Cytogenomix
Affordable Genomics For All

ISO 15189 CERTIFIED Laboratory

CYTOGENOMIX Sdn Bhd
(202101042245/1442545-M)
1-STOP CENTRE MIDLANDS PARK 3RD FLOOR
488D-3-15, JALAN BURMA, 10350 PENANG, MALAYSIA

Cytogenetics Requisition Consent and Requisition Form

CGx#

Patient Information *(or affix label here)*

Name			Gender	☐ Male	☐ Female
NIC/ Passport #			Medical Record #		
Date of Birth	(DD/MM/YYYY)	Newborn DOB (if relevant)	Date	(DD/MM/YYYY)	
Ethnicity	☐ Malay ☐ Chinese ☐ Indian ☐ Caucasian ☐ Others: *(please specify)*				
Address					

Specimen Type

Whole Blood (3-mL Sodium Heparin Green Top)	Whole Blood (3-mL EDTA purple top)	**Prenatal Sample**	Gestation Age	Weeks	Days
Note: Blood should not be sent from patients who have had a recent blood transfusion or bone marrow transplantation.		Maternal Cell Contamination testing using EDTA blood sample is mandatory for any molecular test using AF/CVS/POC/Cord Blood			
DNA [1000ng (20µLx 50ng)] Microarray only	Cord Blood	☐ Amniotic Fluid (20-mL)	☐ Foetal Blood	☐ Cultured amniocytes (2xT25 Flasks)	
Paraffin-embedded tissue slices (5 µm slices, >10 scrolls) Microarray only	Lymph node in Trasport Media	☐ CVS (~10mg) in Trasport Media	☐ POC in Transport Media		

Indications

☐ Abnormal NIPT | High risk for

☐ Abnormal maternal Screen |

☐ Autosomal Trisomies | Downs/Patau/Edward/Other syndromes

☐ Sex Chromosome Abnormalities | Turner/ Klinefelter/XXX/XYY Syndrome

☐ Fetal structural anomaly |

Additional Clinical Notes If Required

Perinatal History
☐ Not evaluated
☐ Within normal limits
☐ Prematurity
☐ IUGR (Unexplained)
☐ Oligohydramnios
☐ Polyhydramnios
☐ Feotal demise
☐ Fetal structural anomaly
☐ Other:

Reproductive
☐ Not evaluated
☐ Within normal limits
☐ Infertility
☐ Azo/oligospermia
☐ Recurrent Miscarriages (≥3)
☐ Unbalanced translocation carrier
☐ Premature Ovarian Failure
☐ Non-hydatidiform Mole

Growth
☐ Not evaluated
☐ Within normal limits
☐ Failure to thrive
☐ Overgrowth
☐ Short stature
☐ Other:

Development
☐ Not evaluated
☐ Within normal limits
☐ Developmental delay
☐ Fine motor delay
☐ Gross motor delay
☐ Speech delay
☐ Other:

Cognitive
☐ Not evaluated
☐ Within normal limits
☐ Learning disability
☐ Intellectual disability
☐ List IQ/DQ, if known:
☐ Other:

Behavioral
☐ Not evaluated
☐ Within normal limits
☐ Asperger syndrome features
☐ Autism spectrum
☐ Oppositional defiant disorder
☐ Obsessive compulsive disorder
☐ Pervasive developmental delay
☐ Other:

Neurological
☐ Not evaluated
☐ Within normal limits
☐ Ataxia/dystonia / chorea
☐ Hypotonia
☐ Neural tube defect
☐ Seizures
☐ Spasticity
☐ Cerebral palsy
☐ Structural brain anomaly
☐ Other:

Ear Defects
☐ Not evaluated
☐ Within normal limits
☐ Deafness
☐ Preauricular:
☐ Pit ☐ Skin Tag
☐ Low-set ears
☐ Outer ear abnormality
☐ Inner ear abnormality

Cardiac
☐ Not evaluated
☐ Within normal limits
☐ ASD
☐ AV canal defect
☐ Coarctation of aorta
☐ Hypoplastic left heart
☐ Tetralogy of Fallot
☐ VSD
☐ Other:

Craniofacial
☐ Not evaluated
☐ Within normal limits
☐ Cleft lip +/- cleft palate
☐ Cleft palate alone
☐ Coloboma
☐ Craniosynostosis
☐ Dysmorphic facial features
☐ Ear malformation
☐ Retrognathia
☐ Micrognathia
☐ Macrocephaly
☐ Microcephaly
☐ List HC, if known:
☐ Other:

Cutaneous
☐ Not evaluated
☐ Within normal limits
☐ Hyperpigmentation
☐ Hypopigmentation

Musculoskeletal
☐ Not evaluated
☐ Within normal limits
☐ Arachnodactyly
☐ Contractures
☐ Club foot
☐ Diaphragmatic hernia
☐ Limb anomaly
☐ Polydactyly
☐ Scoliosis
☐ Syndactyly
☐ Vertebral anomaly
☐ Kyphosis
☐ Other:

Gastrointestinal
☐ Not evaluated
☐ Within normal limits
☐ Gastroschisis
☐ Hirschsprung disease
☐ Omphalocele
☐ Pyloric stenosis
☐ Tracheoesophageal fistula
☐ Other:

Genitourinary
☐ Not evaluated
☐ Within normal limits
☐ Ambiguous genitalia
☐ Hydronephrosis
☐ Hypospadias
☐ Kidney malformation
☐ Undescended testis
☐ Urethra/ureter obstruction
☐ Other:

Family History
☐ Not evaluated
☐ No relevant family history
☐ Parents with ≥ two miscarriages
☐ Other relatives with similar clinical history (explain above)

Laboratory
☐ Elevated liver enzymes
☐ ↑ Creatine kinase history
☐ Diagnostic muscle biopsy (if yes, specific findings below)

Tests	
	Karyotyping (constitutional) by G Banding (Blood in Sodium Heparin Tube – GreenCap, **OR** Amniotic fluid/CVS in Falcon tube)
	Karyotyping with Reflexes to Microarray
	Rapid Aneuploidy Test - Chr.13, 18, 21, X, Y (PCR-CE)
	Low Pass Whole Genome Sequencing for Aneuploidy (Resolution up to 6-MB) - (by NGS)
	Bone Marrow Karyotyping (Na Heparin Tube – Green Cap)
	Karyotyping POC by NGS (Next Generation Sequencing)
	Maternal Cell Contamination (MCC): Amniotic fluid & CVS samples or Maternal Engraftment (ME), cord blood
	Fanconi Anaemia, Chromosome Breakage Analysis, Blood
	Ataxia Telangiectasia, Chromosome Breakage Analysis, Blood
	Microarray 750K SNP – Blood* (Detects deletions and duplications up to 200kb in size.)
	Microarray 750K SNP – Amniotic Fluid* (Detects deletions and duplications up to 200kb in size.)
	Microarray 750K SNP – POC (Detects deletions and duplications up to 200kb in size.)
	Microarray family Study Parental Testing for abnormal foetal SNP results (VUS, Likely pathogenic or pathogenic): Maternal Samples Paternal Sample
	Positive family Member information Positive Results _____

*Chromosomal microarray testing should be the first-line laboratory investigation for patients with developmental delay, intellectual disability, autism, multiple congenital anomalies or dysmorphic features.

Microdeletion/Microduplication Syndromes	
	17q21.31 microduplication syndrome – MLPA
	1p36 deletion Syndrome (MLPA)
	22q11.2 microduplication syndrome – MLPA
	2p16.1-p15 microdeletion syndrome (MLPA)
	2q23.1 microdeletion/microduplication syndrome– MLPA
	3q29 microdeletion/microduplication syndrome – MLPA
	9q22.3 microdeletion syndrome – MLPA
	Cri-du-Chat syndrome (del 5p15.2)– MLPA
	DiGeorge/Velocardiofacial Syndrome Type I (Del 22q11.2) - MLPA
	DiGeorge/Velocardiofacial Syndrome Type II (10p)
	Distal 22q11.2 deletion syndrome – MLPA
	Glass syndrome (MLPA)
	Koolen-de Vries syndrome – MLPA
	Langer-Giedion syndrome (Del 8q24) – MLPA
	Lissencephaly-1 – MLPA
	MECP2 duplication syndrome – MLPA
	Miller-Dieker syndrome (17p13.3) – MLPA
	NF1 microdeletion syndrome – MLPA
	Phelan-McDermid syndrome – MLPA
	Potocki-Lupski syndrome (dup 17p11.2) – MLPA
	Rett syndrome – MLPA
	Rubinstein-Taybi syndrome – MLPA
	Smith-Magenis syndrome (del 17p11.2) – MLPA
	Sotos syndrome
	Witteveen-Kolk / 15q24 microdeletion syndrome – MLPA
	Wolf-Hirschhorn syndrome (del 4p16.3)– MLPA

Imprinting Errors (CNV + Methylation specific testing)	
	Beckwith-Wiedemann syndrome (BWS); Russell-Silver syndrome (RSS)
	Angelman syndrome (del 15q11.2)– MLPA
	Prader-Willi syndrome (del 15q11q13) – MLPA
	Multi-Locus Imprinting Disorders; Chr 6q24, 8q24, 7, 11p15.5, 14q32, 15q11q13, 15q11.2, 16p13.3, 19q13.43, 20q13, 20

Informed Consent and Statement of Medical Necessity

I have supplied information to the patient/guardian regarding genetic testing and the patient/guardian has given consent for genetic testing to be performed. I further confirm that this test is medically necessary for the diagnosis or to rule out a disease, illness, impairment, symptom, syndrome or disorder, and the results will be used in medical management and treatment decisions for the patient requested herein.

Doctor's Name:	Doctor's Signature:	Date:

Informed Consent and Statement of Medical Necessity

General Information About Genetic Testing

What is genetic testing? DNA provides instructions for our body's growth and development. Genes are distinct sequences of DNA, and are arranged on chromosomes. The DNA in a gene contains instructions for making proteins, which determine things like growth and metabolism as well as traits like eye colour and blood type. Genetic disorders are caused by certain changes in DNA affecting the structure or number of chromosomes. Genetic testing is a laboratory test that tries to identify these changes in chromosomes or the DNA. Genetic testing can be a diagnostic test, which is used to identify or rule out a specific genetic condition. Genetic screening tests are used to assess the chance for a person to develop or have a child with a genetic condition. Genetic screening tests are not typically diagnostic, and results may require additional testing. The purpose of this test is to see if I, or my child, may have a genetic variant or chromosome rearrangement causing a genetic disorder or to determine the chance that I, or my child, will develop or pass on a genetic disorder in the future. 'My child' can also mean my unborn child, for the purposes of this consent. If I/my child already knows the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I will inform the laboratory of this information.

What could I learn from this genetic test?

The following describes the possible results from the test:

Positive: A positive result indicates that a genetic variant has been identified that explains the cause of my/my child's genetic disorder or indicates that I/my child is at increased risk to develop the disorder in the future.

Negative: A negative result indicates that no disease-causing genetic variant was identified by the test performed. It does not guarantee that I/my child will be healthy or free from genetic disorders or medical conditions.

Inconclusive/Variant of Uncertain Significance (VUS): A finding of a variant of uncertain significance indicates that a genetic change was detected, but it is currently unknown whether that change is associated with a genetic disorder either now or in the future. A variant of uncertain significance is not the same as a positive result and does not clarify whether I/my child is at increased risk to develop a genetic disorder. The change could be a normal genetic variant, or it could be disease-causing.

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 tell me about the risk for another genetic condition I/my child is not aware of, or it may indicate differences in the number or rearrangement of sex chromosomes. This information may be disclosed to the ordering health care provider if it is likely to impact medical care. Result interpretation is based on currently available information in medical literature, research, and scientific databases. Because literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may replace or add to the information Cytogenomix used to interpret my/my child's results.

What are the risks and limitations of this genetic test?

Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. 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.

Accurate interpretation of test results may require knowing the true biological relationships in a family. Failing to accurately state the biological relationships in my/my child's family may result in incorrect interpretation of results, incorrect diagnoses, and/or inconclusive test results. In some cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. This includes non-paternity (the stated father of an individual is not the biological father) and consanguinity (the parents of an individual are related by blood). It may be necessary to report these findings to the health care provider who ordered the test.

Genetic testing is highly accurate. Rarely, inaccurate results may occur for various reasons. These reasons include, but are not limited to: mislabelled samples, inaccurate reporting of clinical/medical information, rare technical errors, or unusual circumstances such as bone marrow transplantation, or the presence of change(s) in such a small percentage of cells that the change(s) may not be detectable by the test (mosaicism). This test does not have the ability to detect all of the long-term medical risks that I/my child might experience. The result of this test does not guarantee my health or the health of my child/foetus. Other diagnostic tests may still need to be done, especially when only a genetic screening test has been performed previously.

Occasionally, an additional sample may be needed if the initial specimen is not adequate.

Patient Confidentiality and Genetic Counselling

It is recommended that I receive genetic counselling before and after having this genetic test. Further testing or additional consultations with a health care provider may be necessary. To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to me, to other health care providers involved in my/my child's diagnosis and treatment, or to others as entitled by law.

Specimen Retention

After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.

I understand that samples will be retained for at least 12 months after test completion. No tests other than those authorized shall be performed on the biological sample.

Any research that results in medical advances, including new products, tests or discoveries, may have potential commercial value and may be developed and owned by Cytogenomix Sdn Bhd.

Patient's Name	Signature	Date

Reset Form