Cerba

MEDICAL PRESCRIPTION FORM

CONSULTATION CERTIFICATE / CERTIFICAT OF INFORMATION AND CONSENT FOR TESTING

Laboratoire Cerba
Customer relation service
Tel.: +33 (0)1 34 40 97 76
Fax: +33 (0)1 34 40 21 29
Email: intgb@lab-cerba.com

PRENATAL GENETIC, INFECTIOUS AND BIOCHEMICAL DIAGNOSIS

Mandatory completion of the signed consultation certificate and consent form (page 3)

TESTING LABORATORY

Customer n°: |_|_|_|_|_| C /|_|

Mandatory stamp

PATIENT

SURNAME ……

FIRST NAME ……

Maiden name ……

Address ……

CP …… City ……

Date of birth: |_|_|/|_|_|/|_|_|_|_|

PRESCRIBER

SURNAME ……

FIRST NAME ……

Address ……

CP …… City ……

Tel. |_|_| |_|_| |_|_| |_|_| |_|_|

Fax |_|_| |_|_| |_|_| |_|_| |_|_|

E-mail address: ……

PARTNER:

Surname: ..... First name: ..... Date of birth: |_|_|/|_|_|/|_|_|_|_|

SAMPLING

Sampling date: |_|_|/|_|_|/|_|_|_|_| Term: ..... W.A

CURRENT PREGNANCY:

☐ Amniotic fluid

☐ Fetal blood

☐ Chorionic villus (*It is imperative that the sample is taken on the day of despatch in a transport medium available on request.)*

TERMINATED PREGNANCY:

☐ Placenta ☐ Cord

☐ Chorion ☐ Other *(specify)* : ……

CURRENT PREGNANCY:

■ LMP: …….. ■ GA: …….. ☐ Singleton pregnancy ☐ Twin pregnancy

■ 1st trimester ultrasound Date: |_|_|/|_|_|/|_|_|_|_| CRL: …… mm Nuchal translucency: …… mm

Is this a 2nd puncture ☐ No ☐ Yes: date of 1st puncture: |_|_|/|_|_|/|_|_|_|_|

Number of foetuses sampled: ☐ 1: volume …….. ml/mg appearance: ……..

☐ 2: Identifier of fetus no. 1= D1: volume …….. ml/mg appearance: ……..

: Identifier of fetus no. 2= D2: volume …….. ml/mg appearance: ……..

OBSTETRIC MEDICAL HISTORY OF THE PATIENT

Number:	Same partner	Different partner
■ Normal pregnancies:	……..	……..
■ Miscarriage:	……..	……..
■ Child with a genetic or chromosomal abnormality:	……..	……..

MEDICAL HISTORY

	Maternal side	Paternal side
■ Child with a genetic or chromosomal abnormality (description):	…….. ……..	…….. ……..
■ Genetic disease (which) :	…….. ……..	…….. ……..

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CYTOGENETICS, MOLECULAR CYTOGENETICS AND MOLECULAR GENETICS

INDICATION:

- ☐ cfDNA positive screening[5]
  - ☐ (4A) Trisomy 21 ☐ (4B) Trisomy 18
  - ☐ (4C) Trisomy 13 ☐ (4D) Others: ……..
- ☐ (4E) cfDNA screening not usable on a 2nd sample[5]
- ☐ (2A) Parental chromosomal abnormality[2]
- ☐ (5B) Ultrasound anomalies[1] (outside CN ≥ 3.5mm)
- ☐ (5A) Nuchal translucency ≥ 3.5mm[1]
- ☐ Maternal serum markers[3]
  - ☐ (1B) MSM 1stT ☐ (1D) MSM 2ndT alone
    Result: 1 / …….
- ☐ (3A) History of pregnancy with abnormal karyotype for the couple[2]
- ☐ (6A) Maternal age ≥ 38 years where screening for trisomy 21 could not be performed
- ☐ (8A) Convenience
- ☐ (7C) Sampling for infectious disease
- ☐ (7D) Sampling for genetic disease
- ☐ (3A) Investigation of a known fetal chromosomal abnormality
- ☐ (7B) Other *(Specify)* : ……

PRESCRIPTION:

- ☐ Fetal karyotype *(Amniotic fluid: 09601 ; Fetal blood: 09708 ; Chorionic villus: 09901)*
- ☐ Chromosomal analysis by DNA chip (ACPA) *(PPREN)*
- ☐ DNA conservation
- ☐ Test for micro-deletion syndrome *(09984)*: ☐ Wolf-Hirschhorn (4p-) ☐ Di-George (22q11) ☐ Other ……
- ☐ Rapid diagnosis of aneuploidy (FISH) on indication: ultrasound warning sign or on positive cfDNA test for T21 or not usable on a 2nd sample[5] or MSM ≥ 1/50 *(TLA)*
- ☐ Rapid diagnosis of trisomies13,18 and 21 by PCR for indications other than the ultrasound anomalies (non-covered) or MSM < 1/50 or cfDNA positive for T13 or T18 *(TLA)*
- ☐ Test for uniparental disomy of the chromosome[4] *(DUP)* *(specify)*: ……
- ☐ Determination of zygosity *(43902)*
- ☐ Achondroplasia[4] *(43401)* ☐ Hypochondroplasia[4] *(44401)* ☐ Apert Syndrome[4] *(APERT)* ☐ Thanatophoric dysplasia[4] *(THANA)*
- ☐ Study of the SHOX gene[4] *(SHOXM)* ☐ Mucoviscidose[4] *(CFSEQ)* ☐ Steinert's myotonic dystrophy[4]* *(DM1)*
- ☐ Spinal muscular atrophy[4] *(SMA)* ☐ Rett Syndrome[4] *(MECP2)* ☐ Prader-Willi Syndrome[4] *(PWSME)*
- ☐ Sickle cell anaemia[4] *(DREP)* ☐ Beta thalassemia[4] *(HBETA)*
- ☐ Gene panel - Exome (NGS) *(EXOCY)*: see online catalogue: https://www.lab-cerba.com/files/live/sites/Cerba/files/documents/EN/FDE_Exome_EN.pdf
- ☐ Other *(specify)*: ……

DIAGNOSIS OF INFECTIOUS DISEASES

PRESCRIPTION:

- ☐ Cytomegalovirus (CMV) by PCR *(CMPCR)* ☐ *Toxoplasma gondii* par PCR *(TGPCR)* ☐ Parvovirus B19 by PCR *(19PCR)*
- ☐ Varicella-zoster (VZV) by PCR *(VZPCR)* ☐ Enterovirus by RT-PCR *(ENTPT)* ☐ Herpes virus 1 and 2 (HSV) by PCR *(HSPCR)*
- ☐ Rubella by RT-PCR* *(RUBAM)* (mandatory freezing) ☐ Zika by RT-PCR *(ZIKAP)*
- ☐ Other *(specify)*: ……

INDICATION:

- ☐ Ultrasound anomalies[1]
  - ☐ Hypotrophy/ isolated intrauterine growth restriction ☐ Cerebral ventricular dilatation ☐ Hyperechogenic bowel
  - ☐ Hydramnios ☐ Intrauterine fetal demise ☐ Other *(specify)*: ……
- ☐ Maternal seroconversion[6]
  - ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester ☐ Undated
- ☐ Clinical maternal varicella infection ☐ Other *(specify)*: ……..

FETAL BIOCHEMISTRY (amniotic fluid)

PRESCRIPTION:

- ☐ Alpha-fetoprotein *(22207)* ☐ Acetylcholinesterase *(70106)* ☐ Digestive enzymes* *(ENZDI)* ☐ Other *(specify)*: ……

INDICATION:

- ☐ Maternal serum AFP ≥ 2.5 MoM ☐ Ultrasound signs suggesting a NTD[1] ☐ Other ultrasound anomalies[1]
- ☐ Maternal treatment (particularly Depakine®) ☐ History of failure of neural tube closure
- ☐ Systematic analysis ☐ History of nephrotic syndrome

Documents to be enclosed:

[1]The ultrasound report
[2]the cytogenetics result
[3]the report of the calculation of fetal T21 risk
[4]parental blood samples
[5]the cfDNA test report
[6]the serology test results

* test sent

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CONSULTATION CERTIFICAT FROM THE PRESCRIBER
CERTIFICAT OF INFORMATION AND CONSENT PATIENT FOR TESTING

PRENATAL GENETIC,
INFECTIOUS AND BIOCHEMICAL DIAGNOSIS

Mandatory completion of the signed consultation certificate and consent form (document below)

CONSULTATION CERTIFICATE FROM THE PRESCRIBING PHYSICIAN OR THE GENETIC COUNSELOR

☐ **POSTNATAL DIAGNOSIS**

I, the undersigned, Dr./Prof. …… or …… genetic counselor under the supervision of Dr./Prof. …… certify that I have informed the undersigned patient and his/her parents (legal representatives) about the characteristics of the investigated disease, how to diagnose it, how to prevent and treat it, how the disease is transmitted and the possible consequences in other members of the family, the storage of the sample, and that I have obtained the consent of the patient AND his/her guardianship under the conditions provided for by the French public health code (articles R113-4 and 5).

☐ **PRENATAL DIAGNOSIS**

I, the undersigned, Dr./Prof. …… or …… genetic counselor under the supervision of Dr./Prof. …… certify that I have informed the undersigned patient about the risk to her child of being affected by a particularly serious chromosomal, genetic or infectious abnormality, the characteristics of this disease, how to detect it, the associated risk and the possible consequences of an abnormal outcome.

CONSENT OF THE PREGNANT WOMAN FOR SAMPLE COLLECTION AND TESTING FOR AN *IN UTERO* PRENATAL DIAGNOSIS
Decree of January 14, 2014, consolidated on January 2, 2019

- Information on the risk to the unborn child of being affected by a particularly serious disease, the characteristics of this disease; how to diagnose it; the potential options of fetal medicine, treatment or management of the born child.
- Information on laboratory tests likely to allow making an in utero prenatal diagnosis that have been offered to me and that I would like to perform: this or these tests require the collection of a sample of amniotic fluid, chorionic villi (placenta), fetal blood or any other fetal sample; the procedures, risks, disadvantages and possible consequences of each sampling technique necessary to perform this or these tests have been explained to me; I have been informed that a second sample may be required in case of technical failure; if this happens, I will have to sign a new written consent; other diseases than that or those initially investigated could be revealed by the test; I have been informed that the result of the test will be available to me and explained to me by the physician who prescribed it.

I consent to the collection (required for testing) of (*):

☐ amniotic fluid ☐ chorionic villi

☐ fetal blood ☐ other fetal sample (specify)……

I also consent to the test(s) (*) for which this sample is taken:

☐ cytogenetic testing, including molecular tests applied to cytogenetics;

☐ molecular genetic testing;

☐ fetal chemistry diagnostic tests;

☐ laboratory tests for the diagnosis of infectious diseases.

CONSENT FOR GENETIC TESTING OF A PERSON

I, the undersigned, Mrs. …… certify that I have received:

- Information on the genetic test that is offered to me, that will be performed on (check below):
  - ☐ the biosample(s) taken from me
  - ☐ the biosample(s) taken from my child or from the adult under guardianship
  - ☐ the sample that will be taken from my dead fetus
- Information on the genetic tests that will be performed to:
  - confirm or rule out the diagnosis of a genetic disease related to my symptoms;
  - confirm or rule out the presymptomatic diagnosis of a genetic disease;
  - identify a healthy carrier status (screening for heterozygous variants or chromosomal rearrangement)
  - assess my genetic susceptibility to a disease or drug treatment.

I have been informed:

- Of my right to request the interruption of this study, that the results are not communicated to me, or the destruction of the stored samples
- That the full interpretation of these results is based, in some situations, on the definition of biological relationships, which can be analyzed from these samples.
- Of my responsibility regarding my duty to inform my family, if a serious genetic abnormality is revealed, the consequences of which are likely to result in the implementation preventive measures, including genetic counseling or care.

I authorize the storage of a biosample taken to me and its subsequent use to **continue investigations as part of the same diagnostic process**, depending on the evolution of knowledge.	☐ Yes ☐ No
The technique used may **reveal genetic information that is unrelated to the investigated disease, but that may have an impact on my health or that of relatives**. I would like to be informed of these results.	☐ Yes ☐ No
I authorize the transmission of a sample along with the necessary medical data, including any photographs, to another laboratory to **complete this genetic study**. I authorize the **recording and storage of medical data** useful for the management of the diagnostic process in computer databases	☐ Yes ☐ No
I authorize the **recording and storage of medical data** useful for the management of the diagnostic process in computer databases	☐ Yes ☐ No
As part of the diagnostic process, part of my sample may not be used. I authorize its storage and use for internal laboratory quality assurance studies.	☐ Yes ☐ No
I authorize the anonymized use of medical data and/or part of the samples within the framework of research projects, of a scientific study program without direct benefit or loss to me (all my medical data will be protected through total anonymization).	☐ Yes ☐ No

The result of this test will be available to me and explained to me by the prescribing physician (or by the delegated genetic counselor) in the current state of knowledge in the context of a genetic consultation. This or these tests will be performed by a medical biology laboratory authorized by the regional health agency to perform them. The original of this document will be kept in my medical record. A copy of this document will be provided to me and to the practitioner who must perform the tests. The medical biology laboratory in which the practitioner who performed the tests works will keep this document under the same conditions as the test report. I have had the opportunity to ask questions to the geneticist or genetic counselor who prescribed this test and all my questions have been answered satisfactorily.

Done in …… on ……

PATIENT IDENTITY (*Signature*)	IDENTITY of the LEGAL REPRESENTATIVE(S) (*Signature*)	PRESCRIBER (*Signature*)
Last name: *First name:* *Date of Birth:*	*Last name, first name, date of birth:* *Last name, first name, date of birth:* If the patient is minor or an adult under guardianship, relationship to the patient:	*Last name:* *First name:*