

Highlighted fields are required.

Name \_\_\_\_\_  
Last First MI

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Male  Female Date of Birth \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Home Phone \_\_\_\_\_ Work Phone \_\_\_\_\_

Social Security Number \_\_\_\_\_

Lab # \_\_\_\_\_ Hospital # \_\_\_\_\_

I attest that this patient has been informed about and has given consent for the test(s) I have ordered below.

Referring Physician/Designee (print): \_\_\_\_\_

Physician/Designee (signature): \_\_\_\_\_

Genetic Counselor (print): \_\_\_\_\_

**Clinical Information/Test Indications and Laboratory Tests Ordered**

Date drawn: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Date sent: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Drawn by: \_\_\_\_\_

Pregnancy:  Yes  No

Date of ultrasound: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ GA on date of US: \_\_\_\_\_ weeks \_\_\_\_\_ days

Date of LMP: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ GA by LMP: \_\_\_\_\_ weeks \_\_\_\_\_ days

**Gestation History**

# of Fetuses:  1  2  >2 (submit separate requisitions)

Gravida \_\_\_\_\_ Para \_\_\_\_\_ SAB \_\_\_\_\_ TAB \_\_\_\_\_

**Specimen Type and Laboratory Test(s) Ordered** (Check one specimen type.)

**Prenatal**

Amniotic Fluid  CVS  PUBS  Other \_\_\_\_\_

Hold cells for \_\_\_\_\_

POC/Fetal Tissue (weeks gestation \_\_\_\_\_ tissue origin \_\_\_\_\_)

Chromosome analysis – see back for bill codes

300  AF-AFP (alpha-fetoprotein) – See Reflex Policy below

330  AChE (acetylcholinesterase) – See Reflex Policy below

105  InSight® (FISH for 13, 18, 21, X and Y)

FISH other than InSight® – specify \_\_\_\_\_

**Indication(s) for Test (check all that apply)**

Advanced maternal age (≥ 35)

Abnormal maternal serum/first trimester screen. Increased risk of:  
 NTD  Down Syndrome  Trisomy 18

Abnormal fetal ultrasound:  CNS \_\_\_\_\_  Other \_\_\_\_\_

Family history of:  Chromosome abnormality – specify \_\_\_\_\_  
 MR  NTD  Other – specify \_\_\_\_\_

Parent has chromosome rearrangement/mosaicism–specify \_\_\_\_\_

Multiple congenital anomalies – specify \_\_\_\_\_

Clinical features of chromosome abnormality – specify \_\_\_\_\_

Failure to thrive

Developmental delay

Mental retardation (MR)

Autism

Multiple SAB (spontaneous abortion)

Parental analysis following abnormal finding in child/fetus  
Specify \_\_\_\_\_

Confirm prenatal analysis – specify \_\_\_\_\_

Clarify abnormal chromosomes – provide results and a copy of the karyotype

Other – provide ICD-9 code and description \_\_\_\_\_

**Postnatal**

Peripheral Blood  Skin Biopsy

500  Array CGH – Postnatal 44K Oligonucleotide Array (Patient's sex required above.)  
Minimum Specimen Requirements: 4 mL blood in EDTA and 4 mL blood in NaHep tubes

Chromosome analysis – see back for bill codes

162  Mosaicism

161  High Resolution

DEB Breakage Study (Chromosomes included)

**FISH**

105  InSight® (FISH for 13, 18, 21, X and Y)

286  Angelman 287  Smith-Magenis

287  Cri-Du-Chat 287  Steroid Sulfatase Deficiency

287  DiGeorge/VCF 287  Williams

287  Kallmann 287  Wolf-Hirschhorn

287  Miller-Dieker

286  Prader-Willi

Other FISH – specify \_\_\_\_\_

Other – specify (call before sending) \_\_\_\_\_

**REFLEX POLICY:** The following will be performed by reflex at an additional charge. AChE when AF-AFP is elevated. Fetal Hemoglobin when AF-AFP is elevated and amniotic fluid is bloody.

**BILLING INFORMATION**

BC/BS  HMO  PPO  Indemnity  Network  Medicaid

Medicare  Medical Group/IPA  Client Bill  CA XAFP  Self-Pay

Billing Information Attached (Please include a copy of insurance card or face sheet.)\*

\*Do not attach credit card information to this form for security purposes.

Insurance Company Name \_\_\_\_\_

Policy # \_\_\_\_\_ Group # \_\_\_\_\_

Relation to Insured:  Self  Spouse  Child  Other \_\_\_\_\_

Patient Signature \_\_\_\_\_

**GENZYME GENETICS INTERNAL USE ONLY**

Non-Medicare Patients: I hereby authorize Genzyme Genetics to furnish my designated insurance carrier the information on this form if necessary for reimbursement. I also authorize benefits to be payable to Genzyme Genetics. I understand that I am responsible for any amounts not paid by insurance for reasons including, but not limited to, non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.

# Informed Consent/Refusal for Genetic Testing

## Genetic Amniocentesis

1. The purpose of amniocentesis is to detect certain birth defects, including most fetal chromosome disorders and neural tube defects. My reason for having amniocentesis is \_\_\_\_\_.
2. Before the amniocentesis is performed I will have an ultrasound examination to help locate the placenta and fetus. Ultrasound may also detect twins, incorrect dating of the pregnancy, and some, but not all, physical defects in the fetus.
3. Amniocentesis involves inserting a needle through the woman's abdomen into the fluid in her uterus. A small amount of fluid (less than one ounce) is taken out. There may be some discomfort when the needle is inserted.
4. There are serious complications in less than 1% of amniocentesis procedures. The most serious complication is miscarriage. Other possible, but rare, serious complications include hemorrhage, infection or injury to the fetus. Minor complications include cramping, vaginal spotting, slight leakage of amniotic fluid, and soreness where the needle was inserted.  
 I have requested early amniocentesis. I have been informed that early amniocentesis (12–15 weeks gestation) may be associated with a slightly higher risk than standard amniocentesis (after 15 weeks gestation) for pregnancy loss, amniotic fluid leakage, and culture failure.
5. Fewer than 1 in 100 amniocenteses need to be repeated because not enough fluid is obtained the first time. Occasionally, even though fluid is obtained, a diagnosis cannot be made, and the amniocentesis needs to be repeated.
6. The standard laboratory testing performed on an amniotic fluid sample is chromosome analysis, which can identify over 99% of chromosomal disorders, and AFP (alpha-fetoprotein) testing, which can identify over 90% of open neural tube defects. Testing for other conditions will not be performed unless indicated in #1 above.
7. Normal test results do not guarantee the birth of a normal child. As in any laboratory test, there is a small possibility of error, and maternal cells may contaminate the sample. In addition, approximately 3–5% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid or by ultrasound examination.
8. In the case of twins or other multiple fetuses, the results may pertain to only one of the fetuses.
9. In the case of abnormal results, the decision to continue or to terminate the pregnancy is entirely mine.
10. My doctor may release my pregnancy outcome or ultrasound and amniocentesis results to Genzyme Genetics to be used for statistical analysis of the laboratory's performance.

## Genetic Testing for Any Sample Type (Blood, Other Tissue, or Amniotic Fluid)

11. The purpose of array CGH is to detect abnormalities that involve gain or loss of chromosome regions including some regions that are too small for traditional cytogenetic testing to detect. My reason for my child or myself having array CGH testing is \_\_\_\_\_.
12. The decision to consent to, or to refuse any procedure/testing is entirely mine.
13. No test(s) will be performed and reported on my sample other than the one(s) authorized by my doctor; and any unused portion of my original sample will be destroyed within 2 months of receipt of the sample by the laboratory.
14. Genzyme Genetics will disclose the test results ONLY to the doctor named below, or to his/her agent, unless otherwise authorized by the patient or required by law.
15. My signature below indicates that I have read, or had read to me, the above information and I understand it. I have had an opportunity to discuss it, including the purposes and possible risks, with my doctor or with someone my doctor has designated. I know that I may obtain professional genetic counseling if I wish, before signing this consent. I have all the information I want, and all my questions have been answered.

**YES:** I REQUEST that Dr. \_\_\_\_\_ perform amniocentesis and/or the genetic testing marked on the reverse side. I understand and accept the consequences of this decision.

\_\_\_\_\_  
Patient (Parent/Guardian) Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witnessed by

**NO:** I DECLINE to have amniocentesis and/or the genetic testing offered to me. I understand and accept the consequences of this decision.

\_\_\_\_\_  
Patient (Parent/Guardian) Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witnessed by

California, Georgia and New York have statutes requiring laboratories to send confidential results of certain genetic tests to state or federal health agencies for monitoring the detection of birth defects.

It is a standard of care for physicians to obtain informed consent for genetic testing. This model consent form is provided by Genzyme Genetics as a courtesy to physicians and their patients. Relevant patient and/or physician educational materials are also available through Genzyme Genetics.

### Bill Codes for Chromosome Analysis

100 Amniotic Fluid

123 PUBS

180 POC/Fetal Tissue

110 CVS

120 Peripheral Blood

183 Skin Biopsy