SOFIVA Array Test Consent Form

SOFIVA GENOMICS www.sofivagenomics.com T: +886-2-23826615	☐ **SOFIVA Array v1.0** ☐ **SOFIVA Array v2.0** ☐ **SOFIVA Array v3.0**
Hospital / Clinic:	**Physician (Signature):**

Patient Information

Name		Nationality	
ID / Passport No.		Nationality of Spouse	
Date of Birth	(dd) (mm) (yyyy)	Gravida / Para / Abortion	/ /
Mobile Phone No.		Phone No.	
Address			
Gestational Age	weeks days	Estimated Date of Confinement	(dd) (mm) (yyyy)

Clinical Information

Medical Record No.		**Collection Date**	(dd) (mm) (yyyy)
Prenatal Test	Specimen Type: ☐Amniotic Fluid: _____ml (greater than 15 ml) Appearance: ☐Clean ☐Turbid ☐Brown ☐Sanguine ☐Villi ☐Cord Blood ☐Placenta ☐Cord ☐Other _____ Pregnancy: ☐Singleton ☐Twins (☐Identical ☐Non-identical) ☐Multiple _____ Abnormalities by Ultrasound: ☐NO ☐YES (Description: _____) Chromosomal Abnormalities: ☐NO ☐YES (Report: _____)		
Pediatric/General Test	Specimen Type: ☐Blood ☐Other _____ Clinical Signs and Symptoms: _____ _____ _____		

I, the undersigned, understand the SOFIVA Array test serve as the examination of fetal chromosomal abnormalities. I hereby fully understand, agree and undertake the following:

1. SOFIVA Array v1.0 uses microarray to detect abnormalities and disorders associated with chromosome deletion or duplication.
2. SOFIVA Array v2.0 and v3.0 utilize microarray and next generation sequencing (NGS) with bioinformatics analysis for the detection of chromosomal abnormalities and common mutations of specific single gene disorders.
3. If the result shows abnormalities, it indicates that the fetus or the patient may have some kind of abnormal condition or disorder. The patient is strongly advised to see genetic specialists in order to obtain a complete understanding of the contents and implications of the report. In addition, the mother and father may be required to provide blood samples for cross comparison.
4. If the result shows negative, it means that the fetus or the patient is at low risk of chromosomal or specific genetic abnormalities. Due to the considerable variety of diseases as well as the inherent limitations of any test, the test cannot identify all possible abnormalities. Therefore, the negative result does not guarantee that the fetus or the patient is 100% healthy.
5. Non-common mutations of specific single gene disorders and unselected single gene disorders are not included in SOFIVA Array v2.0 and v3.0. Therefore, the risk of single gene disorders in the fetus or the patient cannot be completely ruled out.
6. There is an extremely small chance that the amount of DNA will not be sufficient to perform this test. In these cases, a repeat sampling will be required.
7. SOFIVA Array test specifically focuses on chromosomal aneuploidies, microdeletions, microduplications and the common mutations of specific single gene disorders (for SOFIVA Array v2.0/v3.0). It cannot detect balanced chromosomal translocations and inversions, uniparental disomy, polyploidy, low-level mosaicism, areas not covered by the microarray probes, or unselected genetic mutations.
8. I hereby agree that the hospital/clinic and Sofiva Genomics may collect, process or use my personal information such as medical records, medical treatment, genetic information and health examination records under the specific purpose of medical care, health treatment etc.
9. I ☐agree / ☐do not agree to allow the remainder of my sample to be used for research purposes. (Lack of response indicates consent.)
10. According to my situation, the physician has answered all my questions and adequately explained to me (included but not restricted to the information about the necessary, process, potential risk and successful rate of the test as well as the risk of other screening tests).
11. I fully understand the above terms, statements, and declarations, and I agree to have the test performed at my own expense. I understand and accept that the test may be the most appropriate choice at this time, but it cannot guarantee the prevention of the tested disorders.

_____

Signature, Date (dd/mm/yyyy)

Copy 1: Laboratory Retain (White) Copy 2: Hospital/Clinic Retain (Blue) Copy 3: Patient Retain (Red)