ARUP LABORATORIES

500 Chipeta Way, Salt Lake City, Utah 84108-1221
Phone: (800) 522-2787 Fax: (801) 584-5249
Web site: www.aruplab.com

# PATIENT HISTORY FORM FOR NON-INVASIVE PRENATAL TESTING (NIPT)

Patient Name _____ Date of Birth_____

Physician/Genetic Counselor_____ Phone_____

FAX _____ Pager/Cell_____

Due date (EDD) _____ (or) Gestational age at draw _____weeks _____ days

Fetal gender by ultrasound: [ ] Male [ ] Female [ ] Ambiguous [ ] Unknown

**[ ] I wish to know the fetal gender** **[ ] I do NOT wish to know the fetal gender**

Patient's current weight _____ lbs (or) _____ kgs

Patient's race: [ ] Caucasian [ ] Black [ ] Hispanic [ ] Asian [ ] Other_____

| | |
|---|---|
| Is the patient carrying more than one fetus?<br>[ ] Yes [ ] No [ ] Unknown<br><br>Is the patient the genetic mother of the fetus (i.e. was the fetus conceived using the patient's own egg)?<br>[ ] Yes [ ] No | **The NIPT test is NOT appropriate when there is more than one fetus or when the patient is not the genetic mother of the fetus. If you have questions, please contact genetics at 800-242-2787, ext. 2141 before drawing the patient.** |

**Indication for testing (check all that apply):**

[ ] Advanced Maternal Age

[ ] Abnormal Maternal Serum Screen positive for: [ ] T21 [ ] T18 [ ] T13

[ ] Ultrasound Abnormality (describe) _____

[ ] Other: _____

**Will a cheek swab sample from the father of the fetus accompany the maternal blood sample?** ☐ **No** ☐ **Yes**

Father's Name _____ Date of Birth: _____

# INFORMED CONSENT FOR NATERA'S PANORAMA TEST

Non-Invasive Prenatal Testing (NIPT) is a screening test, which can be performed on women at or after 9 weeks 0 days gestation to identify fetuses at risk for extra or missing copies of chromosomes 21, 18, 13, X or Y. **This test is not intended to diagnose these conditions, and additional tests are recommended to confirm any positive NIPT results.**

**NIPT will identify most fetuses at risk for one of the following chromosomal conditions:**

- **Trisomy 21 (T21)** – is caused by an extra copy of chromosome 21 and is commonly known as Down syndrome. All individuals with T21 have some degree of intellectual disability, and some will also have defects of the heart or other organs that may require surgery or medical treatment.
- **Trisomy 18 (T18)** – is caused by an extra copy of chromosome 18 and is sometimes called Edwards syndrome. During pregnancy, poor fetal growth is common and many fetuses are miscarried or stillborn. Most individuals with T18 have multiple, severe birth defects of the brain, heart and other organs. The majority will die in their first year of life. Babies born with T18 will have profound intellectual disabilities, growth and development problems.
- **Trisomy 13 (T13)** – is caused by an extra copy of chromosome 13 and occasionally called Patau syndrome. The majority of affected fetuses are miscarried or stillborn. Individuals with T13 have severe birth defects of the brain and other organs and most will die in their first year of life. Babies born with T13 will have profound intellectual disabilities, growth and development problems.
- **Turner syndrome (45,X)** – is usually caused by a missing sex chromosome (either X or Y) and is known as monosomy X. Individuals with Turner syndrome are typically shorter than average, may have heart or kidney defects, and are also infertile. Some have minor learning disabilities. Fetuses with Turner syndrome have a high risk of miscarriage or stillbirth.

**Possible results for this test:**

1. **High Risk** – indicates that the test has detected a significantly increased risk (greater than or equal to 1 in 100) for the fetus to have an abnormal number of one (or more) of chromosomes 21, 18, 13, X or Y. The specific risk will be listed on the report. Patients with a high risk NIPT result should be referred for genetic counseling and be offered a fetal karyotype by chorionic villus sampling (CVS) or amniocentesis.
2. **Low Risk** – test detected a very low chance (less than 1 in 100) for the fetus to have an abnormal number of chromosomes 21, 18, 13, X ot Y. The specific risk will be listed on the report. However, your healthcare provider may

recommend a fetal karyotype or other testing if your fetus is found to have ultrasound anomalies or if other concerns about the health pf your fetus exist.

3. **No Call** – the lab is unable to interpret the results of the test. This may be due to not enough fetal DNA present in the mother' sample; presence of mosaicism in the fetus, placenta or mother; an unrecognized twin pregnancy; the patient is not the genetic mother of the fetus; or if the mother and the father of the fetus are related by blood (e.g. cousins). In some cases, the laboratory may request a second sample, at no charge, to clarify the test results.

**The following has been explained to me:**

1. NIPT is a highly accurate screening test, but is not intended to replace a fetal CVS or amniocentesis, which are tests available to me.
2. This test has the ability to identify gender of the fetus.
   a) If I would like to know the gender of my fetus, I must indicate such by checking the appropriate box in the patient history section of this form. If neither box is checked, fetal gender will not be reported.
   b) If the fetus is at high risk to have Turner syndrome, that result will be reported to me, even if I have elected not to have fetal gender disclosed.
3. A cheek swab sample from the father of the baby is optional, but may reduce the likelihood that the laboratory will need a second sample from me for a repeat test.
4. This test may:
   a) indicate that my fetus is at increased risk for one or more specific chromosome abnormalities (Down syndrome, Trisomy 18, Trisomy 13, or Turner syndrome)
   b) suggest a biological relationship between me and the father of the fetus (eg, cousins)
   c) be inconclusive due to biological or technical limitations
5. Limitations of this test:
   a) **Because this is a screening test and not a diagnostic test, positive results should be confirmed by testing a sample from my fetus**.
   b) Testing is limited to the chromosomes and conditions listed above. This test will not identify other abnormalities of those chromosomes such as partial trisomy or monosomy and does not detect abnormalities of other chromosomes not tested.
   c) Balanced chromosomal rearrangements such as translocations or inversions, other genetic disorders, birth defects, and other fetal or pregnancy complications will not be detected.
   d) Results may not be interpretable if there is too little fetal DNA present in my sample. In these cases, a repeat test at no extra laboratory charge will be offered.
   e) Mosaic (the presence of both normal and abnormal cells) monosomy or trisomy for the targeted chromosomes may not be detected.
   f) I should not have this testing if I am not the genetic mother of the fetus (i.e. the fetus was conceived using another woman's egg), I have received an allogeneic bone marrow transplant, or more than one fetus present.
6. A low risk result greatly reduces the chances that the fetus has an extra or missing copy of one of the tested chromosomes but it cannot guarantee normal chromosomes.
7. Sampling errors are possible (including, but not limited to mishandling, misidentification, and contamination).
8. NIPT is a fee-for-service test. I will be responsible for payment after the testing has begun, even if I decide not to receive results. ARUP will provide a local referral for genetic counseling at my request.
9. My sample may be used for test validation or education after personal identifiers are removed. For such use, my sample may be stored indefinitely. I can withdraw my consent at any time by contacting the laboratory at (800) 242-2787, ext. 3301. Refusal to permit the use of my sample will not affect my test result. For more information about ARUP, please refer to www.aruplab.com.

This testing is performed by Natera. The performance characteristics of this test were validated by Natera Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. Natera is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing. These results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

**PATIENT CONSENT STATEMENT:**

I have read or have had read to me the above informed consent information about the Panorama Non-Invasive Prenatal Test (NIPT). I have had the opportunity to ask questions of my health care provider regarding this test, the risks, and the alternatives prior to my informed consent. I request and authorize Natera to test my sample(s) for the fetal chromosome conditions listed above.

Patient/Guardian Signature _____ Date _____

**Physician/Genetic Counselor:**

I have explained NIPT and its limitations to the patient or legal guardian and answered all questions.

Printed Name of Physician/Genetic Counselor _____ Date _____

Signature_____ Phone Number _____