Zentrogene
Bioscience Laboratory

NIPD Zplus

NIPD Request & Consent Form

DX-PD-S88 V1.1

Patient Information

Test Requested	☐ **NIPD (DX0679)** Singleton pregnancy, 19 test items	☐ **NIPD-Twin (DX0668)** Twin pregnancy, T21, T18, T13 & Chr-Y	☐ **NIPD-Zplus 95 (DX1625)** Singleton pregnancy, 95 test items

*Patient name ： _____ * Date of birth (dd/mm/yyyy)：_____Age (_____)

* ID / passport number：_____ * Gestation ：_____W + _____D

* Clinic ref. no.：_____

Family history of genetic diseases：☐No ☐Yes, please specify：_____

Re-sampling sample：☐ * Sampling Tube：☐ Geneseek Tube ☐ Streck Tube

Informed consent of the patient:

1. I fully understand the limitation of this test, which is intended for the detection of Trisomy 21, Trisomy 18 & Trisomy 13 with detection rate >99%.
2. I fully understand the detection sensitivities and specificities of Trisomy 9, Trisomy 16 & Trisomy 22 testing have not been validated, due to inadequate number of reference cases.
3. I fully understand the sensitivity rate of Sex Chromosome Aneuploidies is >95% and that of Fetal Gender Identification sensitivity rate is >98%.
4. I fully understand the NIPD test also detects specific locus relevant to 8 kinds (NIPD) or 84 kinds (NIPD-Zplus 95) of microdeletion/duplication according to OMIM and Decipher database; due to the limited database and reference, the risk of false positive/negative result can be increased compared to T21 T18 T13;
5. I understand that a test report will be available within 7 working days after my sample has been received by the testing laboratory. However, in a small number of cases (around 1% of all samples received), samples are loss by irresistible factors and in other circumstance, for example the fetal DNA is individually too low, re-sampling in these cases are needed and the turnaround time will be prolonged.
6. NIPD is NOT a diagnostic test, a high risk result should be followed by confirmatory test(s), and test report should be interpreted by a physician.
7. I understand that for twin pregnancy, only the result of **Trisomy 21, Trisomy 18, Trisomy 13** & **Y Chromosome Detection** will be provided. **NIPD (DX0679)** and **NIPD-Zplus 95 (DX1625)** are not applicable to woman with twin pregnancy.
8. I understand that for twin pregnancy, the Y chromosome detection is not a diagnostic test and could only be used as a reference, a result that returns as Y chromosome detected does not exclude the possibility that one of the fetuses might be female.
9. I understand that my clinical data (after your personal and identifiable information has been removed) will be provided to your clinician and/or the laboratory for the purpose of auditing, quality assurance and scientific researches. If you do not consent to your clinical data being used for such purposes, please tick the following box:
   ☐ I do not consent to the access of my clinical data by my clinician and/or the testing laboratory for the purposes of auditing, quality assurance and scientific researches.
10. I have read this Patient Consent carefully and fully understood the characteristic, suitable users, purpose and necessity of this test. My physician has fulfilled the obligations of informing, explained my doubts and questions and promised confidentiality of my personal information. I promise all the information provided above are true and accurate. I understand that the commercial terms and conditions of sale of the test that I am taking are provided by the clinic or medical organization but not Zentrogene.
11. With my signature I give my consent for Zentrogene to conduct genetic analysis of my blood sample. It has been pointed out to me that I can withdraw my consent in full or in part at any time without stating reasons and that I have the right to not know the test results.

Limitation of the Test:

1. Although the latest research suggested that this test is highly accurate, this test still cannot be considered as a diagnostic test at present. Abnormalities caused by chromosomal polyploid (triploid, tetraploid, etc), chromosomal balanced translocation, inversion, ring, UPD, monogenic/polygenic disease, etc, cannot be detected by this test; this test cannot exclude the fetal mosaic chromosomal diseases.
2. If the test is performed during very early pregnancy (<10 gestational week), there is a higher possibility of giving false-negative result. An increased chance of sample recollection due to insufficient fetal DNA fraction will be resulted. Therefore, sample with gestational week <10 will not be accepted.
3. NIPD test is performed from 10 to 22 gestational weeks of pregnancy. Testing may be carried out after 22 gestational weeks only in accordance with local law. Zentrogene accepts no legal responsibility for testing that is provided by local healthcare partners that contravenes local law governing the provision of prenatal.
4. Potential sources of false positive or false negative results and patients not suitable for the test include but are not limited to maternal, fetal and/or placental mosaicism (mixtures of chromosomally normal and abnormal cells in the pregnancy), chromosomal abnormality in either parent, transplant surgery, stem cell therapy, heparin therapy, blood transfusion within one year, cellular immunotherapy where exogenous DNA is introduced within 4 weeks, malignant tumor during pregnancy, >2 fetus and low fetal fraction, patient's BMI>40, specific medications such as Heparin during pregnancy. Gender identification can be false if the detected value is within the gray zone. NIPD is also unable to accept samples in cases of 'vanishing twin syndrome' where developmental arrest has been identified as occurring after week 8 of pregnancy, or within 8 weeks prior to NIPD testing date.

I fully understand the terms listed on this document. My Healthcare Practitioner has answered all of my questions including those related to reliability and the risks of the test prior to giving my consent. I agree that my personal information will be sent to Zentrogene and BGI for NIPD test and the test result will be sent to my clinician. With my signature I give my consent for the NIPD test.

* Patient Signature ：_____ * Dated (dd/mm/yyyy) _____

Sample Information

* Sample collection date (dd/mm/yyyy)：_____ * Sample collection time：_____ a.m. / p.m.

Requesting Doctor Information

* Name of doctor：_____ Clinic /medical organization：_____

* Doctor Signature：_____ Contact phone number ：_____