sequenom

PRENATAL TEST REQUEST FORM

877.821.7266

sequenom.com | Mon–Fri 5 am–5 pm PST
3595 John Hopkins Ct San Diego, CA 92121
CLIA# 05D2015356 | CAP# 7527138

PLACE BARCODED PATIENT ID LABEL HERE

Sample collection date: ____/____/_____

PATIENT INFORMATION AND ACKNOWLEDGMENT & PHYSICIAN ACKNOWLEDGMENT

Last name: _____ First name: _____ DOB: ____/____/_____ Sex: ☐ Male ☐ Female

Street address: _____ City / State / ZIP: _____

Phone: (_____) _____ – _____ Email: _____ MRN (optional): _____

Sequenom Laboratories may use information obtained on this form and other information provided by the patient and/or ordering provider or his/her designee to initiate preauthorization with the patient's health plan as required. Pretest counseling has occurred with the patient in accordance with patient's health plan requirements if applicable. The patient understands a preauthorization approval from their health plan does not guarantee full payment and the patient accepts financial responsibility for any amounts not covered by their health plan. If applicable, patient authorizes Sequenom Laboratories to appeal any coverage denial made by carrier on patient's behalf.

Patient's signature: _____ Date: ____/____/_____ Physician/authorized signature: _____ Date: ____/____/_____

Sequenom Laboratories is required by law to maintain the privacy and security of your protected health information in accordance with its notice of privacy practices (www.sequenom.com/notice-patient-privacy-practices).

CLINICIAN INFORMATION

Sequenom lab account #: _____

Account name: _____

Account address: _____

City / State / ZIP: _____

Ordering physician: _____ NPI #: _____

Phone: (_____) _____ – _____ Fax: (_____) _____ – _____

ADDITIONAL COPY OF RESULTS *(optional)*

Referring clinician: _____ Fax: (_____) _____ – _____

Other clinical recipient: _____ Fax: (_____) _____ – _____

NONINVASIVE PRENATAL TEST (NIPT) MENU – *select only one*

☐ **MaterniT® GENOME**
Genome-wide fetal aneuploidies (singleton only)

OR

MaterniT® 21 PLUS
☐ Core (chr 21, 18, 13, sex)
☐ Core + ESS*
☐ Core + SCA**
☐ Core + ESS + SCA

OR

☐ **VisibiliT®**
Risk assessment for fetal aneuploidies for chromosomes 21 & 18, and fetal sex (singleton only)

* ESS = chr 16, chr 22, and select microdeletions **SCA = sex chromosome aneuploidies

☐ Request patient genetic counseling services for selected test

REQUIRED CLINICAL INFORMATION

Gestational age: _____ weeks _____ days *or* EDD: ____/____/_____

Gestation: ☐ Singleton ☐ Twins ☐ Triplets ☐ Other: _____

Maternal height: _____ ft. _____ in. Maternal weight: _____ lbs.

MEDICAL INDICATION(S) FOR GENETIC TESTING

Diagnosis/signs/symptoms in ICD-CM format in effect at date of service (highest specificity required)

Medical indication for testing

☐ Advanced maternal age (ICD-CM: _____)
☐ Positive serum screening (ICD-CM: _____)
☐ Ultrasound findings indicate increased risk (ICD-CM: _____)
☐ Prior pregnancy with trisomy (ICD-CM: _____)
☐ Parental balanced Robertsonian translocation with increased risk of trisomy (ICD-CM: _____)
☐ Routine screening (MaterniT 21 PLUS or VisibiliT only) (ICD-CM: _____)
☐ Other (ICD-CM: _____)

Preauthorization questions

☐ Cell-free DNA testing previously performed during this pregnancy
☐ A pretest discussion of risks, benefits, alternatives, diagnostic testing and the option of no testing has been held with the patient

COMMENTS

BILLING INFORMATION *Attach copy of both sides of insurance card if applicable*

Bill: ☐ Patient (self pay) ☐ Insurance (direct bill) ☐ Client bill

Policyholder name: _____

Relationship to patient: ☐ Self ☐ Spouse ☐ Child ☐ Other: _____

Policyholder date of birth: ____/____/_____

Insurance company name: _____

Billing address: _____

City / State / ZIP: _____

Policy/Medicaid #: _____ Group #: _____

Authorization #: _____

CARRIER SCREENING TEST MENU – *select only one*

HerediT® UNIVERSAL
Pan-ethnic carrier screen test (see reverse for details)
☐ Complete panel ☐ Standard panel ☐ Jewish ancestry panel

OR

☐ **HerediT® CF**
Cystic fibrosis carrier screen test

☐ Request patient genetic counseling services for selected test

REQUIRED CLINICAL INFORMATION

Ancestry
☐ Ashkenazi Jewish ☐ Other Jewish ☐ East Asian ☐ Southeast Asian
☐ African American ☐ Hispanic ☐ Caucasian ☐ Other: _____

Family history of genetic condition? ☐ Yes (indicate relative and disease):
☐ Sibling ☐ Parent ☐ Grandparent ☐ Aunt / Uncle
☐ Niece / Nephew ☐ Cousin ☐ Other: _____
Relative is: ☐ Affected ☐ Carrier of _____ (genetic disease + mutation if known)

MEDICAL INDICATION(S) FOR GENETIC TESTING

Diagnosis/signs/symptoms in ICD-CM format in effect at date of service (highest specificity required)

☐ Procreative management (ICD-CM: _____)
☐ Pregnancy management (ICD-CM: _____)
☐ Other (ICD-CM: _____)

☐ Partner tested
Partner name: _____ DOB: ____/____/_____ Barcode: _____

DIAGNOSTIC TEST MENU

☐ **NextView® ARRAY** microarray analysis on CVS or amniotic fluid (culturing may be required)
☐ Targeted ☐ Whole genome If array normal, reflex to karyotype? ☐ Yes ☐ No

☐ **NextView Karyotype** on CVS or amniotic fluid (culturing may be required)
If karyotype normal, reflex to array (on cultured cells)?† ☐ Yes ☐ No
If yes: ☐ Targeted ☐ Whole genome

☐ **NextView FISH** rapid detection of abnormalities of chromosomes 13, 18, 21, X, Y

☐ **NextView AF-AFP** amniotic fluid AFP with reflex to AChE

☐ **NextView MCC** maternal cell contamination studies

Gestational age: _____ weeks _____ days ICD-CM code: _____

Gestation: ☐ Singleton ☐ Twins ☐ Triplets ☐ Other: _____

† Reflex testing may result in additional CPT codes/cost.

34-30524R1.0 0117

HEREDIT® UNIVERSAL CARRIER SCREEN PANEL DESCRIPTIONS

Complete panel	Over 250 genetic disorders. Please visit https://www.recombine.com/diseases for a complete list of diseases.
Standard panel	18 genetic disorders recommended by ACOG/ACMG (cystic fibrosis, fragile X, spinal muscular atrophy, α/β thalassemia, sickle cell disease, etc.).
Jewish ancestry panel	Over 50 genetic disorders known to be associated with Ashkenazi, Sephardic, or Mizrahi populations.

ULTRASOUND ANOMALIES

ABDOMEN
Absent stomach
Ascites/anasarca/edema
Diaphragmatic hernia
Dilated stomach
Duodenal obstruction
Gastroschisis
Omphalocele

AMNIOTIC FLUID VOLUME
Oligohydramnios
Polyhydramnios

CENTRAL NERVOUS SYSTEM
Acrania
Agenesis of corpus callosum
Anencephaly
Arnold chiari malformation
Cerebellar hypoplasia
Dandy walker
Dolichocephaly
Holoprosencephaly
Hydrocephalus
Meckel gruber
Mega cisterna magna
Neural tube defect
Spina bifida
Ventriculomegaly

FACE
Absent nasal bone
Cleft lip
Cleft palate
Micrognathia

HEART/LUNG
Abnormal outflow tracts
Aortic valve stenosis
Atrial septal defect (asd)
Cardiomegaly
Chest mass (ccam, sequestration)
Coarctation of aorta
Cystic adenomatous malformation of the lung (CAM)
Dextrocardia
Ebstein anomaly
Endocardial cushion defect/a-v canal
Enlarged atrium
Hypoplastic left heart
Hypoplastic right ventricle
Pentalogy of cantrell
Pericardial effusion
Pleural effusion
Pulmonary valve atresia/stenosis
Tetralogy of fallot
Total anomalous pulmonary venous return
Transposition of the great vessels
Tricuspid regurgitation
Tricuspid valve atresia/stenosis
Truncus arteriosus
Ventricular septal defect (vsd)

KIDNEY/URINARY BLADDER/PELVIS
Absent bladder
Absent kidney
Echogenic kidneys
Enlarged kidneys
Hydronephrosis
Multicystic dysplastic kidneys
Pelvic cysts
Potter syndrome
Renal cysts

NECK
Cystic hygroma
Enlarged nuchal translucency (first trimester)
Enlarged nuchal fold (second trimester)

PLACENTA
Placental anomaly (specify)

SIZE/GROWTH/OVERALL APPEARANCE
Hydrops fetalis
Intrauterine growth retardation (iugr)
Macrosomia

SKELETAL SYSTEM
Arthrogryposis multiplex congenita
Caudal regression
Clinodactyly
Clubfeet
Polydactyly
Scoliosis
Short femurs

MATERNIT® 21 PLUS ORDERING OPTIONS. SEE LIMITATIONS OF TESTS SECTION

The core MaterniT 21 PLUS test includes T21, T18, T13 and fetal sex. Please select desired content on the other side of this form.

SEX CHROMOSOME ANEUPLOIDIES OPTION:
Includes sex chromosome aneuploidies. See list in column to the right.

MICRODELETIONS/ENHANCED SEQUENCING SERIES (ESS) OPTION:
Includes T22, T16, and selected microdeletions (Enhanced Sequencing Series). See list in column to the right.

* Reported as additional findings

MATERNIT 21 PLUS TEST
Trisomy 21 (Down syndrome)
Trisomy 18 (Edwards syndrome)
Trisomy 13 (Patau syndrome)
Fetal sex

SEX CHROMOSOME ANEUPLOIDIES*
45,X (Turner syndrome)
47,XXY (Klinefelter syndrome)
47,XXX (Triple X syndrome)
47,XYY (XYY syndrome)

MICRODELETIONS (ESS)*
22q (DiGeorge syndrome)
5p (Cri-du-chat syndrome)
1p36 deletion syndrome
15q (Angelman/Prader-Willi syndromes)
11q (Jacobsen syndrome)
8q (Langer-Giedion syndrome)
4p (Wolf-Hirschhorn syndrome)
Trisomy 22
Trisomy 16

LIMITATIONS OF THE TESTS

NONINVASIVE PRENATAL TESTS: MATERNIT GENOME, MATERNIT 21 PLUS, VISIBILIT- While the results of these tests are highly accurate, discordant results, including inaccurate fetal sex prediction, may occur due to placental, maternal, or fetal mosaicism or neoplasm; vanishing twin; prior maternal organ transplant; or other causes. These tests are screening tests and not diagnostic; they do not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. A patient with a positive or high risk test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative or low risk test result does not ensure an unaffected pregnancy nor does it exclude the possibility of other chromosomal abnormalities or birth defects which are not a part of these tests. An uninformative result may be reported, the causes of which may include, but are not limited to, insufficient sequencing coverage, noise or artifacts in the region, amplification or sequencing bias, or insufficient fetal fraction. These tests are not intended to identify pregnancies at risk for neural tube defects or ventral wall defects. Testing for whole chromosome abnormalities (including sex chromosomes) and for subchromosomal abnormalities could lead to the potential discovery of both fetal and maternal genomic abnormalities that could have major, minor, or no, clinical significance. Evaluating the significance of a positive or a non-reportable result may involve both invasive testing and additional studies on the mother. Such investigations may lead to a diagnosis of maternal chromosomal or subchromosomal abnormalities, which on occasion may be associated with be nign or malignant maternal neoplasms. These tests may not accurately identify fetal triploidy, balanced rearrangements, or the precise location of subchromosomal duplications or deletions; these may be detected by prenatal diagnosis with CVS or amniocentesis. The ability to report results may be impacted by maternal BMI, maternal weight, maternal systemic lupus erythematosus (SLE) and/or by certain pharmaceutical agents such as low molecular weight heparin (for example: Lovenox®, Xaparin®, Clexane® and Fragmin®). The results of this testing, including the benefits and limitations, should be discussed with a qualified healthcare provider. Pregnancy management decisions, including termination of the pregnancy, should not be based on the results of these tests alone.

CARRIER SCREENS: HEREDIT UNIVERSAL AND CF - While the results of these tests are highly accurate, discordant results may occur due to bone marrow transplantation, blood transfusions or other causes. In some cases, genetic variations other than those being tested may interfere with mutation detection, resulting in false negative or false positive results. These tests do not test for all forms of genetic disease, birth defects, and intellectual disability. All results should be interpreted in the context of family history; additional evaluation may be indicated based on a history of these conditions. Additional testing may be necessary to determine mutation phase in individuals identified to carry more than one mutation in the same gene. All mutations included within the genes assayed may not be detected, and additional testing may be appropriate for some individuals. A patient with a positive test result should be referred for genetic counseling and further evaluation.

INVASIVE TESTS: NextView ARRAY, Karyotype, FISH, AF-AFP, and MCC - Genetic counseling, clinical correlation and parental testing are recommended.

ALL TESTS - The healthcare provider is responsible for the use of this information in the management of their patient.

ADDITIONAL INFORMATION

Sequenom Center for Molecular Medicine, LLC, DBA Sequenom Laboratories, a wholly owned subsidiary of Sequenom, Inc., is a CAP-accredited and Clinical Laboratory Improvement Amendment (CLIA)-certified molecular diagnostics laboratory dedicated to improving patient outcomes by offering revolutionary laboratory-developed tests for a variety of prenatal conditions. Sequenom, Inc. is a wholly owned subsidiary of Laboratory Corporation of America Holdings.