Zentrogene™
Bioscience Laboratory

NIPD Zplus

NIPD Zplus Request & Consent Form

ZG - NZ - 2014 V1.0

Patient Information

* Name : _____ * Reference number : _____

* Date of birth (dd/mm/yyyy) : _____ * ID/passport number : _____

* EDC (dd/mm/yyyy) : _____ * Gestation (calculated according to EDC) : _____

* Please select : ☐ Singleton ☐ Twin pregnancy (DCDA / MCDA / MCMA)

Family history of genetic diseases : ☐ Yes, please name the disease : _____ ☐ No

* Additional Option (Only for singleton pregnancy) : Sex Chromosomal Aneuploidy & >10Mb Chromosomal Duplication/Deletion : ☐ Yes ☐ No

Informed consent of the pregnant woman:

1. I fully understand the indication, intended purpose, characteristics, and potential risks of this test. My doctor has answered all of my questions.
2. I fully understand the limitation of this test, in particular i) this test is intended for the detection of Trisomy 21, Trisomy 18 and Trisomy 13 and ii) the detection rate is >99%., Sex Chromosomal Aneuploidy detection rate is >90%, ChrY% detection rate is >97%, >10Mb Chromosomal Duplication/Deletion 1p36 Deletion Syndrome, Cri du Chat Syndrome, 2q33.1 Deletion Syndrome Detection rate according to Zentrogene / BGI's data that >95% of these findings are confirmed.
3. I promise I have provided true and reliable personal information.
4. I understand that the report will be available within 5 working days from the time when the laboratory receives the sample. However, if the test result is abnormal or there are insufficient fetal fractions, it will take more than 5 working days for the report to be processed.
5. I understand that resampling of blood (1% chance) may be required.
6. I understand that the results are only for NIPD Zplus screening only and this test is not for clinical diagnostic purposes.
7. I agree to provide the outcome data of this pregnancy, in particular if subsequently my baby was found to be affected by a chromosomal or genetic disease. I understand and agree that representatives of my clinician may contact me for such outcome data.
8. I agree access of my clinical data by my clinician and/or the laboratory for the purposes of auditing, quality assurance and research provided that I remain anonymous and unidentifiable during data analysis and that all my personal information are removed from any reports or publications.

Additional consent for twin pregnancy woman:

9. I understand that the above figures about the NIPD Zplus test are based on singleton pregnancies, and similar clinical data on twin pregnancies are limited. Based on reported studies so far, and on theoretical grounds, the performance of NIPD Zplus test in twin pregnancies is probably similar to that in singleton pregnancies. However, this requires further confirmation by more studies.
10. For woman with twin pregnancy, the result of this test will only be limited to the detection of Trisomy 21, Trisomy 18 and Trisomy 13; and no other chromosome tests.

Limitations of the test:

1. Although the latest research suggested that this test is highly accurate, with a detection rate of fetal Trisomy 21, Trisomy 18 and Trisomy 13 is >99% and a false positive rate of <1%, this test still cannot be considered as a diagnostic test at present. It could only be considered as a highly accurate screening test. Therefore, a high risk result should still be confirmed using a conventional karyotyping procedure. A low risk result cannot totally exclude the possibility of an affected fetus. This is the limitation of the current technology.
2. If the test is performed during very early pregnancy(<10 gestational week), there is a possibility of a false-negative result due to an inadequate amount of fetal chromosomal material.
3. This test may not be suitable in the following situations: mothers with Chromosomal Aneuploidies, during very early pregnancy, Chimerism, Chromosomal Microdeletion, Microduplication and multiple pregnancies (excluding twin pregnancies). If the pregnant woman has received an allogeneic blood transfusion, transplantation or stem cell therapy, there will be a possibility of inaccurate results due to exogenous DNA.

I agree to undergo this test for the prenatal detection.

*** Patient s ignature :** _____ *** Date (dd/mm/yyyy) :** _____

Blood Sample

* Date of collection (dd/mm/yyyy) : _____ * Time of collection : _____ a.m. / p.m.

Information of Requesting Doctor

* Name of doctor : _____ Name of clinic / hospital : _____

* Signature : _____ Phone : _____

Laboratory Use

Date and time received : _____ Signature : _____