sample (approx. 10 ml) contains both maternal as well as fetal DNA (genetic material).The fetal DNA comes from the placenta; this DNA is identical to the DNA found in the cells of the fetus in ~98% of all pregnancies. The technology used is Next Generation Sequencing.

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
- Advanced maternal age
- 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 3 months ago) received blood transfusion, stem cell therapy, immune therapy or organ transplantation.
- Multiple gestations other than twins. Please note that 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 again fails 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. 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.

Patient Consent:

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

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.

☐ I have read and understood the above/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 may be used for research collaborations as well as scientific presentations and publications to further existing medical knowledge.

Signature:	Clinician Signature:
Name:	Clinician Name:
Relationship to patient:	Date, time and place:

*For any queries, please contact lab

FORM- G

[Refer rule 10]

FORM OF CONSENT

(For Non-invasive / invasive techniques)

I, _____ wife/daughter of _____, age __ years residing at _____ (full address) 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 fetus will not be disclosed to me.

I understand that breach of this undertaking 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: **Signature of the patient**

I have explained the contents of the above to the patient and her companion

(Name_____Address_____ _____Relationship_____) In a language she/they understand.

Date:
Place: **Signature of the patient**

Name, signature and registration Number of Gynaecologist/Medical Geneticist/Radiologist/ Paediatrician/Director of the Clinic/Centre/Laboratory

Name, address and registration number of Genetic Clinic/Institute [SEAL]