HUMAN GENETICS
APPLICATIONFORM
BabyDetect Newborn Screening

Contact : tél. +32 4 323 66 57 / +32 4 321 83 15 (secr) ou +32 4 323 76 95 (labo) Email : contact@babydetect.be www.babydetect.be

PATIENT IDENTITY (Baby & Mother labels)

Name :	First name :
MOTHER'S LABEL	
BABY'S LABEL	

CLINICAL INFORMATION (MANDATORY)

Mother's Name : _____
Parent 2's Name : _____

Maternity Hospital : _____
Birth date : ___/___/20__

Sexe : **Girl** ❑ Boy ❑
Twin pregnancy ❑

Gestational age : _____week _____ day
Birth weight : _____ g

BLOOD COLLECTION

❑ capillary venous (4 rounds, blotting card) Collection date : ___ / ___ / 20___ Time : __ h___

DOCTORS TO INFORM IN CASE OF POSITIVE RESULT

Maternity pediatrician (mandatory) : _____Mail : _____
tel : _____ Address : _____

Other: Pediatrician / Gyneacologist / Family physician : _____Mail : _____
tel : _____ Address : _____

INFORMED CONSENT : MANDATORY

The BabyDetect test cannot be performed without the informed consent of at least one parent and the referring physician. Please read and complete the reverse side of this form.

I hereby certify that I have been informed by a healthcare professional and consent to the BabyDetect screening test for my child.
I would like my child to benefit from the BabyDetect screening test. I understand that this is a screening test, not a diagnostic test, to detect treatable early-onset genetic diseases in newborns.
I have been informed of the financial cost of six hundred and fifty (650) EUR and commit to pay this amount according to the terms and conditions indicated in a separate invoice, provided by the CHU from Liège.

Parents
Name of legal representative n°1 : _____
Relationship to the Patient : _____
Date : ___ / ___ / 20___
Email :
Signature preceded by « read and approuved » :
_____

Name of legal representative n°2 (if possible) :
_____
Relationship to the Patient : _____
Date : ___ / ___ / 20___
Signature preceded by « read and approuved » :
_____

Address :
Street _____
N°_____
Postal Code : _____ City : _____

Physician
I hereby certify that the legal representative of the above-mentioned patient has received clear and precise information, in accordance with the national legislation on genetic testing.
I certify that I also declare to be convinced that the legal representative is capable of giving consent, even if he/she is minor or under guardianship.

REQUEST DATE :__/____/20_____ TIME _____h_____
Dr. : _____
N° INAMI : _____
Tel : _____
Stamp and signature :

INFORMED CONSENT FORM
Baby Detect Newborn Screening

By signing this form, I acknowledge :

1. Consent to the genetic screening test

The genetic screening test is voluntary and must remain free of any constraint, it requires the signature of this form expressing my consent as the patient's legal representative. My consent may be revoked in accordance with the terms described above.

I have been clearly informed of the following :

- I have the right to withhold all or part of the tests results, or to have them destroyed, if I change my mind after placing the order.
- The BabyDetect screening test is not free of charge. I have been informed of the financial cost of six hundred and fifty (650) EUR. I undertake to pay this amount in accordance with the terms and conditions set out on the invoice which I will receive in a separate document.
- I have the right to revoke my consent in writing within 15 days, by notifying contact@babydetect.be if I change my mind after placing my order. Any financial costs already incurred at the time of the revocation will remain my responsability.
- I have had a reasonable amount of time to make up my mind. I agree to provide the samples required for the neonatal genetic tests.
- I certify that I have read all the information given in this consent form and that I have been given clear and precise information about the neonatal genetic screening test.

2. Consent to the specifics of the genetic screening test

I have understood the possibilities and limitations of this test. I have had the opportunity to ask questions of my physician, who has provided clear, complete and satisfactory answers. I clearly understood the answers I was given.

I have been clearly informed of the following :

- I have received a clear explanation of the nature and purpose of the genetic screening test.
- This is a screening test for known genetic mutations. Mutations that are not known or that are not definitely associated with a disease are not reported. If the test detects nothing, this is no guarantee that the patient does not have one of the diseases screened for.
- The diseases screened for are early onset and treatable diseases. The list of these diseases can be found on the website : www.babydetect.be. Untreatable or late-onset diseases are not included.
- Due to the test nature, false negatives (the test indicates a negative result, wheras the fact under investigation corresponds to a positive case) or false positives (the test result indicates a disease when it is a false alarm) are possible. In the case of false negatives, the disease will not be identified by the test. In the case of false positives, a further examination by a specialist doctor may rule out the suspected disease. The risks of false positves and/or false negatives are small, but they do exist. In the event of a positive result, a sample from the parents may be required to confirm the disease (segregation study).

3. Consent to data processing

I have been clearly informed of the following :

- The information I provide, as well as all the results of the examination, are subject to medical confidentiality and data protection, in accordance with European legislation. I agree that my doctor may send the sample to the CHU of Liège, for administrative processing and analysis.
- To carry out the analyses, the CHU of Liège collects the patient's data (surname, first name, date of birth, weight, gestational age) and processes them in its laboratory information system. The results will be sent exclusively to the gynaecologist and/or paediatrician at the maternity unit and to the doctor specialising in the disease detected and will only be passed on to third parties with my written consent.
- I agree that the sample collected and the data collected anonymously may be used for quality insurance purposes or for local, national and international scientific research aimed at developing the BabyDetect genetic test. If I wish to object, I tick this box ❑
- I agree that my sample may be sent by the CHU of Liege to another appropriate laboratory if necessary.

4. Information on the processing of your personal data under this consent.

Data controler : the CHU de Liège, Avenue de L'Hôpital 1, 4000 Liège, hereinafter referred to as « CHU de Liège » ;

Processed data : surname, first name, date of birth, weight, gestational age of the patient and signature, surname, first name, that you provide to us as part of this consent ;

Purpose(s) : Your personnal data is collected and processed for and to the extent necessary to achieve the following purpose(s) :

- To detect treatable early-onset genetic diseases in the first few days of life
- To archive your consent

Legal basis : The collection and processing of your data are based on your consent.

Recipients of : In accordance with the purposes stipulated in the consent, your personnal data will not be transmitted to any recipient of third party other than :

- CHU de Liège staff, in particular members of the laboratory ;
- Services providers supporting / facilitating the activities of the CHU de Liège laboratory.
- The gynaecologist and/or the paediactrician of the maternity hospital and the doctor specialising in the disease detected.

Data security and storage : The personal data that you send to the CHU de Liège is stored in a database managed by and under the responsability of the CHU de Liège laboratory. Your data is stored exclusively on servers located in the EEA.

International data transfers : The personal data you send to the CHU de Liège is stored in a database managed by and under the responsability of the CHU de Liège laboratory. Your data is stored exclusively on servers located in the EEA. However, in the event that your personal data is transferred outside the EEA, to countries that the European Commission considers do not ensure an adequate level of protection of personal data, the CHU de Liège will take appropriate guarantees for this transfer of data in accordance with the Data Protection Regulations (GDPR), as well as, if necessary, additional protection measures. These can be consulted at the CHU de liège head office. Please contact the hospital's DPO for this purpose via dpo@chuliege.be.

Your rights: you and the patient you represent have the right to obtain access to your data, and, where appropriate, to request rectification, restriction of processing, delation of inaccurate, incomplete or irrelevant data or data portability. You and the patient you represent also have the right to lodge a complaint with the Data Protection Authority whose contact details are available on the following website: www.autoriteprotectiondonnees.be. To find out how to exercise your rights and for any further information on the processing of your data, please visit our website: https://www.chuliege.be/jcms/c2_17519932/declaration-de-confidentialite