| LG-OrT-FR-025 | MOLECULAR GENETICS AND CYTOGENETICS TESTS INFORMED CONSENT FORM |
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| **PATIENT INFORMATION** | **NAME SURNAME** | | **COLLECTION DATE** | |
| **BARCODE** | **DATE OF BIRTH** | | **GENDER** | □ **FEMALE** □ **MALE** |
| | **ADDRESS** | | **GESTATION WEEKS** | |
| | **TELEPHONE (GSM)** | | **TYPE OF SAMPLE** | |
| **REFERRING PHYSICIAN** | **NAME SURNAME** | | ☐ **Peripheral blood** | ☐ **Fresh sample** |
| | | | ☐ **Bone marrow** | ☐ **Paraffin section** |
| **SEAL SIGNATURE** | **INSTITUTION** | | ☐ **Amniotic liquid** | ☐ **Paraffin block** |
| | | | ☐ **Chorionic villus (CVS)** | ☐ **Skin biopsy** |
| | **TELEPHONE** | | ☐ **Abortus material** | ☐ **DNA** |
| | | | ☐ **Cordocentesis** | ☐ **Other……** |
| | **E-MAIL** | | | |

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| **CLINICAL INDICATIONS/OBSERVATIONS** | |
| **FAMILY HISTORY** | |

**Informed Consent Form for Genetic Test**

**1)** Your physician will decide the sample and the collection way of the sample. Special samples such as amniotic fluid and chorionic villus biopsy (CVS), abortus material, biopsy will be obtained by your physician in special conditions with a separate consent form by informing you.

**2)** Genetic tests are quite new and continuously developing tests compared to the other laboratory tests. Rare differences in the DNA of individuals may also cause ambiguity in the detection of carrier status or disease. The data obtained may need to be reevaluated over time, and it is the responsibility of the assigned clinician to make this and any additional test (for example parents and other family members) or analysis required.

**3)** The cytogenetic tests may not be possible if there are no cells or tissues in the samples collected, the cells do not multiply or the cells are contaminated with microorganisms. In some cases, cytogenetic studies may not be possible because of the low quality of the chromosomes in spite of the presence of reproduction in cells. In such cases, it may be necessary to collect sample again or it may not be possible to collect new sample.

**4)** Cytogenetic analysis is only for the identification of numerical and structural chromosome anomalies at a certain resolution, and there is a possibility of false positive or negative result due to the technical limitations. Numerical or large structural anomalies can be recognized in chromosome analysis, but small structural anomalies and mosaicism may not be observed.

**5)** Molecular karyotyping (array karyotyping) analysis is performed with kits designed for different purposes. For example; the molecular karyotyping studies for prenatal screening have a kind of “high resolution chromosome analysis” function, and allow simultaneous scanning of a large number of micro deletions and micro duplications with a certain resolution. Prenatal screening study is performed together with parental analysis. In addition, parental analyses may be required for the other analyses.

**6)** As a result of any genetic tests, paternity or another genetic feature can become known involuntarily. There may be cases where the mother and/or father or a second test must be performed. Data out of the testing purpose cannot be reported as per ethical and legal requirements. **Additional studies requested by the physician are subjected to a separate approval.**

**7)** The tests are performed as quickly as possible, but the mean turnaround time may be exceeded due to patient-specific differences or the need for further study or due to the collaboration with other national/international laboratories.

**8) All genetic data are private and cannot be disclosed to third parties. Only the physician who requested the test is informed in our center. The original signed document shall be delivered by hand. If you give your consent, your final report may be delivered to your physician or physicians who follow you clinically, to you or to the person you may authorize by courier. In that purpose, you shall declare your authorization in the consent part below in handwriting.**

**9)** According to the Genetic Diseases Diagnostic Center Regulation (only for Turkey), no gender information except sex-related diseases and anomalies can be reported in prenatal diagnosis karyotyping reports (In other countries, local rules should be observed).

**10)** Genetic diagnosis studies may involve different processes for each case. We hereby declare that our center is not responsible for recommendations of other persons/instutions and genetic studies performed from the DNA and/or other samples requested form our laboratory by patients or a person whom have patient's custody.

### Consent for the Conservation

Your nucleic acid (DNA, RNA) sample, primary sample (blood, bone marrow, gestationel material), archival material (such as culture sample, cell pellet) prepared for studies and as well as data obtained from your studies can be retained as long as possible in order to be used in additional studies after reporting.

□ I accept

□ Destroy my sample at the expiry of the legal obligations.

### Consent for the Usage

It may be used anonymously (unnamed) provided that your identity information is preserved.

Your test data can be share in scientific platform. Your data and sample can be used as a control sample.

□ I accept

□ I refuse, it can be kept only for the additional studies I approved.

### Consent of the Patient or the Tutor

I was fully informed about the properties and limitations of the laboratory analyses to be performed for the genetic analysis requested by me or my family member or my physician. Possibilities for false positive/negative results, the possibility of re-sampling and requesting additional samples required for repetition of the test and/or need to be re-analyzed. The medical terms have been explained and enough time has been given to ask questions and decide. I read the information given above (or it has been read to me by the responsible) and I understood it.

I understood the necessity of the test(s) below and all its positive/missing aspects of the procedure to be performed in order to identify the ..... (indication) disease in me/my baby to be born/my child as per the information given.

| Test(s) : |
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I acknowledge that I am aware of my responsibility for genetic diagnosis, that I accept genetic diagnosis without any threat or material or moral pressure, and that I allow the above mentioned genetic diagnosis to be performed and I may withdraw this consent at any time.

| PATIENT/TUTOR<br>(Name, Surname, Signature, Date) | WITNESS*<br>(Name, Surname, Signature, Date) | PHYSICIAN IN CHARGE<br>(Name, Surname, Signature, Date) |
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*Witness signed is not obligatory.

| AUTHORIZATION FOR REPORT DELIVERY (see item 8) |
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