sequenom Laboratories

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RML
REGIONAL MEDICAL LABORATORY
www.RMLOnline.com

PLACE BARCODED PATIENT ID LABEL HERE

PRENATAL TEST REQUISITION FORM

PATIENT INFORMATION

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

Street address: _____ City / State / ZIP: _____

Tel: (_____) _____-_____ SS#: _____ – _____ – _____

BILLING INFORMATION

Bill: ☐ Patient ☐ Patient's insurance *(Attach copy of both sides of insurance card)*

Policy holder name: _____

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

Insurance company:

Company: _____ Authorization #: _____

Billing address: _____

City / State / ZIP: _____

Policy #: _____ Group #: _____

CLINICAL INFORMATION

All tests

Gestational age: Wks: _____ Days: _____

Multiple gestation? ☐ Twins ☐ Triplets ☐ Other: _____

Maternal height: ____ft. ____in. Maternal weight: ____lbs.

OTHER

☐ Opt-Out for subchromosomal copy variants (microdeletions), chromosomes 22 and 16.

SAMPLE COLLECTION

Collection date: _____ / _____ / _____ **# Tubes:** _____

Sample types: ☐ Blood ☐ Buccal ☐ Other: _____

Sample container: ☐ Black/tan top ☐ Purple top ☐ Green top ☐ Other: _____

AUTHORIZATION TO USE LEFTOVER SAMPLE AND TEST DATA

Upon completion of the test, and with my consent, the remaining sample and test data may be "de-identified" and all personal information will be removed. Sequenom Laboratories may use de-identified samples and test data for quality improvement, and/or research studies. My name or other personal identifying information will not be used in or linked to the results of any studies and publications.

☐ **I authorize Sequenom Laboratories** to store and use my de-identified patient sample and test data as described above. Date: _____ / _____ / _____

☐ **I do not authorize Sequenom Laboratories** to store and use my de-identified patient sample and test data as described above. Date: _____ / _____ / _____

Print name of patient: _____

Patient's signature: _____

CLINICIAN INFORMATION

Referring clinician: _____

NPI: _____

Tel: (_____) _____-_____ Fax: (_____) _____-_____

PRENATAL TEST MENU

☐ **MaterniT21™ PLUS for fetal chromosomal abnormalities** *(see reverse for About Test)*

ICD9 Code Required. Increased risk due to *(Check one or more)*:

- ☐ Maternal age: ☐ 659.50 ☐ 659.60 ☐ 659.63 ☐ Other _____
- ☐ Abnormal serum biochemical screening: ☐ 796.5 ☐ Other _____
- ☐ Ultrasound finding: ☐ 655.13 Type: _____
- ☐ Personal or family history ☐ 655.23

REMINDERS

Final check list for each sample shipped

- ✓ Is the Ordering Physician notated on the TRF?
- ✓ Is the Reason for Test indicated on the TRF? (ie. Maternal Age, etc.)
- ✓ Is the correct ICD9 code(s) notated on the TRF?
- ✓ Are all required Clinical Information questions notated on the TRF?
- ✓ Did you include two patient identifiers on the blood tube label?
- ✓ Did you include the Collection Date on the blood tube label?
- ✓ Did you include copies of both sides of the insurance card?

CONSENT ACKNOWLEDGMENT

My health care provider has provided me with information regarding the tests requested on this form and advised me of the availability of professional genetic counseling. I authorize laboratory provider to furnish my insurance/health plan provider with this form, my test results, or other information requested for reimbursement, to appeal any reimbursement denial, and authorize all reimbursements to be paid directly to laboratory provider. I understand that I am responsible for any amount not paid, including amounts for non-covered services. Patient's signature: _____

I certify that the patient has been informed of the benefits, risks, and limitations of the tests requested, informed the patient of the availability of genetic counseling, and have obtained informed consent from the patient for the tests requested. Clinician's signature: _____

ABNORMAL FINDINGS: Fetal Ultrasound, Serum Biochemical Screen, Patient/Family History, Prior NIPT Results

FORM-SQNM-34-30031R1.0

LIMITATIONS OF THE TESTS

DNA test results do not provide a definitive genetic risk in all individuals. The MateriniT21™ PLUS test evaluates fetal genetic material and makes a determination for chromosome 21, 18 and 13 representation and other chromosomal abnormalities, including fetal chromosome 22, 16 and sex aneuploidies, the presence of the Y chromosome, and subchromosomal copy number variants (microdeletions). Cell-free DNA does not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. A patient with a positive test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative test result does not ensure an unaffected pregnancy. The absence of an Additional Finding does not indicate a negative result. While results of this testing are highly accurate, not all chromosomal abnormalities may be detected due to placental, maternal or fetal mosaicism, or other causes. Sex chromosomal aneuploidies are not reportable for multiple gestations.

ADDITIONAL INFORMATION

The MateriniT21™ PLUS and SensiGene® Fetal RHD Genotyping tests are laboratory-developed tests that were validated under Federal CLIA laboratory guidelines by Sequenom Laboratories, a wholly owned subsidiary of Sequenom, Inc.

The HerediT™ Carrier Screening tests are laboratory-developed tests that were validated under Federal CLIA laboratory guidelines. HerediT CF tests are performed by Sequenom Laboratories. HerediT AJP and FX tests are performed by Mt. Sinai Genetic Laboratory, a CLIA certified laboratory. HerediT SMA tests are performed by Quest Laboratories, a CLIA certified laboratory.

The NextView™ prenatal individual options for amniocentesis and CVS analysis are laboratory-developed tests that were validated under Federal CLIA laboratory guidelines by CombiMatrix, a CLIA-certified laboratory. Tests include NextView™ Array for direct microarray analysis (uncultured CVS tissue or amniotic fluid), NextView™ Karyotyping Reflex on CVS or amniotic fluid with reflex to NextView microarray, NextView™ Karyotyping on CVS or amniotic fluid, NextView™ FISH for rapid detection of aneuploidies of chromosomes 13, 18, 21, X, Y, NextView™ AF-AFP amniotic fluid AFP with reflex to AChE, NextView™ MCC: maternal cell contamination studies (for normal female microarray and karyotype results).