variantyx

DCVXUTCP7002B

Genomic Unity® Prenatal Analysis Test Requisition Form

Proband	Fetus	Affix barcode label of Proband's (Fetus') sample here
Mother's Name		
Mother's Date of Birth	___ /___ /_____	

Ordering Healthcare Provider

First Name	Last Name	Title	NPI #
Facility Name			Phone
Facility Address			Fax
City	State	Zip Code	Email

Additional Report Recipients

Name	Phone	Fax	Email
Name	Phone	Fax	Email

Healthcare Provider's Statement

By my signature below, I attest that I am the referring physician, an authorized healthcare provider for the patient, or procurator thereof and this testing is medically necessary for diagnosis and/or treatment of the patient. I attest that the patient has been appropriately consented about the test including possible results and outcomes, has been given the opportunity to ask questions about the testing and/ or seek genetic counseling, and agrees to allow an independent genetic counselor facilitated through a third party, DNAVisit, to provide pre-test and/or post-test genetic counseling, if required by the insurer and/or referring institution. I attest that the patient (or guardian) has voluntarily consented to testing performed by Variantyx for diagnostic purposes through both oral and written consent.

Healthcare provider signature _____ **Date** _____

Billing Information

○ Insurance Billing

Insurance Company	Policy #	Group #
Policy Holder First Name	Policy Holder Last Name	Policy Holder DOB ___ /___ /_____
What is the Policy Holder's Relationship?	Policy Holder's Employer	
Employer's Address		

○ Institutional Billing	○ Patient Payment
An invoice will be sent to the institution listed above. Please contact us for alternate billing.	An invoice will be sent to the patient email provided. Insurance will not be billed.

Mother's Information

First Name	Last Name	MI	Date of Birth ___ /___ /_____
Address			ID / MR#
City	State	Zip Code	Ethnicity ○ African/African American ○ Latino ○ Ashkenazi Jewish ○ East Asian ○ Other: ○ European ○ South Asian _____
Phone	Email		
Sample Type ○ Blood	Collection Date* ___ /___ /_____		

Medical History

*Note that the collection date is not the same as the date of service for test billing purposes. For more information, please see CMS guidelines.

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Mother's Name		
Mother's Date of Birth	___ /___ /_____	

Father's Information

First Name	Last Name	MI	Date of Birth ___ /___ /_____
Address			ID / MR#
City	State	Zip Code	Ethnicity ○ African/African American ○ Latino ○ Ashkenazi Jewish ○ East Asian ○ Other: ○ European ○ South Asian _____
Phone	Email		
Sample Type ○ Blood	Collection Date* ___ /___ /_____		

Medical History

Pregnancy Details

Sample Type ○ Amniotic fluid ○ Cultured cells ○ Genomic DNA

Collection Date* ___ /___ /_____

Age of Pregnancy (Weeks) at Specimen Delivery _____

Expected Delivery Date ___ /___ /_____

Fetus Gender ○ Male ○ Female

Twin Pregnancy? ○ Yes ○ No

Sperm Donation? ○ Yes ○ No

Egg Donation? ○ Yes ○ No If Yes, Donor Age _____

Obstetric History

Any previous miscarriages? ○ Yes ○ No If Yes, How Many? _____

Any previous stillbirths? ○ Yes ○ No If Yes, How Many? _____

Abnormal Genetic Findings in Previous Pregnancies

Cause for Referral – Please attach detailed genetic counseling summary letter and family tree

Abnormal Findings in Pregnancy

Expected Inheritance ○ Autosomal dominant ○ Autosomal recessive ○ X-linked ○ Mitochondrial ○ De novo ○ Other _____

Is there known consanguinity between the parents? ○ Yes ○ No If yes, what is the degree of consanguinity? _____

Has Fragile X (FRAX) carrier testing been performed? ○ Yes ○ No If yes, what was the number of repeats? _____

Is either parent a carrier for a known genetic disease or chromosomal abnormality? ○ Yes ○ No If yes, please describe:

Known medical conditions / genetic disorders / birth defects in the family (please specify the affected relative):

Additional testing performed

Has either parent received a blood transfusion in the past 30 days? ○ Yes ○ No If yes, who? _____

Has either parent received a bone marrow transplant? ○ Yes ○ No If yes, who? _____

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Genomic Unity® Prenatal Analysis
Test Requisition Form

Proband	Fetus	Affix barcode label of Proband's (Fetus') sample here
Mother's Name		
Mother's Date of Birth	___ / ___ / _____	

Please specify the ultrasound findings and the fetus' phenotypes.
ICD-10 codes must be specified here and/or in attached clinical notes.

Clinical Information

ICD-10 Code(s)*

Ultrasound Information / Findings

Date of Ultrasound ___ / ___ / _____

GA at Time of Ultrasound ___ Weeks ___ Days

Date of Last Menstrual Period ___ / ___ / _____

Fetus Phenotypes

		Phenotype
Primary Indication	○	Abnormal NIPT result
	○	Abnormal serum screen
	○	Increased NT/cystic hygroma
	○	Advanced maternal age
	○	Fetal abnormality
Growth	○	Hydrops
	○	IUGR
	○	Macrosomia
	○	Molar pregnancy
	○	Oligohydramnios
	○	Placental abnormality
	○	Polyhydramnios
	○	Single umbilical artery / 2 vessel cord
	○	Other:
Neurological	○	Abnormal gyri / Lissencephaly
	○	Agenesis of the corpus callosum
	○	Cerebellar hypoplasia
	○	Choroid plexus cyst(s)
	○	Dandy Walker (posterior fossa abnormality)
	○	Decreased fetal movement
	○	Holoprosencephaly
	○	Open neural tube defect (ONTD)
	○	- Anencephaly
	○	- Spina bifida
	○	Structural brain anomaly
	○	Ventriculomegaly / hydrocephaly
	○	Other:
Craniofacial	○	Cleft lip and/or cleft palate
	○	Hypertelorism
	○	Hypotelorism
	○	Macrocephaly
	○	Microcephaly
	○	Micrognathia
	○	Pierre Robin sequence
	○	Hypogonadism
	○	Other:
Pulmonary	○	CCAM
	○	Diaphragmatic hernia
	○	Eventration of diaphragm
	○	Pleural effusion
	○	Pulmonary sequestration
	○	Small thoracic cavity

		Phenotype
Gastrointestinal	○	Anal atresia
	○	Absent stomach
	○	Duodenal atresia (double bubble sign)
	○	Echogenic bowel
	○	Gastroschisis
	○	Omphalocele
	○	Tracheoesophageal fistula
	○	Other:
Cardiac	○	Aortic atresia
	○	Atrial septal defect (ASD)
	○	AV canal defect
	○	Coarctation of aorta
	○	Ebstein anomaly
	○	Echogenic intracardiac focus
	○	Hypoplastic left heart
	○	Hypoplastic right heart
	○	Pericardial effusion
	○	Pulmonary atresia
	○	Tetralogy of Fallot
	○	Transportation of the great vessels
	○	Truncus arteriosus
	○	Ventricular septal defect (VSD)
Genitourinary	○	Ambiguous genitalia
	○	Hydronephrosis
	○	Megacystis
	○	Pyelectasis
	○	Polycystic kidneys
	○	Renal agenesis
	○	Urethral / ureteral obstruction
Musculoskeletal	○	Contractures (arthrogryposis)
	○	Club foot
	○	Limb anomaly (lower)
	○	Limb anomaly (upper)
	○	Polydactyly (feet)
	○	Polydactyly (hands)
	○	Rocker-bottom feet
	○	Scoliosis
	○	Shortened long bones
	○	Skeletal dysplasia
	○	Syndactyly (feet)
	○	Syndactyly (hands)
	○	Vertebral anomaly

Other

Proband	Fetus	Affix barcode label of Proband's (Fetus') sample here
Mother's Name		
Mother's Date of Birth	___ /___ /_____	

Informed Consent

Consent

I have read the Test Information section on pages 5 and 6 of this document. I have discussed Genomic Unity® Prenatal Analysis test with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my fetus' prenatal DNA and perform genetic testing as described.

2. I give permission for my fetus' prenatal anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my fetus' prenatal anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. In the case of direct insurance billing: I acknowledge that the information provided by me is true and correct. I authorize my healthcare provider and/or insurer to share medical information with Variantyx related to my condition, diagnosis and treatment as relevant to my genetic testing, as well as information about my healthcare plan benefits. I authorize Variantyx to release my medical information concerning my testing to my insurer. I authorize Variantyx to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that Variantyx will notify me if my out of pocket costs are determined to exceed $100. I authorize my insurance benefits to be paid directly to Variantyx. I understand that I am responsible for sending Variantyx any and all of the money that I receive directly from my insurer in payment for this test.

5. In the case that independent pre-test and/or post-test genetic counseling is required by my insurance provider and/or physician, I agree, by signing this consent form, to have DNAVisit, a third party, facilitate the genetic counseling services. By signing this consent form, I authorize Variantyx to release my contact information and any medical information necessary to DNAVisit, as well as authorize communication and sharing of information between DNAVisit and my referring physician, in order to complete pre-test and/or post-test genetic counseling. Information about DNAVisit is available at https://www.dnavisit.com/.

6. For NY state residents : ◯ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Mother's first name _____ **Last name** _____

Mother's signature _____ **Date** _____

Proband	Fetus
Mother's Name	
Mother's Date of Birth	___ /___ /_____

Affix barcode label of Proband's (Fetus') sample here

Informed Consent

Test Information

Background

The Genomic Unity® Prenatal Analysis utilizes whole genome sequencing technology for reading the DNA sequence of a fetus from an amniotic fluid sample and its biological parents. The purpose of the test is to identify variants in the fetus' DNA sequence that correlate with prenatal findings and/or are predicted to result in severe, early onset genetic disorders. This test focuses on a set of genes (listed below) that are known to be disease causing. The types of genetic changes identified in the test are small sequence changes (single nucleotide variants and deletion/insertions), structural variants in chromosomes (deletions, duplications, copy number changes, aneuploidy), and short tandem repeat (STR) expansions. Structural variants are considered genome-wide and are not limited to those overlapping the gene list. Identified genetic changes are subject to the test limitations as described herein after.

Test Process

The referring medical provider will coordinate collection of the amniotic fluid sample and the parental blood samples. The collected amniotic fluid sample will be shipped to and cultured by the Center for Human Genetics (CHG). Fetal DNA, derived from cultured embryonic cells, will be extracted and undergo quality control by CHG including determination of maternal cell contamination (MCC). Extracted fetal DNA will be shipped to Variantyx and its affiliates for sequencing and interpretation. Parental blood samples will be shipped separately to Variantyx and its affiliates for DNA extraction and sequencing. The test is offered as a "trio" test, which compares the fetus's DNA sequence to its biological parents' samples. A report with the test results will be delivered to the referring clinician and it is their responsibility to provide post testing genetic counseling and follow-up, if necessary. In certain cases, confirmatory testing may be required to verify the test results obtained, and may take several weeks to complete.

Possible Test Results

This test will report genetic variants with evidence in the medical literature reported to be disease-causing, or that are computationally predicted to be disease-causing, and are classified as likely pathogenic or pathogenic in accordance with the ACMG (American College of Medical Genetics and Genomics) classification guidelines, in the genes and regions tested (see section 5). Variants of uncertain clinical significance (VUS) will not be reported with this test, except in cases of abnormal findings or medical history strongly correlated with the provided clinical symptoms of the fetus, the pregnancy and/or the family history.

If there are abnormal findings in the pregnancy, interpretation will be done with reference to the provided personal medical and family history, therefore, it is important to provide accurate and complete medical notes.

Parental samples are used as reference for the fetus' test interpretation only. Parental inheritance will be listed for variants reported in the fetus, but no specific reports are issued in the parent's name. Findings in parents alone will not be reported, and therefore this test is not intended to identify diseases or carrier status in parents. However, positive findings in the fetus may disclose parental genotype, or reveal a risk to a parent.

Fetal sex is calculated from the sequencing data and displayed in the analysis report.

This test will not report variants related to infertility, carrier status of autosomal recessive disease, carrier status of X-linked recessive diseases, variants that increase statistical risk for a disease (including but not limited to cancer), variants for late-onset conditions (including but not limited to cancer, neurological diseases, etc.) and variants associated with low penetrance diseases. Variants are not confirmed unless stated and confirmations are not part of the test turn-around time. Secondary findings as defined by the ACMG are not reported. Additional testing may be recommended to assist in the clinical correlation of results.

Single Nucleotide Variants (SNVs)

Single nucleotide variants and small delins (<35 bp) are reported in the genes in this test if they are pathogenic/likely pathogenic, or VUS if there is correlation to the clinical findings and/or family history.

Structural Variants (SVs)

Structural Variants (deletions, duplications, copy number changes, aneuploidy) are reported if pathogenic/likely pathogenic and/or if there is clinical correlation to the clinical findings and/or family history with the genes contained within the structural region. Pathogenic/likely pathogenic structural variants are reported if they are predicted to result in disease in the neonatal or juvenile period.

Short Tandem Repeats (STRs)

Genes with short tandem repeat expansions reported in this test: DMPK, FMR1, FXN, AR. Short tandem repeats in the FMR1, DMPK, and FXN genes will be reported if the repeat is in a range associated with juvenile onset.

Technical Limitations

This test requires high-quality DNA derived from cultured amniotic fluid cells and from parental blood. In some cases, an additional sample may be needed if the volume, quality and/or condition of the initial sample is not adequate. It may be necessary to repeat the test or parts of it, and therefore the duration of the test may be longer than expected.

Maternal cell contamination (MCC) will be determined and may influence the confidence of the results or the ability to proceed with testing. In the case of a sample failing the CHG evaluation of MCC but still passing the Variantyx QC, testing will proceed but may lead to an indeterminate result. In the case of a sample failing the Variantyx QC, testing will not proceed and an additional sample will be requested, extending the turnaround time.

Due to the time sensitive nature of the test, in the event that a parent is not a biological parent, mosaicism is discovered in one of the parents, or one of the parent's DNA has low quality, the assay will be processed without the parent and the report will contain only positive or likely positive results (i.e. no variants of uncertain clinical significance).

Variantyx is not responsible for specimen errors (e.g. labeling, extraction) of samples received that may have occurred prior to our receipt.

With the exception of the genome-wide structural variant analysis, this test is intended to detect variants in the genetic sequence only in the genes listed in the "List of Genes" section hereinafter found below. Mitochondrial variants are not considered by this test.

Not all the targeted regions are completely covered, and each individual may have slightly different coverage yield distributions within the genome. The *HBA2, NEB, CBS* and *PRODH* genes are not fully covered and therefore there may be false negative results in these genes. Variants are not reported if they are not uniquely mappable, are of low coverage or are otherwise determined to be of low quality. This test will not report variants related to infertility, carrier status of autosomal recessive disease, carrier status of X-linked recessive diseases, variants that increase statistical risk for a disease (including but not limited to cancer). This test will only report variants that correlate with prenatal findings and/or predicted to result in severe, early onset genetic disorders.

Proband	Fetus	Affix barcode label of Proband's (Fetus') sample here
Mother's Name		
Mother's Date of Birth	___ /___ /_____	

Informed Consent

Test Information

While most variant types are detectable, some genetic aberrations, such as gross genomic rearrangements or variants in portions of genes with highly homologous pseudogenes, are identified with a lower efficiency. In addition, this test is not intended to detect other aberrations in the genome, such as, but not limited to, mosaicism, gene expression, epigenetic modifications, fusion, chromosome conformational changes, skewed X-inactivation and variants in regions homologous to pseudogenes, X-linked recessive variants in females who manifest disease due to skewed X-inactivation and other unknown abnormalities.

All next generation sequencing (NGS) technologies, including whole genome sequencing analysis, may generate false positive and false negative results. Deletions and duplications 50bp to 300bp in size may be detected with reduced sensitivity, particularly in repetitive regions. Mosaic aneuploidy is detectable at levels above 15%, however, the occurrence of both trisomy and monosomy for the same chromosome may not be detected. Variants are not reported if they are not uniquely mappable, are of low coverage or are otherwise determined to be of low quality. The test sensitivity, specificity, accuracy and PPV for different variant types are available upon request.

Special conditions such as bone marrow transplant, blood transfusion, and variants that exist in only a small number of cells (mosaicism) may prevent the identification of genetic variants. There are rare situations where, due to technical problems and / or other limitations, conclusive results cannot be reached.

The interpretation of the test relies on medical literature available in public databases used by Variantyx, Variantyx internal databases, and the software version available at the time of testing. Not all pathogenic variants are documented and the interpretation is subject to human error. Non-concordant parental samples might limit the ability to accurately and timely interpret the test results. A negative test result does not exclude the existence of a genetic disease.

Sample Retention

DNA extracted from submitted samples will be stored for at least 3 months following completion of the testing and may be anonymized and used for research or discarded thereafter. The raw data files containing the DNA sequences (BAM files) can be transferred to the tested individuals at no additional charge, upon request, for a minimum of two years.

Cultured amniocytes may be maintained for up to two weeks following the completion of testing. During this limited time period, cultures may be made available to the clinician, upon written request, for confirmatory testing such as chromosome analysis and/or fluorescence in situ hybridization (FISH).

List of Genes

AAAS, ABCA12, ABCB11, ABCC6, ABCC8, ABCC9, ABCD1, ACAD8, ACAD9, ACADM, ACADS, ACADSB, ACADVL, ACAT1, ACOX1, ACSF3, ACTA1, ACTB, ACTG1, ADA, ADAMTS2, ADGRG1, AFF2, AGA, AGL, AGPS, AGXT, AHCY, AHI1, AIRE, ALDH3A2, ALDH5A1, ALDH7A1, ALDOB, ALG6, ALMS1, ALPL, ALX4, AMER1, AMN, AMPD2, AMT, ANO5, ANOS1, APOPT1/COA8, AQP2, AR, ARG1, ARL13B, ARL3, ARMC9, ARSA, ARSB, ARSE, ARX, ASL, ASNS, ASPA, ASPM, ASS1, ATM, ATP5A1/ATP5F1A, ATP6V0A2, ATP6V1B1, ATP7A, ATP7B, ATR, ATRX, B3GALNT2, B4GAT1, B9D1, B9D2, BBS1, BBS10, BBS12, BBS2, BCKDHA, BCKDHB, BCS1L, BLM, BMP1, BMPR2, BRAF, BSND, BTD, BTK, C5ORF42/CPLANE1, CACNA1C, CANT1, CAPN3, CASK, CBL, CBS, CC2D2A, CDH23, CDKL5, CDKN1C, CECR1, CEP104, CEP120, CEP290, CEP41, CERKL, CFC1, CFTR, CHD2, CHD7, CHM, CHMP1A, CHRNA1, CHRNB1, CHRND, CHRNE, CHRNG, CHST3, CIITA/MHC2TA, CIT, CLCN5, CLN3, CLN5, CLN6, CLN8, CLRN1, CNGB3, CNTN1, CNTNAP1, CNTNAP2, COL11A1, COL11A2, COL17A1, COL1A1, COL1A2, COL27A1, COL2A1, COL4A3, COL4A4, COL4A5, COL6A1, COL6A2, COL6A3, COL7A1, COMP, COX10, COX15, COX20, COX6B1, CPS1, CPT1A, CPT2, CRB1, CREBBP, CRTAP, CSPP1, CTNNB1, CTNS, CTSD, CTSK, CUL4B, CYBA, CYBB, CYP11A1, CYP11B1, CYP11B2, CYP17A1, CYP19A1, CYP27A1, CYP27B1, DAG1, DBT, DCLRE1C, DCX, DHCR7, DHDDS, DHH, DKC1, DLD, DLG3, DLL3, DMD, DMPK, DMXL2, DNAH5, DNAI1, DNAI2, DNM2, DOK7, DUOX2, DYM, DYNC2H1, DYRK1A, DYSF, EBP, ECEL1, EDA, EDNRB, EGR2, EHMT1, EIF2AK3, EIF2B5, ELN, EMD, ENG, EP300, ERCC2, ERCC3, ERCC4, ERCC5, ERCC6, ERCC8, ESCO2, ETFA, ETFB, ETFDH, ETHE1, EVC, EVC2, EXOSC3, EXT1, EXT2, EYA1, EYS, F11, F2, F8, F9, FAH, FAM149B1, FAM161A, FANCA, FANCB, FANCC, FANCD2, FANCG, FBN1, FGD1, FGD4, FGF8, FGFR1, FGFR2, FGFR3, FH, FIG4, FKBP10, FKRP, FKTN, FLNA, FLNB, FMR1, FOXC1, FOXC2, FOXF1, FOXG1, FOXH1, FOXP2, FOXP3, FOXRED1, FXN, FZD4, G6PC, G6PD, GAA, GABRB3, GABRD, GALC, GALE, GALK1, GALNS, GALT, GAMT, GATA3, GATA4, GATA6, GBA, GBE1, GCDH, GCH1, GDAP1, GDF1, GDF5, GDI1, GFM1, GH1, GJA1, GJA8, GJB1, GJB2, GJB3, GJB6, GK, GLA, GLB1, GLDC, GLE1, GLI2, GLI3, GMPPB, GNAS, GNE, GNMT, GNPAT, GNPTAB, GNPTG, GNS, GORAB, GP1BA, GP9, GPC3, GPC6, GRHPR, GRIA3, GRIP1, GUCY2C, GUCY2D, GUSB, H19, HADH, HADHA, HADHB, HAX1, HBA1, HBA2, HBB, HCCS, HCFC1, HDAC8, HEXA, HEXB, HFE2/HJV, HGD, HGSNAT, HK1, HLCS, HMGCL, HMOX1, HNF1B, HOGA1, HOXD13, HPD, HPRT1, HPS1, HPS3, HPS4, HPSE2, HRAS, HSD17B10, HSD17B3, HSD17B4, HSD3B2, HSPG2, HUWE1, HYLS1, IDS, IDUA, IFITM5, IFT172, IGF1R, IGF2, IGF2R, IGHMBP2, IKBKAP/ELP1, IKBKG, IL1RAPL1, IL2RG, INPP5E, INPPL1, INSR, IRF6, ISPD, ITGA7, ITGB3, ITGB4, IVD, JAG1, JAK3, KATNB1, KCNJ1, KCNJ11, KCNJ2, KCNK9, KCNQ1, KCNQ1OT1, KDM5C, KDM6A, KIAA0556/KATNIP, KIAA0586, KIAA2022/NEXMIF, KIF7, KLHL40, KMT2D, KRAS, L1CAM, LAMA2, LAMA3, LAMB1, LAMB3, LAMC2, LAMP2, LARGE1/LARGE, LBR, LCA5, LDLR, LDLRAP1, LEMD3, LGI4, LHX3, LIFR, LIPA, LMBRD1, LMNA, LMOD3, LMX1B, LOXHD1, LPL, LRPPRC, LSS, LYRM7, LYST, MAGEL2, MAN2B1, MAOA, MAP2K1, MAP2K2, MAT1A, MCCC1, MCCC2, MCEE, MCOLN1, MECP2, MED12, MED13L, MED17, MEFV, MEN1, MESP2, MFN2, MFSD8, MID1, MID2, MITF, MKRN3, MKS1, MLC1, MLYCD, MMAA, MMAB, MMACHC, MMADHC, MOCS1, MPI, MPL, MPV17, MPZ, MRE11A, MSX1, MTFMT, MTHFR, MTM1, MTR, MTRR, MTTP, MUSK, MUT/MMUT, MVK, MYBPC1, MYCN, MYH3, MYH7, MYO15A, MYO7A, NAGLU, NAGS, NBN, NCF1, NDE1, NDN, NDP, NDRG1, NDUFA1, NDUFA10, NDUFA12, NDUFA6, NDUFA9, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFAF6, NDUFB11, NDUFB8, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, NEB, NEK1, NEU1, NF1, NF2, NIPBL, NKX2-5, NOTCH1, NPC1, NPC2, NPHP1, NPHP3, NPHS1, NPHS2, NR0B1, NR2E3, NR5A1, NRAS, NRXN1, NSD1, NTRK1, NUBPL, OAT, OCA2, OCRL, OFD1, OPA3, OPHN1, OTC, OTX2, P3H1, PAFAH1B1, PAH, PANK2, PAX3, PAX6, PAX8, PC, PCBD1, PCCA, PCCB, PCDH15, PDHA1, PDHB, PEPD, PET100, PEX1, PEX10, PEX12, PEX13, PEX14, PEX16, PEX19, PEX2, PEX26, PEX3, PEX5, PEX6, PEX7, PFKM, PHF21A, PHF6, PHGDH, PHOX2B, PIBF1, PIEZO2, PIGN, PITX2, PKD1, PKD2, PKHD1, PLA2G6, PLEC/PLEC1, PLOD2, PLP1, PMM2, PMP22, PNPO, POLG, POLR1C, POLR1D, POMGNT1, POMGNT2, POMT1, POMT2, POP1, POR, PORCN, PPIB, PPT1, PQBP1, PREPL, PRODH, PROP1, PRPS1, PSAP, PSAT1, PTCH1, PTEN, PTPN11, PTS, PUS1, PYGM, QDPR, RAB23, RAD21, RAF1, RAG2, RAI1, RAPSN, RARS2, RB1, RBM10, RBM8A, RDH12, RELN, RET, RIPK4, RIT1, RLBP1, RMRP, RNASEH2A, RNASEH2B, RNASEH2C, ROR2, RP2, RPE65, RPGRIP1L, RPL10, RPS19, RPS6KA3, RS1, RTEL1, RUNX2, RYR1, SACS, SALL1, SALL4, SAMD9, SAMHD1, SATB2, SBDS, SBF2, SCN1A, SCN5A, SCO1, SDHA, SDHAF1, SDHD, SEPN1/SELENON, SEPSECS, SERAC1, SERPINA1, SERPINH1, SGCA, SGCB, SGCD, SGCE, SGCG, SGSH, SH2D1A, SH3TC2, SHANK3, SHH, SHOC2, SHOX, SHROOM4, SIL1, SIX1, SIX3, SIX5, SIX6, SKI, SLC12A1, SLC12A3, SLC12A6, SLC16A2, SLC17A5, SLC19A2, SLC19A3, SLC22A5, SLC25A12, SLC25A13, SLC25A15, SLC25A20, SLC25A24, SLC25A4, SLC26A2, SLC26A3, SLC26A4, SLC2A1, SLC35A3, SLC35D1, SLC37A4, SLC39A4, SLC3A1, SLC45A2, SLC4A11, SLC5A5, SLC6A8, SLC7A7, SLC7A9, SLC9A6, SMAD4, SMARCAL1, SMC1A, SMC3, SMN1, SMN2, SMPD1, SMS, SNRPN, SNTA1, SOS1, SOST, SOX10, SOX2, SOX3, SOX9, SPRED1, SRD5A2, SRPX2, SRY, ST3GAL5, STAR, SUCLA2, SUFU, SUMF1, SUOX, SURF1, SUZ12, SYN1, TAT, TAZ, TBCE, TBX1, TBX5, TCAP, TCF4, TCIRG1, TCN2, TCOF1, TCTN1, TCTN2, TCTN3, TECPR2, TERT, TG, TGFBR1, TGFBR2, TGIF1, TGM1, TH, THRA, TIMM8A, TMEM107, TMEM126B, TMEM138, TMEM216, TMEM231, TMEM237, TMEM38B, TMEM5/RXYLT1, TMEM63A, TMEM67, TMEM70, TNNC1, TNNI2, TNNI3, TNNT1, TNNT2, TNNT3, TNXB, TP53, TP63, TPM1, TPM2, TPM3, TPO, TPP1, TREX1, TRIM32, TRIM37, TRIP11, TRMU, TRPS1, TRPV4, TSC1, TSC2, TSEN54, TSFM, TSHB, TSHR, TTC19, TTC21B, TTC37, TTN, TTPA, TUBA1A, TUBB2B, TUBB3, TWIST1, TYMP, TYR, TYRP1, UBE3A, UGT1A1, UNC13D, UPF3B, USH1C, USH1G, USH2A, VHL, VLDLR, VPS13A, VPS13B, VPS45, VPS53, VRK1, VSX2, VWF, WAS, WDR34, WDR35, WDR62, WISP3, WNT10A, WNT7A, WRN, WT1, XIAP, XPA, XPC, ZC4H2, ZDHHC9, ZEB2, ZFPM2, ZFYVE26, ZIC1, ZIC2, ZIC3, ZMPSTE24

Proband	Fetus	Affix barcode label of Mother's sample here
Mother's Name		
Mother's Date of Birth	___ /___ /_____	

The biological mother's signature is required in the consent section below.

Biological Mother Consent

I have discussed Genomic Unity® Prenatal Analysis test with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing for the purpose of improving the interpretation of genetic variants identified in the fetus' prenatal DNA.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. For NY state residents : ○ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Biological mother's first name _____ **Last name** _____

Biological mother's signature _____ **Date** _____

Proband	Fetus	Affix barcode label of Father's sample here
Mother's Name		
Mother's Date of Birth	___ /___ /_____	

The biological father's signature is required in the consent section below.

Biological Father Consent

I have discussed Genomic Unity® Prenatal Analysis test with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing for the purpose of improving the interpretation of genetic variants identified in the fetus' prenatal DNA.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. For NY state residents : ○ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Biological father's first name _____ **Last name** _____

Biological father's signature _____ **Date** _____