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PFI# 7955 CLIA#: 33D0982993  
**CLIENT INFORMATION**

**GENETICS REQUISITION**

**PATIENT INFORMATION**

Name LAST FIRST MI  
 Address  
 City State Zip  
 Date of Birth Patient Sex:  Male  Female  
 Home Phone Number Patient Social Security  
 Work Phone Number Patient ID#  
 ICD-9 CODE (Required)

**BILLING / INSURANCE**

**PHOTOCOPY BOTH SIDES OF INSURANCE CARD & ATTACH**

Client Bill:  Yes  No  Primary Insurance  Secondary Insurance  Other  
 Medical Group  HMO  PPO  Hospital  Medicaid (Copy of Card Required)  
 Medicare (Copy of Card Required) Medicare patients MUST REVIEW and SIGN the Advanced Beneficiary Notice for non-covered services.  
 Policy#: \_\_\_\_\_ Group #: \_\_\_\_\_  
 Ins. Company Name: \_\_\_\_\_  
 Claim Address: \_\_\_\_\_  
 City: \_\_\_\_\_  
 State: \_\_\_\_\_ Zip: \_\_\_\_\_  
 Claim Phone: \_\_\_\_\_ Employer #: \_\_\_\_\_  
 Name of Insured: \_\_\_\_\_ D.O.B.: \_\_\_\_\_

**CLINICAL INFORMATION - Mark All That Apply**

Date of Collection: \_\_\_/\_\_\_/\_\_\_ Last Menstrual Period: \_\_\_/\_\_\_/\_\_\_  
 Ethnic Background:  Caucasian  African-American  Asian  
 Hispanic  Other: \_\_\_\_\_  
 Patient Weight: \_\_\_\_\_ lbs.  G / P / Ab: \_\_\_/\_\_\_/\_\_\_  
 Insulin Dependent Diabetes  Vaginal Bleeding with this Pregnancy  
 Is/Was Patient a Smoker - If Yes, Indicate Date Quit: \_\_\_/\_\_\_/\_\_\_  
 IVF Pregnancy  EGG Donor, DOB: \_\_\_/\_\_\_/\_\_\_  
 Previous Pregnancy History of:  ONTD  Down Syndrome  
 Genetic Disorders  Other: \_\_\_\_\_ (Attach Pedigree if Available)

**ULTRASOUND INFORMATION**

Date of CRL: \_\_\_/\_\_\_/\_\_\_ CRL: \_\_\_\_\_ mm (Valid range from 41 - 79 mm)  
 GA at time of CRL Ultrasound: \_\_\_\_\_ Weeks \_\_\_\_\_ Days  
 Date of NT Ultrasound: (if different than CRL US) \_\_\_\_\_ Weeks NT: \_\_\_\_\_ mm  
 GA at time of NT Ultrasound: \_\_\_\_\_ Weeks \_\_\_\_\_ Days  
 Nasal Bone:  present  absent  
 NT Sonographer: \_\_\_\_\_ NTQR#: \_\_\_\_\_ FMF#: \_\_\_\_\_  
 US Reviewer of NT (MD/DO): \_\_\_\_\_ NTQR#: \_\_\_\_\_ FMF#: \_\_\_\_\_  
 If  Multiple Births - # of Fetuses: \_\_\_\_\_ if Twins ( \_\_\_\_\_ Dichorionic \_\_\_\_\_ Monochorionic)  
 2nd CRL (if Twins): \_\_\_\_\_ mm | 2nd NT (if Twins): \_\_\_\_\_ mm | 2nd Nasal Bone:  present  absent

**INDICATIONS FOR TESTING**

Clinical Findings  AMA  Positive Maternal Serum Screen for: \_\_\_\_\_  
 Carrier Analysis (No Family History)  Family History  Clinical Suspicion of Disease  
 Ashkenazi Jewish Ancestry  Other: \_\_\_\_\_

**INFORMED CONSENT FOR RISK ASSESSMENT/GENETIC TESTING**

I have received information regarding the nature of the test(s) noted, either from my healthcare provider or on the back of this form and hereby give my consent to perform this test and further consent that my blood, amniotic fluid and or urine shall be property of LENETIX®, that you may contact me for outcome information and authorize payments of medical benefits to LENETIX® for services described.  
 Patient's Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
 I decline any of the above tests offered to me and understand the consequences of my decision.  
 Patient DECLINE: Signature \_\_\_\_\_ Date: \_\_\_\_\_

\* Your second blood sample should be drawn between  
 \_\_\_\_\_ and \_\_\_\_\_ Date Drawn: \_\_\_\_\_

Treating Physician: \_\_\_\_\_ UPIN#: \_\_\_\_\_

I have reviewed the back of this form and authorize the testing of this specimen for test(s) noted. If the results are abnormal, follow-up will be recommended by the diagnostic center at: \_\_\_\_\_

Physician's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Send Duplicate of Report to: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 City/State/Zip: \_\_\_\_\_  
 Phone/Fax: \_\_\_\_\_ EMAIL: \_\_\_\_\_

**LABORATORY TESTS ORDERED**

**MATERNAL RISK ASSESSMENT**

**FIRST & SECOND TRIMESTER**

Integrated 190\*  Serum Integrated 270\*(no NT)  
 3327  Stage 1: PAPP-A (11 weeks 0 days - 13 weeks 6 days)  
 3325  Stage 2: AFP, total βhCG, uE3, inhibin A (15 weeks 0 days - 22 weeks 6 days)  
 Modified Sequential 30•190\*  Contingent 30•1500•190\*  
 1414  Stage 1: PAPP-A, total βhCG (11 weeks 0 days - 13 weeks 6 days)  
 3325  Stage 2: AFP, total βhCG, uE3, inhibin A (15 weeks 0 days - 22 weeks 6 days)

**FIRST TRIMESTER - (11 weeks 0 days - 13 weeks 6 days)**

1414  Combined (total βhCG, PAPP-A)  
 1414A  Combined Plus (total βhCG, PAPP-A, inhibin A)

**SECOND TRIMESTER - (15 weeks 0 days - 22 weeks 6 days)**

3121  Quad Screen (AFP, total βhCG, uE3, inhibin A)  
 1520  Triple Screen (AFP, total βhCG, uE3)  
 1101  Inhibin A  
 608  AFP (ONTD Only)

**MOLECULAR GENETIC TESTS**

3417  Ashkenazi Jewish Carrier 9 Risk Assessment: Cystic Fibrosis, Tay-Sachs, Canavan Disease, Gaucher Disease, Bloom Syndrome, Niemann-Pick Disease (Type A and Type B), Fanconi Anemia (Group C), Familial Dysautonomia, Mucopolipidosis (Type IV)  
 738  Fanconi Anemia (Group C)  
 2006  Fragile X Syndrome  
 1509  Gaucher Disease  
 318  Glycogen Storage (Type 1A)  
 319  Maple Syrup Urine Disease  
 6410  Mucopolipidosis (Type IV)  
 3127  Niemann-Pick Disease (Type A & B)  
 243  Sickle Cell Anemia  
 2312  SRY, X & Y  
 558  Tay-Sachs DNA (Reflex)  
 2313  Y Chromosome Microdeletion  
 Other: \_\_\_\_\_  
 1278  Bloom Syndrome  
 1508  Canavan Disease  
 1800  CF (5T-Allele)  
 1341  Cystic Fibrosis  
 3135  Familial Dysautonomia  
 1788  Familial Hyperinsulinism  
 1118  Rhd & SRY Genotyping (must be drawn after 15 weeks gestational age)

**CYTOGENETICS**

1655, 3108  Amniotic Fluid Chromosome Analysis (Includes Amniotic Fluid AFP)  
 1118  Chorionic Villus Sampling (CVS)  
 2314  Percutaneous Umbilical Blood Sampling (PUBS)  
 1116  POC/Other Tissue, Specify: \_\_\_\_\_  
 1094  AneuVysion® FISH (Chromosomes 13,18,21,X,Y)  
 684  Peripheral Blood Chromosome Analysis  
 Other: \_\_\_\_\_

**OTHER BIOCHEMICAL TESTS**

556  Tay-Sachs (Enzyme) 0505  Inhibin B  
 3108  Amniotic Fluid AFP 82103  Acetylcholinesterase (AChE)  
 1052  Fetal Fibronectin  
 Scheduled / Routine Visit  Unscheduled Visit  
 Symptomatic Patient  Asymptomatic Patient

**Please check all that apply:**

Uterine Contractions With or Without Pain  Bleeding  
 History of Preterm Delivery in Previous Pregnancy  Patient at Term  
 Uterine or Cervical Abnormalities  Multiple Gestation  
 Repeat fFN Test  Other: \_\_\_\_\_

**REFLEX POLICY:** AChE and HbF are run in cases of elevated AFAP. CFTR Intron 8 poly(T) is run in cases of R117H.

Req-1010808GR



# INFORMED CONSENT FOR RISK ASSESSMENT/GENETIC TESTING

Before signing this consent form, you should discuss risk assessment/genetic testing with your healthcare provider or genetic counselor. I authorize my physician to obtain a sample of my blood, cheek cells or my amniotic fluid or chorionic villus cells for Risk Assessment and/or DNA testing to determine if I am a carrier, my fetus is affected with any of these diseases as noted on the reverse of this form, or to determine if my pregnancy is at increased risk.

- ✧ Bloom Syndrome  
*(A chronic disorder affecting growth and susceptibility to cancer)*
- ✧ Canavan Disease  
*(A fatal neurological disorder)*
- ✧ Cystic Fibrosis  
*(A chronic disorder affecting lungs and digestive tract)*
- ✧ Cystic Fibrosis  
*(5T-Allele)*
- ✧ Familial Dysautonomia  
*(A severe neurological disorder)*
- ✧ Familial Hyperinsulinism\*  
*(A pancreatic disorder leading to fatal low blood sugar in newborns)*
- ✧ Fanconi Anemia Group C  
*(A chronic disorder causing birth defects and increased risk for cancer)*
- ✧ Fragile X Syndrome\*  
*(One of the most common causes of inherited mental retardation)*
- ✧ Gaucher Disease  
*(A chronic disorder affecting bones and blood cells)*
- ✧ Glycogen Storage Disease Type 1A\*  
*(A fatal neurological disorder)*
- ✧ Maple Syrup Urine Disease\*  
*(Metabolic disorder resulting in physical and mental retardation)*
- ✧ Mucopolidosis IV  
*(A fatal neurological disorder)*
- ✧ Niemann-Pick Disease (Type A and B)  
*(A chronic biochemical disorder resulting in mental and physical deterioration)*
- ✧ Sickle Cell Anemia\*  
*(Inherited disorder of the blood caused by abnormal hemoglobin)*
- ✧ SRY, X and Y\*  
*(Rule out ambiguous sexual development and/or male infertility)*
- ✧ Tay-Sachs Disease  
*(A fatal neurological disorder)*
- ✧ Y Chromosome Microdeletion\*  
*(A possible cause of male infertility)*
- ✧ RhD & SRY Genotyping  
*(Rule out maternal and fetal RhD incompatibility, a common cause of hemolytic disease)*
- ✧ Other \_\_\_\_\_

\*Familial Hyperinsulinism, Fragile X, Glycogen Storage Disease Type 1A, Maple Syrup Urine Disease, Sickle Cell Anemia, SRY, X and Y, and Y Chromosome Microdeletion are offered by LENETIX® but are not performed by the technicians at LENETIX® Medical Screening Laboratory. These specific risk assessment/genetic tests are sent out to other laboratories.

- ✧ I understand that a sample of blood will be drawn by venipuncture or cheek cells will be obtained from saliva collected in a sterile container, procedures which carry a negligible risk. In the event that I am having prenatal diagnosis for my fetus, I understand that a specimen of amniotic fluid or chorionic villus cells will be obtained by amniocentesis or chorionic villus sampling respectively, procedures which carry modest risk to the fetus.
- ✧ I understand that if I am Ashkenazi Jewish, and am a carrier of any of the above diseases, the probability of detecting my mutation by molecular methods is 95-98%. If I am not of Ashkenazi Jewish origin, the probability of detecting a mutation is less and depends on my ethnic/racial origin. If I am positive for any of the tests (i.e. I am a carrier) genetic counseling will be offered to me and additional recommendations for testing may be provided.
- ✧ I understand that my result, when negative, will be reported as "negative for all mutations analyzed". The result is reported this way because there remains a small chance that I may be a carrier of an uncommon mutation, as these tests cannot detect all mutations/carriers.
- ✧ I understand that Prenatal Risk Assessment identifies pregnancies that may be at high risk for certain disorders. An unaffected pregnancy may be designated as high risk, and not all affected pregnancies will be identified through this type of testing. Certain diagnostic tests may be offered to me if I am determined to be at high risk.
- ✧ I understand that the testing laboratory has procedures that provide a high level of quality assurance. In rare instances, it may be necessary to obtain another sample in order to determine a result. This will be at no additional cost.
- ✧ I understand that results will be reported to the indicated healthcare provider and if noted, to the additional healthcare provider indicated on the front of this form. I understand that results may only be disclosed to others by my written consent and/or if demanded by an order of a court of competent jurisdiction.
- ✧ My signature constitutes my acknowledgment that I have had the opportunity to have my questions answered by a healthcare provider or genetic counselor, and that I give my authorization and consent for the testing noted on the reverse of this form.
- ✧ I hereby authorize LENETIX® to furnish my designated insurance carrier the information on this form if necessary for reimbursement. I also authorize payment to LENETIX®. I understand that I am responsible for any amount 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. I confirm that I have read and understand the consent information on this form and agree to have the tests noted on the reverse of this form, performed. My signature on front of form allows you to contact my physician's office and/or me for outcome information.

In addition:  I Agree [\_\_\_\_\_]  I Do Not Agree [\_\_\_\_\_]
Initials Initials

to have any remaining specimen left after the completion of these tests, held in a DNA bank for medical research or education. To maintain my privacy, I understand that any remaining material will not have my name attached to it. If I do not agree to have DNA/serum banked for research, remaining material will be destroyed in 60 days. If not noted, then it is hereby understood that I "agree."

Education and Counseling: It is your physician's responsibility to provide you with guidance regarding your test results and how they will affect your health care and/or reproductive plans. LENETIX® is not responsible for providing genetic counseling to patients.

Physician Statement: I, the physician agree that it is my responsibility to personally provide genetic counseling to the patient whose signature appears on this form. If I am unable or unwilling to do so, I will refer the patient to a genetic counseling professional, as appropriate.

LENETIX® provides this consent form for your use or as a template according to New York state regulations. It is the physician's responsibility to obtain informed consent from the patient/guardian. If a signed consent form is not forwarded to the laboratory, according to New York State regulations, it is believed that the physician has obtained consent and that the patient's signature is on file in his/her medical records.

