ARUP LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

500 Chipeta Way
Salt Lake City, UT 84108-1221
phone: 801-583-2787 | toll free: 800-242-2787
fax: 801-584-5249 | aruplab.com

NONINVASIVE PRENATAL ANEUPLOIDY SCREENING (NIPT/NIPS) PATIENT HISTORY FORM

THIS IS NOT A TEST REQUEST FORM. Please complete and submit with the test request form or electronic packing list.

Patient Name: _____ **Date of Birth:** _____ **Sex:** ☐ Female ☐ Male
Ordering Provider: _____ **Provider's Phone:** _____
Practice Specialty: _____ **Provider's Fax:** _____
Genetic Counselor: _____ **Counselor's Phone:** _____

Number of Fetuses (REQUIRED): ☐ Unknown* ☐ One ☐ Multiple**

*If 'Unknown' is indicated, ARUP will perform testing with analysis and interpretation using singleton pregnancy protocols.

**ARUP only performs testing on singleton pregnancies. Multiple gestations will be sent out to Integrated Genetics to perform the MaterniT21 PLUS Core test. (Test code 451927)

Is the gestational age at draw ≥10 weeks? (REQUIRED): ☐ No* ☐ Yes

*Testing will NOT be performed for patients with a gestational age <10 weeks. Testing will be canceled upon receipt at ARUP.

Gestational age: _____ weeks OR Estimated Date of Conception (EDC) _____ (Optional)

Does the patient want the sex of the fetus reported? ☐ No ☐ Yes (Sex will be reported if not specified)

Patient's current weight: _____ lbs OR_____ kgs

Does the patient have a family history of chromosomal abnormalities? ☐ No ☐ Yes (If yes, please specify):

_____

Has the patient had a high-risk screening result in this pregnancy? ☐ No ☐ Yes

Specify high-risk result: ☐ T21 ☐ T18 ☐ T13 ☐ Neural Tube Defect (NTD)

☐ Other: _____

Specify test method: ☐ Maternal Serum Screening (MSS) ☐ NIPT

Has the patient had an abnormal ultrasound in this pregnancy? ☐ No ☐ Yes (If yes, please specify):

_____

Patient/Legal Guardian: My signature below constitutes my desire to undergo NIPT testing and my acknowledgment that the benefits, risks, and limitations of NIPT have been explained to my satisfaction by a qualified health professional.

_____ _____ _____
Patient/Guardian Printed Name **Signature** **Date**

Ordering Healthcare Provider: I have explained NIPT, its limitations and alternatives to the patient or legal guardian and answered all of their questions.

_____ _____ _____
Health Provider Printed Name **Signature** **Date**

_____ _____
Patient Name **Date of Birth**

NONINVASIVE PRENATAL ANEUPLOIDY SCREENING (NIPT/NIPS) PATIENT HISTORY FORM

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 cognitive 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 www.nsgc.org or www.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: This indicates that 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: This indicates that 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: This indicates that 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 pregnant individual; 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 gestations 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.

For questions, contact an ARUP genetic counselor at 800-242-2787 ext. 2141

Master Label

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