PRENATAL *XOMEDX®* TEST REQUISITION FORM

GeneDx

All sections on this page are required unless otherwise specified. Important fields are highlighted. Incomplete information could result in a delay of testing.

PATIENT INFORMATION

First Name	**Last Name**	
Fetal Sex (if known): ◯ **Male** ◯ **Female** Fetal Karyotype (if known): _____	**Date of Birth (mm/dd/yy)**	
Email		
Address		
City	State	Zip Code
Primary Phone	Is this fetus deceased? ◯ Yes ◯ No Deceased Date: _____	

SAMPLE INFORMATION

Specimen ID	**Medical Record #**	**Date Sample Collected (mm/dd/yy)**

☐ Chorionic Villi (CV) ☐ Amniotic Fluid ☐ Fetal Blood (PUBS)
☐ Cultured CV ☐ Cultured Amniocytes
☐ Products of Conception (POC), specify tissue: _____
☐ DNA, specify source: _____

Contact GeneDx by email (WESPrenatal@genedx.com) to discuss a case or to inform us that samples will be sent.

PATIENT CONSENT

By signing this form, I acknowledge as the patient or relative being tested that I have read or have had read to me the GeneDx Informed Consent document at the end of this test requisition form, and understand the information regarding molecular genetics testing. I have had the opportunity to ask questions about the testing, the procedure, the risks, and the alternatives. By signing this form, I authorize GeneDx to perform genetic testing as ordered. I understand that, for tests that evaluate data from multiple family members concurrently, test results from these family members may be included in a single comprehensive report that will be made available to all tested individuals and their healthcare providers.

☐ By checking this box, I confirm that I am a New York State resident, and I give permission for GeneDx to retain any remaining sample longer than 60 days after the completion of testing, and to be used as a de-identified sample for test development and improvement, internal validation, quality assurance, and training purposes. Otherwise, New York law requires GeneDx to destroy my sample within 60 days, and it cannot be used for test development studies.

☐ Check this box if you wish to opt out of being contacted for research studies

☐ Check this box if you do not wish to receive ACMG secondary findings (Full Exome Sequencing and Genome Sequencing Tests ONLY; not for *Xpanded®* or Slice tests).

Signature of Patient/Legal Guardian (required)	**Date**
Signature of Relative A/Legal Guardian	**Date**
Signature of Relative B/Legal Guardian	**Date**

FOR COMMERCIAL INSURANCE ONLY:
By entering my preferred contact information below, I give my permission to GeneDx to contact me with an estimate of the patient's financial responsibility for testing. Data rates may apply.

Email (required)*	Mobile Number

*Contact information provided must be for the individual authorizing the genetic testing.

ACCOUNT INFORMATION

GeneDx Account Number	**Account Name**	
Phone	Fax	
Address		
City	State	Zip Code
Ordering Provider Name		**Role/Title**
NPI	Phone Number	

Send Report Via: ☐ Fax ☐ Email ☐ Portal
Fax #/Email: _____

Additional Ordering Provider Name (optional)	**Role/Title**
NPI	

Send Report Via: ☐ Fax ☐ Email ☐ Portal
Fax #/Email: _____

SEND ADDITIONAL REPORT COPIES TO (optional)

Provider Name	GeneDx Acct#
Fax #/Email:	

STATEMENT OF MEDICAL NECESSITY

By submission of this test requisition and accompanying sample(s), I: (i) authorize and direct GeneDx to perform the testing indicated; (ii) certify that the person listed as the ordering provider is authorized by law to order the test(s) requested; (iii) certify that any custom panel and/or ordered test(s) requested on this test requisition form are reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome or disorder; (iv) the test results will determine my patient's medical management and treatment decisions of this patient's condition on this date of service; (v) have obtained this patient's and relatives', when applicable, written informed consent to undergo any genetic testing requested; and (vi) that the full and appropriate diagnosis code(s) are indicated to the highest level of specificity.

Signature of Ordering Provider	**Date**

ICD-10-CM CODES

ICD-10-CM Codes	
Clinical Diagnosis	Age of Onset

PAYMENT OPTIONS *(Select One)*

◯ **INSURANCE BILL**
Select all that apply
☐ Commercial
☐ Medicaid
☐ Medicare
☐ Tricare
☐ CHAMPVA

FOR ALL INSURANCE PROVIDE FRONT AND BACK COPY OF CARD(S)

Patient Status
◯ Hospital outpatient ◯ Hospital inpatient; Date of Discharge: _____
◯ Not a hospital patient

Name of Insurance Carrier	**Insurance ID#:**

Relationship to Insured
◯ Self ◯ Spouse ◯ Child ◯ Other: _____

Policy Holder's Name	Policy Holder's Date of Birth
Referral/Prior Authorization # (please attach)	☐ Hold test for cost estimate and contact patient if estimate is >$250 (commercial insurance only)
Secondary Insurance Type:	

Insurance Carrier	Insurance ID #	Subscriber Name	Date of Birth

Relationship to Insured
◯ Self ◯ Spouse ◯ Child ◯ Other: _____

◯ **PATIENT BILL**
If Patient Bill is selected, I am electing to be treated as a self-pay patient for this testing. I agree that neither GeneDx nor I will submit a claim to my insurance for this testing, if I have insurance. GeneDx will send an invoice to the patient listed above.

Authorized Patient/Guardian Signature

◯ **INSTITUTIONAL BILL**

GeneDx Account #	Place Sticker/Stamp Here
Hospital/Lab Name	

PRENATAL *XOMEDX®* TEST REQUISITION FORM

GeneDx

First Name	Last Name	Date of Birth

CLINICAL EXOME TESTING OPTIONS

TEST CODE	TEST NAME	TEST CODE	TEST NAME
EXPEDITED CLINICAL EXOME *(INSTITUTIONAL OR PATIENT PAY)*			
☐ 959	*XomeDx®* Prenatal Targeted	☐ J499	*XomeDx®* Prenatal Comprehensive
STANDARD CLINICAL EXOME *(INSTITUTIONAL, PATIENT PAY, INSURANCE)*			
☐ TK89a	*XomeDx®* Fetal — Trio	☐ TK89e	*XomeDx®* Fetal — Duo
☐ TK89b	*XomeDx®* Fetal — Proband		

FAMILY MEMBER SAMPLES TO BE INCLUDED IN TESTING

FAMILY MEMBER INFORMATION MUST BE PROVIDED BELOW AND SAMPLES MUST BE RECEIVED WITHIN 3 WEEKS FOR INCLUSION IN THE PROBAND'S TEST. Ordered test codes may require adjusting to appropriately correspond with family member samples received. A change in the ordered test will impact billing, including prior benefits investigations. Family members will not receive a separate report.

Biological Mother	First Name	Last Name	DOB	○ Asymptomatic ○ Symptomatic ○ At GeneDx (Accession #: _____) ○ Not available ○ To be sent within 3 weeks
Biological Father	First Name	Last Name	DOB	○ Asymptomatic ○ Symptomatic ○ At GeneDx (Accession #: _____) ○ Not available ○ To be sent within 3 weeks
Other Biological Relative	Relationship to Proband			
	First Name	Last Name	DOB	○ Asymptomatic ○ Symptomatic ○ At GeneDx (Accession #: _____) ○ Not available ○ To be sent within 3 weeks

REANALYSIS OF *XOMEDX®* TESTING OPTIONS

These test options are only appropriate if the patient previously had a *XomeDx®* test (full exome analysis) at GeneDx. We recommend waiting at least one year from original/prior analysis before ordering a Reanalysis.

TEST CODE	TEST NAME	REASON FOR REANALYSIS
☐ 660	*XomeDx®* First Time Reanalysis (no charge)	Is there new clinical information available?
☐ 947	*XomeDx®* Subsequent Reanalysis (charged)	○ Yes ○ No ○ Other: _____

DID YOU REMEMBER TO...?

- ☐ Label specimen tube appropriately with TWO identifiers
- ☐ Get a signature for medical necessity and patient consent

(Continue to the next page)

ACMG secondary findings, as discussed in the Informed Consent and Authorization Form, are only returned for the patient if an *XomeDx®* test (full exome analysis) is completed.

GeneDx tests are frequently updated and improved based upon the most recent scientific evidence. The test codes, genes, and gene quantities listed on this test requisition are subject to change by GeneDx at any time. The most current test menu, list of genes, and technical limitations included for a specific test panel may be found on our website, genedx.com. Please note that GeneDx reserves the right to modify and upgrade any ordered panel to the version currently listed on our website.

PRENATAL *XOMEDX®* TEST REQUISITION FORM

GeneDx

First Name	Last Name	Date of Birth

CLINICAL INFORMATION (DETAILED MEDICAL RECORDS MUST BE ATTACHED)

☐ IVF Pregnancy ☐ Egg Donor ☐ Sperm Donor Last Menstrual Period (mm/dd/yy): _____

ULTRASOUND INFORMATION/FINDINGS

Date of Ultrasound (mm/dd/yy): _____ GA at time of Ultrasound: _____ Weeks _____ Days

Please check all that apply. This is not a substitute for submitting clinical records.

Pre/Perinatal History
- ☐ Cystic hygroma
- ☐ Diaphragmatic hernia
- ☐ Encephalocele
- ☐ Increased nuchal translucency
- ☐ Intrauterine growth retardation
- ☐ Maternal diabetes mellitus
- ☐ Neural tube defect
- ☐ Nonimmune hydrops fetalis
- ☐ Oligohydramnios
- ☐ Omphalocele
- ☐ Polyhydramnios
- ☐ Increased nuchal fold (_____ mm)

Structural Brain Abnormalities
- ☐ Abnormal myelination
- ☐ Abnormality of periventricular white matter
- ☐ Abnormality of the corpus callosum
- ☐ Arnold Chiari malformation
- ☐ Cerebellar atrophy
- ☐ CNS hypomyelination
- ☐ Cortical dysplasia
- ☐ Cortical tubers
- ☐ Holoprosencephaly
- ☐ Hydrocephalus
- ☐ Lissencephaly
- ☐ Pachygyria
- ☐ Polymicrogyria
- ☐ Ventriculomegaly

Craniofacial/Dysmorphism
- ☐ Cleft lip
- ☐ Cleft palate
- ☐ Macrocephaly
- ☐ Microcephaly

Eye Defects/ Vision
- ☐ Anophthalmia
- ☐ Microphthalmia

Cardiac Findings
- ☐ Atrial septal defect
- ☐ Cardiac rhabdomyoma
- ☐ Heterotaxy
- ☐ Tetralogy of Fallot
- ☐ Ventricular septal defect

Gastrointestinal Findings
- ☐ Congenital diaphragmatic hernia
- ☐ Duodenal stenosis/atresia
- ☐ Gastroschisis
- ☐ Omphalocele

Musculoskeletal Findings
- ☐ Abnormal form of the vertebral bodies
- ☐ Abnormality of the ribs
- ☐ Abnormality of the upper limb
- ☐ Arthrogryposis
- ☐ Bowing of the long bones
- ☐ Ectrodactyly
- ☐ Fractures of the long bones
- ☐ Limb joint contracture
- ☐ Multiple prenatal fractures
- ☐ Polydactyly
- ☐ Scoliosis
- ☐ Small chest circumference
- ☐ Syndactyly
- ☐ Talipes equinovarus
- ☐ Thoracic hypoplasia

Genitourinary Findings
- ☐ Ambiguous genitalia
- ☐ Cystic renal dysplasia
- ☐ Horseshoe kidney
- ☐ Polycystic kidney dysplasia
- ☐ Renal agenesis
- ☐ Umbilical hernia

Attach pedigree and/or include additional clinical information:

_____
_____
_____
_____
_____
_____
_____

OTHER RELEVANT INFORMATION (SUMMARIZE OR ATTACH REPORTS)

- ☐ Chromosomes/FISH: _____
- ☐ Array CGH: _____
- ☐ Fetal echo: _____
- ☐ Fetal MRI/CT: _____
- ☐ Other relevant results (clinical or research): _____
- ☐ Previous relevant pregnancy and/or family history (attach pedigree):

_____
_____

Please choose test(s) and provide clinical information in the appropriate section above. All tests will be performed concurrently unless order of testing is specified.

PRENATAL *XOMEDX®* TEST REQUISITION FORM

GeneDx

First Name	Last Name	Date of Birth

FAMILY HISTORY
***This section is not intended for ordering a targeted variant testing report.**

☐ No Known Family History ☐ Pedigree Attached ☐ Adopted

Relationship	Maternal	Paternal	Relevant History	Age at Dx
1	○	○		
2	○	○		
3	○	○		

PREVIOUS GENETIC TESTING
***This section is not intended for ordering a targeted variant testing report.**

Personal or family history of genetic testing ○ No ○ Yes (If yes, please complete all fields below)

Relation to patient (self, sibling, etc.), Genetic Test(s) and Result (e.g. positive, negative, etc.). If relative was tested at GeneDx, please also provide their accession #:

If patient or relative(s) were found to have a positive or VUS result on prior testing, please provide details below.
Indicate any Variants of Interest‡ via the checkbox below.

Relation (self, sibling, etc.)	Gene	Transcript #	c./p. (SNV) or exon # (CNV)	Build, coordinates (CNV)	Variant of Interest‡?
1					☐
2					☐
3					☐

Required for sequence variants: gene, c./p., transcript #
Required for CNVs: gene, transcript #, exon # OR build, coordinates

Abnormal karyotype, FISH, or other results:

‡ For certain tests, GeneDx **may** be able to specifically comment upon the presence or absence of previously identified variant(s) of interest in the report. Complete variant information must be provided in the table above at the time the test order is placed. If you do not complete the table above and check off that a previously identified variant is a variant of interest, it will not be possible to comment upon the presence or absence of the variant in the report retrospectively. This service is not applicable to targeted variant testing.

INFORMED CONSENT

First Name	Last Name	Date of Birth

For the purposes of this consent, "I", "my", and "your" will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST
The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or pass on a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?
1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.
2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.
3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.
4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. We may disclose this information to the ordering healthcare provider if it likely affects medical care.

Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information GeneDx used to interpret my results. Healthcare providers can contact GeneDx at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?
For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as "trio tests" since they typically include samples from the patient and both parents.

Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that GeneDx will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information about a relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING
1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.
2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.
3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.
4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.
5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING
It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary.

To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

INTERNATIONAL SAMPLES
If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION
After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. GeneDx will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made.

I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and GeneDx will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. GeneDx will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION
De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this deidentified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. GeneDx shares this type of information with healthcare providers, scientists, and healthcare databases. GeneDx will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. GeneDx believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

INFORMED CONSENT

First Name	Last Name	Date of Birth

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

- Applicable only for full exome sequencing and genome sequencing tests
- Does not pertain to *Xpanded*® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called "incidental" or "secondary" and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

WHAT WILL BE REPORTED FOR THE PATIENT?
All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

WHAT WILL BE REPORTED FOR RELATIVES?
The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS
Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified nor reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE
For insurance billing, I understand and authorize GeneDx to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to GeneDx.

I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by GeneDx as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by GeneDx on my behalf, I agree to endorse the insurance check and forward it to GeneDx within 30 days of receipt as payment towards GeneDx's claim for services rendered.

If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by GeneDx. I further understand and agree that, if I fail to make payment for genetic testing, in accordance with the payment policies of GeneDx, my account may be turned over to an external collection agency for non-payment. I agree to pay any associated collection costs, including attorney fees. By my signature on the GeneDx Test Requisition Form or at the bottom of this form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider.

MEDICARE
A completed Advance Beneficiary Notice (ABN) is required for Medicare patients, when applicable. Please visit our website, www.genedx.com/billing for more information.