



Icahn
School of
Medicine at
Mount
Sinai

MOUNT SINAI GENETIC TESTING LABORATORY

Department of Genetics and Genomic Sciences
Icahn School of Medicine at Mount Sinai

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CLIA # 33D0653419

Prenatal Testing Consent Form

I hereby request and authorize the Mount Sinai Genetic Testing Laboratory of the Department of Genetics and Genomic Sciences to determine the chromosome constitution, copy number status, biochemical or molecular status of my unborn fetus.

I, _____, hereby request the following genetic testing:

- Chromosome analysis
- AFP (amniotic fluid)
- Aneuploidy FISH (chromosomes 13, 18, 21, X & Y)
- Microdeletion panel (9 common microdeletion syndromes)
- Array CGH with or without SNP (whole genome chromosome microarray)
- Molecular testing for (disease and gene): _____
- Biochemical testing for (disease and test): _____

On the sample specified below:

- Chorionic Villus Sampling
- Amniotic Fluid
- Other: _____

It has been explained to me and I understand that:

1. An attempt to obtain a viable tissue culture from cells of any particular sample of chorionic villi or amniocytes may be unsuccessful or the chromosome preparation may be of poor quality and unusable, or the biochemical study may be unsuccessful due to technical difficulties. A second prenatal diagnostic procedure or fetal blood sampling, may be offered to provide cells to make the diagnosis.
2. Amniocentesis is available for the verification of chromosomal and/or biochemical and/or molecular test results or for the provision of information to aid in interpretation of results from the CVS studies which might be difficult to interpret, due to factors including placental mosaicism and/or maternal cell contamination.
3. I have received verbal and written information on this testing from my physician or genetic counselor. The nature of chromosome, array CGH (with or without SNP information), biochemical and/or DNA analyses has been explained to me and the accuracy of the test and its limitations have been detailed. I understand that while results obtained from this testing are usually highly accurate, infrequent errors may occur. There is the possibility that the cell culture or direct tissue specimen may not accurately reflect the status of the fetus due to mosaicism or maternal cell contamination. It is also possible that the results of the genetic testing performed may not accurately reflect the status of the fetus due to inherent limitations of the testing performed.

4. In addition, due to insufficient specimen size or cell growth, testing may fail to yield results. The likelihood of this occurring has been estimated to be less than 1%. Additionally, an error in diagnosis may occur if the true biological relationships in the family involved in this study are not as I have stated. My results will be explained to me by a genetic counselor or by my physician who will have the opportunity to discuss my results with a clinical geneticist.
 5. I understand that if the results of this test are normal it is possible that the fetus/baby may still be affected with the disorder/syndrome that was tested for due to other causes than were tested for, or another disorder/syndrome that was not tested for.
 6. I also understand that maternal cell contamination studies will be performed on all specimens that have molecular or biochemical analysis as part of the testing process, which may result in discovery of non-maternity and/or invalidate the test results due to the presence of maternal DNA.
 7. I understand that this testing may yield results that are of unknown clinical significance and that parental blood samples will be tested to better interpret the results. As a result of parental studies, non-maternity and/or non-paternity may be detected. In addition, I understand that I may receive a result for which no clinical information can be provided. I also understand that I may receive a result relating to an adult onset condition or infertility regarding my fetus.
 8. No test will be performed and reported on my fetal sample other than the one(s) authorized by my doctor; and any unused portion of my sample will be discarded within 60 days of completion of the testing. I give consent to have my fetal DNA specimen to be used anonymously by the laboratory for the purposes of quality control or for research related to genetic disease. My sample will be destroyed within 20 years.
- I consent to have my sample used anonymously for research by the laboratory. _____
Initials
9. I have had the opportunity to have all of my questions answered and undertake professional genetic counseling prior to signing the form. I understand that this consent is being obtained in order to protect my right to have all of my questions answered before testing. I also understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information.

 Signature of Person Being Tested / Date

 Witness (Genetic Counselor or Physician) / Date