Zentrogene
Bioscience Laboratory

NIPD Zplus

NIPD Request & Consent Form

DX-PD-S88 V1.0

Patient

Test Requested	☐ **NIPD (DX0679)** For **Singleton pregnancy** only, Test for **19 items** in total	☐ **NIPD-Twin (DX0668)** For **Twin pregnancy** only, Test for **T21**、**T18**、**T13** only

* Name of pregnant woman：_____ * Date of birth (dd/mm/yyyy)：_____Age (_____)

* ID / passport number：_____ * Working EDC (dd/mm/yyyy)：_____

* Clinic ref. no.：_____ * Gestation (calculated according to EDC) ：_____W + _____D

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

Informed consent of the patient:

1. I fully understand the indication, intended purpose, characteristics, and potential risks of this test. My Healthcare Practitioner has answered all of my questions regarding the test.
2. I fully understand the limitation of this test, which is intended for the detection of Trisomy 21, Trisomy 18 and Trisomy 13 with detection rate >99%.
3. I fully understand the detection sensitivities and specificities of Trisomy 9, Trisomy 16 and Trisomy 22 testing have not been validated, due to inadequate number of reference cases.
4. I fully understand the sensitivity rate of Sex Chromosome Aneuploidies is>95% and that of Gender Identification sensitivity rate is >98%.
5. I fully understand the detection sensitivities and specificities of chromosomal deletion, including 5p deletion syndrome, 1p36 deletion syndrome, 2q33.1 deletion syndrome, 10p14 deletion syndrome, 16p12.2 deletion syndrome, 11q23 deletion syndrome, 1q32.2 deletion syndrome and 15q11.2 deletion syndrome, have not be validated due to inadequate number of reference cases. For chromosomal deletion suspected cases, alternative diagnostic tests should be used.
6. I confirm that I have provided true and reliable health and personal information.
7. I understand that a test report will be available within 5~7 working days after my sample has been received by the testing laboratory. However, under uncontrollable or unforeseeable circumstances, including but not limited to, insufficient fetal DNA fraction and abnormal test result due to unqualified sample, a longer testing time will be required. Sample recollection may be arranged in some cases (approximately 1% of the testing population).
8. I understand that the NIPD test is only a screening test and is not intended for diagnostic purpose.
9. I agree to provide the fetal outcome 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 information.
10. Your 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, even if all my personal information are removed from any reports or publications.

Additional consent for twin pregnancy woman:

11. I understand that the testing statistics of NIPD test listed above are based on singleton pregnancies, and that on twin pregnancies testing statistics are limited. Based on reported studies available, theoretically, the performance rate of NIPD test on twin pregnancies is comparable to that on singleton pregnancies.
12. For woman with twin pregnancy, only the results of **Trisomy 21, Trisomy 18 and Trisomy 13** will be provided**. NIPD (DX0679)** is not applicable to woman with twin pregnancy.

Limitations 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. It could only be considered as a highly accurate screening test. A **high risk result** should be confirmed using a conventional karyotyping procedure. A **low risk result** cannot totally exclude the possibility of an affected fetus. Decisions about your pregnancy should not be made solely based on the result of the test as the test could give a false result and does not detect other abnormalities, genetic disorder or birth defects in the fetus.
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. If the test is performed after 24 gestational weeks, the pregnant woman may miss the best diagnosis timeframe. For the one who opted for NIPD after 24 gestational week, the one has to take full responsibility of any possible outcomes.
4. This test is not appropriate for testing on the sample with the following conditions: mosaicism, chromosomal abnormalities such as translocation microdeletion and microduplication, multiple pregnancies (except twin pregnancies), patients with chromosomal translocation, aneuploidies or has received an allogeneic blood transfusion, transplantation or stem cell therapy, less than a 4 weeks gap between last injection of blocking antibodies therapy and sampling; multiple pregnancies undergoing fetal reduction after 8 weeks of gestation; any pregnancy undergoing fetal reduction with the past 8 weeks.

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.

* Signature of pregnant woman：_____ * Dated (dd/mm/yyyy)_____

Sample Information

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

Information of Requesting Doctor

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

* Doctor Signature：_____ Phone：_____

Remarks：a. * Requested items. b. Please put a "√" on appropriate ☐. c. The test will be processed only if requested information has been provided

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