

NONINVASIVE PRENATAL ANEUPLOIDY SCREENING (NIPT/NIPS) CONSENT FORM

Patient Name: _____ **Date of Birth:** _____

Sex Assigned at Birth: Female Male Intersex **Gender Identity (optional):** Female Male _____

NIPT is a screening test that identifies pregnancies at increased risk for specific chromosome abnormalities: trisomy 21 (Down syndrome), trisomy 18, and trisomy 13. These disorders cause a range of physical birth defects and intellectual disability. NIPT may also suggest an increased risk for an extra or missing sex chromosome. High-risk NIPT results should be confirmed by diagnostic tests; irreversible clinical decisions should never be based solely on a screening test result.

The following has been explained to me:

1. NIPT is a screening test, not a diagnostic test. False positive and false negative results may occur.
2. Participation in genetic testing is completely voluntary. Genetic counseling is available. See nsgc.org or acmg.net to find a medical genetic professional.
3. ARUP prohibits the use of these results to facilitate any form of discrimination or violation of ethical or legal guidelines outlined by national and international standards.
4. Patients with a high-risk result, or no result, by NIPT screening should be referred for genetic counseling, comprehensive ultrasound, and offered diagnostic testing (chorionic villus sampling [CVS] or amniocentesis).
5. There are three possible test results:
 - a) High risk: indicates screening has detected a significantly increased chance for the fetus to have an abnormal number of one of the following chromosomes: 13, 18, 21, X, or Y.
 - b) Low risk: indicates there is less than 1 in 100 chances for one of the screened conditions. However, healthcare providers may still recommend a fetal karyotype or other testing. If clinical results contradict test results, diagnostic testing should be considered.
 - c) No result: indicates the lab is unable to interpret the results of the screen. NIPT may be indeterminate due to biological or technical limitations. There may be too little fetal DNA present in the sample (low fetal fraction); mosaicism for a chromosome abnormality in the fetus, placenta, or mother; and other maternal and fetal factors. Note that no result due to low fetal

fraction is more common at early gestational ages and with high maternal BMI.

6. This test can identify fetal sex. Fetal sex will be reported unless "No" is marked on the patient history form. If the fetus is at increased risk for Turner syndrome, XXX, XXY, or XYY, this result will be reported, even if opting out of fetal sex reporting was chosen. In rare instances, incorrect sex results are reported.
7. Testing is limited to the chromosomes and conditions listed above. This test does not assess triploidy, microdeletions, other abnormalities of the tested chromosomes, or abnormalities involving nontested chromosomes. This test does not detect other genetic disorders or birth defects.
8. The cfDNA analyzed is both fetal and maternal. NIPT occasionally indicates that a chromosomal abnormality, or malignancy, is present in the maternal DNA portion of the NIPT sample.
9. NIPT cannot be interpreted accurately in pregnancies with a fetal demise/nonviable twin. NIPT in pregnancies with an unrecognized/unreported twin demise are more likely to have a false positive result.
10. ARUP only performs testing on singleton pregnancies. Multiple pregnancies will be sent out to Integrated Genetics to perform the MaterniT21 PLUS Core test. (Test code 451927). Undisclosed twin pregnancies will be analyzed as a singleton pregnancy. Accuracy may be impacted and repeat testing may be necessary for twin pregnancies not disclosed prior to testing.
11. NIPT cannot be interpreted accurately in pregnancies less than 10 weeks gestation. Testing will NOT be performed for patients with a gestational age <10 weeks. Testing will be canceled upon receipt at ARUP.
12. Although genetic test results are usually accurate, several sources of error are possible including, but not limited to, sample mishandling, misidentification, contamination, and twin pregnancies disclosed as singleton pregnancies.

Most samples are discarded after testing is completed. Some samples may be stored indefinitely for test validation or education purposes after personal identifiers are removed. All New York samples are discarded 60 days following test completion. You may request disposal of your sample by calling ARUP Laboratories at 800-242-2787 ext. 3301.

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Patient, Legal Guardian, Power of Attorney (POA): I authorize ARUP Laboratories to perform NIPT testing. The benefits, risks and limitations of this testing have been explained to my satisfaction by a qualified health professional.

Patient/Guardian/POA Printed Name

Signature

Date

Ordering Healthcare Provider, Genetic Counselor: I have explained this genetic test and its risks, benefits, and alternatives to the patient or legal guardian and addressed all their questions.

Provider/Genetic Counselor Printed Name

Signature

Date

Specialty

Phone Number

Fax