Ambry Genetics®

Patient Consent for Non-Invasive Prenatal Testing - Page 1 of 2

Genetic Testing Introduction:
All pregnant individuals have a baseline risk for fetal chromosome abnormalities. Screening for genetic conditions is complex. Pre- and post-test genetic education is recommended for all individuals undergoing a genetic screening test.

Genetic Test Purpose and Specimen:
Non-Invasive Prenatal Testing (sometimes referred to as NIPS or NIPT), is a laboratory test to screen a fetus for specific chromosome abnormalities. This test will provide information about fetal chromosomes based on the specific Non-Invasive Prenatal Testing panel that was ordered by your healthcare provider.

Specimen:
The blood specimen submitted is required for isolation and purification of DNA for molecular genetic testing. Non-Invasive Prenatal Testing is performed on a blood sample from a pregnant individual, which contains DNA from both the pregnant individual and the fetus. The fetal DNA in the blood sample originates from the placenta and circulates in the blood stream of the pregnant individual. This DNA is typically expected to be the same as the DNA found in the cells of the fetus. The Non-Invasive Prenatal Testing offered by Ambry Genetics is validated for pregnancies with a gestational age of at least 10 weeks 0 days. In some cases, this test may require an additional blood sample to obtain accurate results.

Ambry Genetics' Results Disclosure Policy:
Due to the complexity of genetic testing for fetal chromosomal abnormalities and the important implications of the test results, these results will be reported through your ordering provider. Your results report may be available to you after it has been released to you by your healthcare provider, upon your request, or as required to comply with local, state and/or federal regulations and laws. You should contact your provider to obtain and discuss the results of the test and additional testing and/or family planning options. Additionally, the test results could be released to all who, by law, may have access to such data.

See Ambry's Privacy Policy for more details: https://www.ambrygen.com/legal/notice-of-privacy-practices.

Genetic Testing Results and Risk Information:
Results of this test could identify an increased risk for various types of chromosomal conditions. Your healthcare provider's recommendations for additional testing and/or family planning options could differ depending upon the test results. Identification of an increased risk for a fetal chromosome abnormality does not imply that additional testing and/or family planning options will be covered by health insurance. Dependent on the test results, there may not be enough information available to determine your risk.

There are several types of Non-Invasive Prenatal Testing results, including:

- **Negative: No aneuploidy detected.** Results are consistent with the correct number of chromosomes. No chromosome abnormalities were identified in any of the chromosomes included in the test ordered by your healthcare provider. A normal result does not eliminate the possibility that the pregnancy is affected with other chromosomal abnormalities, birth defects, genetic conditions, or other conditions such as neural tube defects or autism.

- **Positive: Aneuploidy detected.** Results are consistent with a pregnancy at increased risk for a chromosome abnormality. Genetic counseling is recommended to discuss your results. No irreversible clinical decision should be made based on these screening results alone. Clinical correlation is indicated. Your healthcare provider will make recommendations for additional testing based on your results.

- **Positive: Microdeletion detected.** Results are consistent with a pregnancy at increased risk for a type of chromosome abnormality called a microdeletion. Genetic counseling is recommended to discuss your results. No irreversible clinical decision should be made based on these screening results alone. Clinical correlation is indicated. Screening for microdeletions is only performed when specifically requested by the ordering provider.

NIPT is a screening test, meaning that false positive and false negative results can occur. There are multiple other screening and testing options available during pregnancy, which can be discussed with your healthcare provider. If a definitive diagnosis is desired, diagnostic testing options such as chorionic villus sampling (CVS) or amniocentesis may be considered. Your healthcare provider will discuss additional testing and/or family planning options based on the results of your testing.

Genetic Discrimination:
There are federal laws in place that prohibit health insurers and employers from discriminating based on genetic information (for example, the Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233)). There are currently no federal laws that prohibit life insurance, long term care, or disability insurance companies from discriminating based on genetic information. Your state may have more comprehensive laws in this area. The results of genetic testing are considered protected health information and are confidential to the extent allowed by state and federal law. Release of test results is limited to authorized personnel, such as the ordering physician, and to other parties as required by law.

Technical Testing Limitations:
Although this screening test will detect the majority of chromosome abnormalities in the tested chromosomes, it cannot detect 100% of pregnancies with these conditions.

Standard Laboratory Limitations:
Inaccurate results or a failure to obtain test results may occur as a result of (but not limited to) the following reasons: sample mix-up, inaccurate or misleading medical information, technical problems, or biological factors. Biological factors that can affect results include: sample contamination, low level of fetal DNA (fetal fraction) in the blood sample, mosaicism, or an unrecognized multiple pregnancy. There is also a possibility that the result findings will be uninterpretable. In rare circumstances, results may be suggestive of a condition different than that which was originally considered for purpose of consenting to this testing.

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Ambry Reserves the Right to:
- Contact you to share additional genetic testing or clinical trial opportunities that may help understand your result.
- Retain your deidentified sample.
- Utilize the deidentified sample for laboratory quality control or for laboratory test validation optimization purposes.
- Utilize the deidentified sample for research to improve genetic testing for all patients and contribute to scientific research.

Patient Acknowledgement:
- I understand that genetic testing is voluntary, and I may choose not to have my sample tested.
- I have read and I understand the information provided in this consent, and all my questions have been answered.
- I acknowledge that the information provided by me on the test requisition form (TRF) is true and correct.
- I have had the opportunity to ask questions about the purpose of testing, about the test procedure, the test results, the risks, the limitations to testing, and my rights prior to me signing this informed consent.

Terms and Conditions:
Patient Acknowledgement: I acknowledge that the information provided by me is true and correct. For direct insurance billing: I authorize my insurance benefits to be paid directly to Ambry Genetics Corporation (Ambry), authorize Ambry to release medical information concerning my testing to my insurer, to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that I am financially responsible for any amounts not covered by my insurer and responsible for sending Ambry money received from my health insurance company.

For patient payment by credit card: I hereby authorize Ambry Genetics Corporation to bill my credit card as indicated above. In order to expedite consideration for eligibility for Ambry's Patient Assistance Program, please provide the total annual gross household income: $_____ and the number of family members in the household supported by the listed income: _____. I authorize Ambry Genetics Corporation to verify the above information for the sole purpose of assessing financial need, including the right to seek supporting documentation.

For NY Residents: I understand that under New York State law, Ambry Genetics must discard my sample after the longer of (a) testing completion and (b) 60 days after the Date of Collection above.

☐ I agree that Ambry Genetics may retain my sample for 6 months after the completion of all testing, including the testing above, any additional testing of my sample that I authorize within the initial 6-month retention period, and any extended or additional testing of the sample necessary and required to demonstrate the integrity of the sample tested or to resolve the analysis of a test with a previously indeterminate result.

☐ I do not agree that Ambry Genetics may retain my sample for 6 months after the testing above has been completed.

My signature below acknowledges my voluntary participation in this genetic screening test and such genetic analysis in no way guarantees my health, the health of an unborn child, or the health of other family members.

_____ _____

Patient Signature (or Parent/Guardian if patient is a minor) Date

_____ _____

Patient Name (Print) Name/Relationship (if patient is a minor)

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MKT-RPHT-FORM-10021-EN v2 06.01.23