CONSENT FORM

PRENATAL CHROMOSOME MICROARRAY ANALYSIS	ACCOUNT NO. NRIC NO. NAME ADDRESS BIRTH DATE/RACE DATE AND TIME OF ADMISSION

What is Chromosome Microarray Analysis (CMA)?

Chromosomes are structures in each of our body's cells that carry genetic information (DNA) telling the body how to develop and function. They come in pairs with one from each parent. Cytogenetic (chromosome) testing can detect if there is too much (gain) or too little (loss) of chromosomes or pieces of chromosomes. Changes in the number or structure of chromosomes may cause an increased risk of birth defects, developmental delay, behavioural problems or intellectual disability.

Karyotyping or conventional chromosomal analysis means looking at the chromosomes under a microscope to detect loss, gain or rearrangement if the change is large enough to be seen. Smaller changes however may be missed.

CMA is an advanced technology that allows detection of these smaller or sub microscopic alterations which can still disrupt growth and development of the foetus and the child.

Why do you need this test and what are its limitations?

You may be offered prenatal CMA if there are abnormal ultrasound findings in your pregnancy, abnormal first trimester screening results, or if there are some other high-risk indications for the test. Common high-risk indications include:

1. Abnormally thick nuchal translucency (NT)
2. Presence of fetal structural abnormalities
3. High risk results from first trimester screening for aneuploidy
4. Others (please specify): _____

_____

The results may provide important information that can be used to guide medical decisions and/ or future reproductive decisions.

Although CMA is a very sensitive test, it only detects changes in the number of DNA copies. It cannot detect many other conditions in which there is a change or a mutation in a gene but the number of DNA copies remains the same. It will also not detect changes that occur in parts of chromosomes not included in the microarray.

What does it involve?

A sample is obtained via amniocentesis (sampling of amniotic fluid), chorionic villus sampling (sampling of tissue from placenta) or cordocentesis (sampling of umbilical cord blood) for CMA. A separate consent will be taken for these procedures and your doctor will discuss which sampling method is most appropriate.

Sometimes blood samples from parents or other family members, may be requested to determine if additional DNA copies (also known as copy number variations) detected is/are inherited from the parents or is/are present in the fetus only. This will help towards interpretation of results.

What precautions must you take for this test?

Please inform your doctor of the following as it could affect the accuracy of the results:

1. If you have received bone marrow transplant or recent blood transfusion.
2. If the pregnancy is a result of egg, sperm or embryo donation.
3. If you or your partner are closely related biologically.

What are the possible results?

1. A gain or loss in chromosomal material is identified and this gain or loss is known to cause problems such as birth defects or disabilities.
   (i) Some gains or losses can cause diseases that vary from mild to severe. It may not be possible to predict the resultant clinical features in a particular individual.
   (ii) Some gains or losses may not affect health in the womb or in childhood but may result in disease in adult life. A parent may also be identified to be at risk of developing disease in adult life. These results may have medical and psychological implications and some families may find it difficult to deal with these results.
   (iii) Further fetal or parental samples may be required in some circumstances to conduct further tests to better understand an unusual result.
2. A gain or loss in chromosomal material is identified, but this gain or loss is known to *not* cause problems.
3. A gain or loss in chromosomal material is identified, but it is not known whether it can cause problems (“variants of uncertain significance”)
4. No gains or losses detected. A “normal” prenatal CMA report (no clinically significant CNVs detected) does not exclude all genetic conditions in the fetus being tested. It also does not guarantee that the fetus being tested will be healthy or will not develop diseases later in life.

What are the concerns of the test?

1. The interpretation of the test results is based on the necessary clinical information which the laboratory has access to, as at the date of issuance of the report.
2. All genetic tests have limitations. False negative and false positive results, though rare, may occur.
3. Additional material may be required if the sample collected is insufficient, damaged in handling or not viable.

4. Genetic testing of parents may reveal unexpected information about yourself, your fetus or your family. For example, the test may reveal non-paternity, the use of an egg or sperm donor or that the parents are closely related biologically.
5. Genetic test results may result in some forms of discrimination (insurance, employment or others) as they form part of your medical record and may be accessed by and/or disclosed to a third party who has obtained necessary consent or when such access is otherwise allowed or required by law.
6. The test results may reveal incidental findings not related to the original indication for the test. Please discuss this further with your clinician.

What will happen to your test results and sample once the test is complete?

Due to the complexity of the test, your results will be explained to you by your ordering clinician, genetic counsellor or suitably qualified and appointed healthcare professional at your next appointment / at a suitable appointment.

After testing is completed, the unused sample may be destroyed or anonymised, stored and used for laboratory internal validation, quality control and process development. When anonymised, any results obtained cannot be traced to the original source and no further results will be reported. In all instances, the sample will be handled according to laboratory retention and storage policy. No other tests other than those authorised will be performed. Your information and records will be maintained according to the hospital's standard policies on medical confidentiality

What are your options?

1. You may choose not to do any testing and carry on the natural course of the pregnancy.
2. You may choose to do the test but can withdraw from the test any time before completion of the test. You can do so by requesting your ordering clinician to inform the laboratory but you will be charged for the full cost of the test.
3. Decide not to be informed nor act on the result regardless of what it may be even after the test is completed.

Others (to be filled by Healthcare Professional) [if applicable]

Part I – Patient's Declaration

1. I, _____ (NRIC/Passport No. _____) have read this information sheet and/or had the information explained to me (and translated in the relevant language/dialect, if necessary) and confirm that I understand the nature, purpose, concerns, and limitations with regard to **Prenatal Chromosome Microarray Analysis**. ("Test")
2. I agree and give permission for my clinical details, sample(s) or derivatives, and any personal data set out in the accompanying test order form to be used by my ordering clinician and/or the Hospital for performing the test and any necessary follow-up actions.
3. I acknowledge that the concerns listed are not intended to be exhaustive. I have had an opportunity to ask for more information about (i) the above-mentioned concerns; (ii) the concerns in general; and (iii) specific concern(s) of relevance to me during pre-test genetic counselling.
4. I hereby consent to the Test.
5. I consent to any other treatment and monitoring procedures deemed necessary; and further or alternative procedural measures as may be found to be necessary during the course of the Test.
6. I consent to the administration of local anaesthesia, the use of drugs and medicines as may be deemed advisable or necessary for this Test.
7. I acknowledge that the SingHealth institution (where the Test is performed) may collect, use and/or disclose my photographs, video and audio recordings ("Recordings") for the purposes of medical care, education and quality assurance, in accordance with the SingHealth Data Protection Policy (available at https://www.singhealth.com.sg/pdpa or via hard copies on request). If the Recordings are to be used for any other purposes, a separate consent will be obtained from me if required by applicable laws.
8. I acknowledge that the Test will be performed by the appropriate SingHealth institution and I will be registered as a patient of that SingHealth institution.
9. I acknowledge that no representation has been made to me that the Test will be performed by any particular Healthcare Professional.

_____ _____

(Signature/**[*Left/Right]** Thumbprint of Patient) (Date of Signing)

*** Please delete accordingly**

Part II – Parent's / Legal Guardian's / Donee's / Deputy's Declaration (herein referred to as the "Authorised Person") (if applicable)

1. I, _____ (NRIC/Passport No. _____), the

   ***Parent / Legal Guardian / Donee / Deputy** of _____

   (NRIC/Passport No. _____) ("Patient"), have read this information sheet and/or had the information explained to me (and translated in the relevant language/dialect, if necessary) and confirm that I understand the nature, purpose, concerns, and limitation with regard to **Prenatal Chromosome Microarray Analysis**. ("Test")

2. I agree and give permission for the Patient's clinical details, sample(s) or derivatives, and any personal data set out in the accompanying test order form to be used by the Patient's ordering clinician and/or the Hospital for performing the test and any necessary follow-up actions.

3. I acknowledge that the concerns listed are not intended to be exhaustive. I have had an opportunity to ask for more information about (i) the above-mentioned concerns; (ii) the concerns in general; and (iii) specific concern(s) of relevance to me during the pre-test genetic counselling.

4. I hereby consent for the Patient to undergo the Test.

5. I consent to any other treatment and monitoring procedures deemed necessary; and further or alternative procedural measures as may be found to be necessary during the course of the Test.

6. I consent to the administration of local anaesthesia, the use of drugs and medicines as may be deemed advisable or necessary for this Test.

7. I acknowledge that the SingHealth institution (where the Test is performed) may collect, use and/or disclose my photographs, video and audio recordings ("Recordings") for the purposes of medical care, education and quality assurance, in accordance with the SingHealth Data Protection Policy (available at https://www.singhealth.com.sg/pdpa or via hard copies on request). If the Recordings are to be used for any other purposes, a separate consent will be obtained from me if required by applicable laws.

8. I acknowledge that the Test will be performed by the appropriate SingHealth institution and I will be registered as a patient of that SingHealth institution.

9. I acknowledge that no representation has been made to me that the Test will be performed by any particular Healthcare Professional.

_____ _____

(Signature/**[*Left/Right]** Thumbprint of Patient) (Date of Signing)

*** Please delete accordingly**

Part III – Healthcare Professional's Declaration

I confirm that I have explained to the Patient, or the Authorised Person (if applicable), the Patient's medical condition as well as the nature, purpose, concerns, and limitations with regard to the test and have addressed queries of the Patient, or the Authorised Person (if applicable).

_____ _____

(Signature, Full name, and Professional Registration/*Employee No. of Healthcare Professional)

(Date of Signing)

**Only for those without professional registration number*

Part IV – Interpreter's Declaration (if applicable)

I, _____confirm that I have interpreted to the Patient, or the Authorised Person (if applicable), the Healthcare Professional's explanation of the Patient's medical condition, nature, purpose, concerns, and limitations with regard to the test and the Healthcare Professional's response to the Patient's, or the Authorised Person's (if applicable), queries in _____ (language / dialect).

_____ _____

(Signature of Interpreter)

(Date of Signing)