8 Enterprise Lane, Oakdale CT-06370
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CT-ST License # CL-0687

Women's Health Molecular Requisition Form

1: PATIENT INFORMATION

PATIENT NAME (LAST) (FIRST) (M.I.)	☐ Male ☐ Female	Electronic Medical Record #	Hospital /Accession#
PATIENT ADDRESS (STREET) CITY STATE ZIP PATIENT PHONE #			Ethnicity (check all that apply) ☐ African-American ☐ Asian ☐ Caucasian/NW European ☐ E. Indian ☐ Hispanic ☐ Jewish-Ashkenazi ☐ Jewish-Sephardic ☐ Mediterranean ☐ Native American ☐ Other:
SOCIAL SECURITY #	BIRTH DATE (MM/DD/YYYY)		
- -	/ /		
Date and Time Collected:	Drawn By:		

Ordering Physician Name & Signature	POLICY HOLDER NAME	POLICY HOLDER DATE OF BIRTH	MEMBER/POLICY # GROUP #
	RELATIONSHIP OF PATIENT TO INSURED ☐ SELF ☐ SPOUSE ☐ DEPENDENT	INSURANCE CO. NAME	
	☐ MEDICARE PRIMARY ☐ MEDICARE SECONDARY		
	MEDICARE/MED. NUMBER	STATE	
Phone **Fax**	MEDICAL ASSISSTANCE NUMBER	STATE	

ICD-10 DIAGNOSIS CODE(S) FOR TESTS ORDERED (MUST BE PROVIDED)

Genetic Counselor	**Dx1**	**Dx2**	**Dx3**	**Dx4**

Medical Necessity Statement: Tests ordered on Medicare patients must follow CMS rules regarding medical necessity and FDA approval guidelines and must include diagnosis, symptoms and reason for testing as indicated in the medical record. If testing does not come under Medicare guidelines for payment a 'signed' Advanced Beneficiary Notice must be included.

2: PRENATAL TEST INFORMATION(Required)
Ultrasound gestation = ---------- Gravida --------- Parity---------- Spontaneous Abortion---------- Therapeutic Abortion ----------

3: TESTS PROVIDED

☐ FRAGILE X SYNDROME SCREENING
☐ CYSTIC FIBROSIS SCREENING
☐ SPINAL MUSCULAR ATROPHY SCREENING

5: SPECIMEN TYPE

☐ PERIPHERAL BLOOD
☐ AMNIOTIC FLUID
☐ CHORIONIC VILLI
☐ PUBS BLOOD
☐ PRODUCT OF CONCEPTION/AUTOPSY
☐ PLACENTA ☐ SKIN ☐ TISSUE
☐ BUCCAL SWAB

4: Reason for Testing

☐ Screening for Genetic Disease Carrier Status (Z31.430, Z31.440, Z13.71)
☐ Consanguinity (Z84.3)
☐ Supervision, normal 1st pregnancy (Z34.00, Z34.01, Z34.02, Z34.03)
☐ Supervision, other normal pregnancy (Z34.80, Z34.81, Z34.82, Z34.83)
☐ Other Genetic carrier status (Z14.8)
☐ High Risk Ethnicity (Z15.89)
☐ Family History of related disorder (Z84.99) Please Describe:

6: HEALTHCARE PROVIDER AUTHORIZATION

I certify that (i) this test is medically necessary, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law and Genesys's Patient Informed Consent. I agree to provide Genesys, or its designee, any and all additional information reasonably required for this testing to be performed.

Signature of Healthcare Provider (Required) _____ Date (Required) _____

7: PATIENT BILLING INFORMATION:

PLEASE INCLUDE A COPY OF THE INSURANCE CARD(S) FOR BILLING PURPOSES.

☐ CLIENT BILL	☐ INSURANCE	☐ MEDICARE/MEDICAID	☐ SELF PAY

8: PATIENT AUTHORIZATION

I understand that I am responsible for providing accurate information about my insurance to Genesys Diagnostics Inc. I understand that Genesys Diagnostics Inc. will be providing testing service and billing my insurance. However, I understand that charges that are not covered by my insurance, including any applicable co-payments and deductibles are my responsibility and I agree to pay such charges promptly.

Signature of Patient/Responsible Party (Required)_____Date (Required)_____

☐ Authorization signature is on file

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Patient Informed Consent

PATIENT CONSENT (Required for New York and Massachusetts Patients)*
By signing this form, I, the patient having the testing performed, or the patient authorized individual acknowledged that: (i) I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits, risks, and limitations of the test to be performed; (ii) I have discussed with the healthcare provider ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for a given disease or condition serves as a predictor of that disease or condition; (iii) I have been informed identifying an appropriate healthcare provider from whom I might obtain such counseling; (iv) I have received and read the Patient Informed Consent in its entirety and realize I may retain a copy for my records; (v) I consent to the use of the leftover specimen and health information as described in the Patient Informed Consent; (vi) I consent to having this test performed and I will discuss the results and appropriate medical management with my healthcare provider.
Signature of Patient (Required) _____ Date(Required)_____

Introduction: This form describes the benefits, risks, and limitations of these screening tests. You should seek genetic counseling prior to undergoing this testing. Read this form carefully before making your decision about testing.

Purpose: The purpose of this test is to screen for mutations or variants associated with Cystic Fibrosis, Fragile X Syndrome and Spinal Muscular Atrophy. Your healthcare provider has determined that this/these test(s) are appropriate for you. Consult your healthcare provider for more information about this/these test(s), including the limitations and risks, performance data, and error rates, descriptions of the mutations and variants, and what the test results may mean to you.

Description:
Cystic Fibrosis- An inherited life threating disorder that damages the lungs and digestive system.
Fragile X- A genetic condition that causes a range of developmental problems including learning disabilities and cognitive impairment.
Spinal Muscular Atrophy- A genetic disorder that affects the control of muscle movement caused by a loss of motor neurons in the spinal cord and the brainstem.

How these Tests Work: These tests screen for specific mutations and variants by looking at the DNA (genetic material) in your blood or buccal samples.

Limitations of the Tests: These are screening tests that only look for specific mutations and variants. This means other mutations or variants may be present and could cause health concerns. Normal test results do not rule out other possible genetic syndromes or other mutations and variants associated with these syndromes. This test, like many tests, has limitations including, false positive and false negative rates. This means that the mutation being tested for, may be present even though it was not really present (this is called a "false negative"); Or that you may receive a positive result for the mutation(s) being tested for, even though it was not really present (this is called a "false positive"). Further testing of the pregnancy and in some cases you, may be needed to confirm your test results which could result in additional expense. We recommend that no irreversible clinical decisions be made based on these screening results alone. Consult your healthcare provider for more information about the limitations of this test, including error rates (false positives and false negatives). Genetic counseling before and after testing is recommended.

Test Procedure: A tube of your blood will be drawn or a buccal swab will be obtained and analyzed.

Physical Risks: Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection.

Discrimination Risks: Genetic information could be used as a basis of discrimination. To address concerns regarding possible health insurance and employment discrimination, some countries, U.S. states and the U.S. government have enacted laws to prohibit genetic discrimination in those circumstances. The laws may not protect against genetic discrimination in other circumstances, such as when applying for life insurance or long-term disability insurance. Talk to your healthcare provider or genetic counselor if you have concerns about genetic discrimination prior to testing.

Pregnancy Outcome Information: Collecting information on your pregnancy after testing is part of a laboratory's standard practice for quality purposes, and is required in several states. As such, Genesys or its designee may contact your healthcare provider to obtain this information.

Incidental Findings: In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations may become evident (called Incidental Findings). Our policy is to NOT REPORT on any Incidental Findings that may be noted in the course of analyzing the test data.

Privacy: We keep test results confidential. Your test results will only be released in connection with the testing service, to your healthcare provider, his or her designee, other healthcare providers involved in your medical care, or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required or authorized by applicable law.

Use of the Information and Leftover Specimens: Pursuant to best practices and clinical laboratory standards leftover de-identified form specimens (unless prohibited by law) as well de-identified genetic and other information learned from your testing may be used by Genesys or others on its behalf for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable law. Leftover specimens from New York State will be destroyed within 60 days.

Research: We may use your leftover specimen and your health information, including genetic information, in an anonymized or de-identified form (unless otherwise allowed by applicable law) for research purposes. Such uses may result in the development of commercial products and services. You will not receive notice of any specific uses and you will not receive any compensation for these uses. All such uses will be compliance with applicable law. This does not apply to leftover specimens collected from New York State.

Test Results: Your test results will be sent to the healthcare provider that ordered the test. Speak with him/her if you would like a copy of the test results. Your healthcare provider is responsible for interpreting the test results and explaining the meaning to you. Genesys does provide genetic counseling services directly to patients.