Integrated GENETICS
LabCorp Specialty Testing Group

PREGNANCY/PRECONCEPTION TEST REQUISITION

PLEASE SUBMIT A SEPARATE REQUISITION FOR EACH PATIENT, INCLUDING TWINS

Highlighted fields are required.

Patient Information

Client Information

Name
Last First MI

☐ Male ☐ Female Date of Birth / /

Address

Home Phone Work Phone

Social Security Number

City State Zip

Lab # Hospital #

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

Physician/Authorized signature:

Referring Physician (print):

Genetic Counselor (print):

NPI#: Taxonomy#:

Date drawn: / / Drawn by:

Pregnant: ☐ Yes ☐ No First pregnancy ☐ Yes ☐ No Date sent: / /

Specimen Type (Check one only):

Parental ☐ Peripheral Blood ☐ Mouthwash ☐ Blood spot card

Fetal ☐ Fetal Blood ☐ Amniotic Fluid ☐ Chorionic Villi ☐ POC

Back-up culture by: ☐ Integrated Genetics ☐ Other _____ Hold for: _____

Ethnicities (Check all that apply):

☐ Caucasian ☐ Ashkenazi Jewish ☐ Sephardic Jewish ☐ Asian ☐ African American

☐ Native American ☐ Hispanic ☐ Other: _____

Single Gene Disorders/Diseases

Ashkenazi Jewish Testing

(may be appropriate for other ethnicities)

☐ Check here for all Ashkenazi Jewish Carrier Tests or check separately (V82.89)

562 ☐ Bloom syndrome*
554 ☐ Canavan disease*
530 ☐ CF*plus*® (97 mutation test)†*
519 ☐ Dihydrolipoamide dehydrogenase deficiency*
207 ☐ Familial dysautonomia*
585 ☐ Familial hyperinsulinism*
534 ☐ Fanconi anemia (Group C)*
595 ☐ Gaucher disease*
522 ☐ Glycogen storage disease type 1a*
501 ☐ Joubert syndrome 2*
518 ☐ Maple syrup urine disease*
573 ☐ Mucolipidosis type IV*
587 ☐ Nemaline myopathy*
557 ☐ Niemann-Pick type A*
593 ☐ Tay-Sachs enzymes and DNA*
350 ☐ Tay-Sachs enzymes only
589 ☐ Usher syndrome type IF*
599 ☐ Usher syndrome type III*
502 ☐ Walker-Warburg syndrome*

Other test:_____

Pan Ethnic Testing

☐ Check here for all Pan Ethnic Carrier Tests or check separately (V82.89)

530 ☐ CF*plus*® (97 mutation test)†*
523 ☐ Fragile X Carrier Screen (no family history, PCR only)†
516 ☐ Spinal muscular atrophy (SMA)* Both parents bloods required for prenatal dx

Other Tests‡

521 ☐ Fragile X Test (symptomatic/family history, PCR and Southern blot)*
528 ☐ Maternal cell contamination*
538 ☐ Poly (T) Testing for CFTR Intron 8
535 ☐ Sickle cell anemia* (prenatal dx only)
574 ☐ Rhc/E analysis (also send parental bloods)*
575 ☐ RhD analysis (also send parental bloods)*
593 ☐ Tay-Sachs DNA (prenatal dx only)*
591 ☐ Y chromosome microdeletions

Thrombophilia‡

549 ☐ Factor II (prothrombin G20210A)
548 ☐ Factor V (Leiden)
526 ☐ MTHFR (C677T)

*Maternal cell contamination analysis required for all prenatal dx (send a maternal sample).

Clinical Information/Single Gene Testing (‡If not checked, screening assumed (V82.89))

Parental: ☐ No family history (V82.89) ☐ Abnormal fetal U/S* (655.83) ☐ Family hx: relative* (655.23)
☐ Known carrier (655.23)* ☐ Thrombophilia* (286.9) ☐ Infertility (M: 606.9, F: 628.9)
☐ Egg donor (V59.70) ☐ Sperm donor: (V59.8) ☐ Congenital absence of vas deferens (752.89)

Fetal: ☐ Abnormal fetal U/S* (655.83) ☐ Family hx: relative* (655.23) ☐ Parent(s) known carrier(s)* (655.23)

*Provide additional information: _____

Maternal Serum/Plasma Screening

240 ☐ Harmony™ Prenatal Test (10w+ for singleton pregnancies)
315 ☐ First*Screen*®* (10w 3d – 13w 6d)
335 ☐ Sequential*Screen*℠*
302 ☐ Integrated*Screen*℠*
302 ☐ Serum Integrated*Screen*℠* (without NT measurement)
325 ☐ AFP4® (15w 0d – 21w 6d)
310 ☐ MSAFP (ONTD only; 15w 0d – 23w 6d)

*Dried blood spot samples acceptable for first trimester only.

Clinical Information for Maternal Serum/Plasma Screening

Gravida: Para: SAB: TAB:
U/S date: / / GA on U/S date: wks days
Sonographer Name: NTQR ID#:
Reading MD NTQR ID#: Practice Location ID#:
NT: mm CRL: mm
NT: mm CRL: mm (Twin, if applicable)
LMP date: / / EDC date: / / by ☐ U/S ☐ LMP ☐ PE ☐ IVF
IVF fertilization date: / / IVF egg donor age (if applicable):
Maternal Weight lbs. # Fetuses: 1 ☐ 2 ☐ >2 ☐ Repeat Screen ☐
Y ☐ N ☐ Patient is Rx-dependent diabetic prior to pregnancy (648.03, 250.00)
☐ insulin (V58.67) ☐ oral hypoglycemics (V58.69)
Y ☐ N ☐ Previous Down syndrome pregnancy/child (655.23)
Y ☐ N ☐ Family hx of NTD (655.23), specify: Relative (V18.9):

Cytogenetics/FISH/Biochem

100 ☐ Amniotic fluid chromosomes
300 ☐ AF-AFP†
330 ☐ Acetylcholinesterase (AChE)
110 ☐ CVS chromosomes
105 ☐ InSight® (FISH for 13, 18, 21, X, Y)
Other_____

287 ☐ DiGeorge/VCF (22q11.2 deletion)
☐ Other FISH:_____
123 ☐ Fetal blood (PUBS) chromosomes
180 ☐ POC chromosomes: GA week: _____
POC tissue type:_____
120 ☐ Blood Chromosomes (parental)

Clinical Information/Test Indications for Cytogenetics/FISH

Gravida: Para: SAB: TAB: # Fetuses: ☐ 1 ☐ 2 ☐ >2
U/S date: / / LMP date: / / GA on U/S date: wks days

☐ AMA (para gravida: 659.53, multigravida: 659.63)
☐ Positive serum screen (655.83): ☐ NTD (655.03) ☐ Down syndrome (655.13) ☐ Trisomy 18 (655.13)
☐ Abnormal fetal U/S (655.83): ☐ CNS* (655.03) ☐ Other* (655.83)
☐ Family history of (655.23): ☐ NTD ☐ Chromosome abnormality* ☐ MR* ☐ Other*
☐ Parental cytogenetics following abnormal prenatal results* (F: 655.13, M; V26.39)
☐ Multiple Spontaneous abortions (SAB):
☐ F (Pregnant: 646.33, Not Pregnant: 629.81) ☐ M (V26.35)

*Provide additional information:_____

†Reflex policy: The following will be performed by reflex at additional charge: AChE when AF-AFP is elevated &/or gestational age is out of range of normative values; Fetal HGB when AF-AFP is elevated and amniotic fluid is bloody; CFTR Intron 8 poly(T) when R117H CF mutation is present; Southern blot analysis when Fragile X PCR shows >54 CGG repeats.

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 _____

INTEGRATED GENETICS INTERNAL USE ONLY

All Patients: I hereby authorize Esoterix Genetic Laboratories, LLC to furnish my designated insurance carrier the information on this form if necessary for reimbursement. I also authorize benefits to be payable to Esoterix Genetic Laboratories, LLC. I understand that I am responsible for any amounts not paid by insurance for reasons including, but not limited to, noncovered and nonauthorized services. I permit a copy of this authorization to be used in place of the original.

Informed Consent/Refusal for Genetic Testing

Maternal Serum/Plasma Screening

1. The purpose of maternal serum/plasma screening is to identify pregnancies that may be at increased risk for open neural tube defects (ONTD), Down syndrome, trisomy 18, or trisomy 13.
2. The screening test I am having is (circle one):
   - Harmony™ Prenatal Test – detects trisomy 21, trisomy 18, and trisomy 13; no information about ONTD
   - FirstScreen® – detects 83% of Down syndrome and 80% of trisomy 18; no information about ONTD
   - SequentialScreen℠ – detects 80% of ONTD, 90.4% of Down syndrome, and 90% of trisomy 18
   - IntegratedScreen℠ – detects 80% of ONTD, 92% of Down syndrome, and 90% of trisomy 18
   - Serum IntegratedScreen℠ – detects 80% of ONTD, 87% of Down syndrome, and 90% of trisomy 18
   - AFP4® – detects 80% of ONTD, 81% of Down syndrome, and 80% of trisomy 18
   - MSAFP – detects 80% of ONTD, no information about Down syndrome or trisomy 18
3. Not all affected fetuses can be detected: some will be missed by any of these screening tests.
4. Some women with normal fetuses will have abnormal screening results.
5. Abnormal screening results may indicate the need for further testing, such as ultrasound and/or CVS or amniocentesis.

DNA Testing

1. The purpose of my DNA test is to determine whether I, or my fetus if fetal testing is ordered, have mutation(s) known to be associated with the following genetic condition or disease:_____.
2. This testing is done on a small sample of blood; in some cases a mouthwash sample can be used. For the fetus, testing is done on amniotic fluid, CVS or fetal blood.
3. Mutations are often different in different populations. I understand that the laboratory needs accurate information about my family history and ethnic background for the most accurate interpretation of the test results.
4. When DNA testing shows a mutation, then the person is a carrier or is affected with the condition or disease tested for. Consulting a doctor or genetic counselor is recommended to learn the full meaning of the results and to learn if the additional testing might be necessary.
5. When the DNA testing does not show a known mutation, the chance that the person is a carrier or is affected is reduced. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
6. In some families, DNA testing might discover non-paternity (someone who is not the real father), or some other previously unknown information about family relationships, such as adoption.

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 I will have an ultrasound 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 1 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. Early amniocentesis (12-15 weeks gestation) may have 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 or further testing might be necessary.
6. The standard testing performed on an amniotic fluid sample is chromosome analysis, which can identify over 99% of chromosomal disorders, and AFP (alpha-fetoprotein) analysis, 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, 3-5% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid or by ultrasound examination.

Additional items of consent/refusal applicable to any of the above screening/testing

1. In the case of twins or other multiple fetuses, the results may pertain to only one of the fetuses.
2. In the case of abnormal diagnostic results, the decision to continue or to terminate the pregnancy is entirely mine.
3. The decision to consent to, or to refuse any of the above procedures/testing is entirely mine.
4. No test(s) will be performed and reported on my sample other than those 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.
5. My doctor may release my pregnancy outcome or ultrasound and amniocentesis results to Esoterix Genetic Laboratories, LLC to be used for statistical analysis of the laboratory's performance.
6. Esoterix Genetic Laboratories, LLC 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.
7. My signature below indicates that I have read, or had read to me, the above information and I understand it. I have also read or had explained to me the specific disease(s) or conditions(s) tested for, and the specific test(s) I am having, including the test descriptions, principles, and limitations. I have had the opportunity to discuss the purposes and possible risks of this testing with my doctor or someone my doctor has designated. I know that genetic counseling is available to me before and after the testing. I have all the information I want and all my questions have been answered.

YES: I REQUEST that Dr./or an associate physican _____ perform amniocentesis and/or the genetic screening or testing marked above. I understand and accept the consequences of this decision.

_____	_____	_____
Patient Signature	Date	Obtained by

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

_____	_____	_____
Patient Signature	Date	Obtained 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 designed to address the requirements of New York State Civil Rights Law Section 79-1 and Massachusetts General Law Chapter 111, Section 70G. Integrated Genetics requires that all reproductive genetic testing sent to any of our laboratories be accompanied by the signed attestation on the front of this Test Requisition Form. Relevant patient educational materials are also available through Integrated Genetics.

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