Laboratoire CERBA

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FOETAL RHD GENOTYPE

PRENATAL TESTING USING MATERNAL BLOOD

IMPORTANT: CHECKLIST BEFORE SENDING

☐ Sample**: Two <u>5-mL</u> EDTA tubes of whole blood (shipped to the laboratory from +2°C to +8°C within 5 days)**
☐ Medical prescription (specify below if it is the 1st or 2nd test)
☐ **If it is the 2nd test, a copy of report of 1st test**
☐ Informed consent of patient and documentation of consultation and consent signed by patient AND prescriber (see page 2)
☐ Copy of ultrasound reportfor the 1st trimester (or for subsequent trimester if it was not performed)
☐ Copy of the blood group and Rhesus-Kell phenotypes card

PATIENT

Surname
I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I

First name

I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I__I

Maiden name...............…..…......

Address...

....

Date of birth: I__I__I / I__I__I / I__I__I__I__I

Height and weight I__I__I__I (cm) I__I__I__I (kg)

PRESCRIBER

Obligatory stamp

Signature:

Email address:

INFORMATION

Date of start of pregnancy according to ultrasound:

I__I__I / I__I__I / I__I__I__I__I

Pregnancy
☐ From unassisted conception
☐ From medically assisted reproduction

Number of foetuses: ☐ 1 ☐ 2 ☐ 3

Number of placentas: ……………………………….

Vanishing twin: ☐ Yes ☐ No ☐ Unknown

Geographic origin of	**the patient:**	**the partner:**
Europe	☐	☐
North Africa	☐	☐
Sub-Saharan Africa	☐	☐
Reunion Island	☐	☐
The Antilles, French Guiana	☐	☐
Asia	☐	☐
Other:	☐	☐

INDICATION

☐ Caring for an RhD-alloimmunized patient
☐ Testing for anti-D prophylaxis purposes limited to pregnant women with RhD-positive babies
- ☐ Systematic
- ☐ Amniocentesis, chorionic villus sampling, on: I__I__I / I__I__I / I__I__I__I__I
- ☐ Metrorrhagia
- ☐ Molar pregnancy
- ☐ Embryo reduction
- ☐ External cephalic version
- ☐ Risk of premature birth requiring treatment
- ☐ Cervical cerclage
- ☐ Ectopic pregnancy
- ☐ Intrauterine foetal demise
- ☐ Pelvic or abdominal surgery
- ☐ Abdominal or pelvic trauma
- ☐ Miscarriage
- ☐ Termination of pregnancy

BLOOD SAMPLING

☐ 1st test: from the 11th week of amenorrhoea
☐ 2nd test: at least 15 days after the first test **<u>AND</u>** after the 18th week of amenorrhoea

Sampling date: I__I__I / I__I__I / I__I__I__I__I Time of sample: I__I__I:I__I__I

Customer no.: C I__I__I__I__I__I / I__I Stamp from sampling laboratory:

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Section reserved for Cerba Laboratory

Type code: SGE (EDTA whole blood x 2) Analysis code: RHFOE	*CERBA record label*

INFORMATION FOR THE PATIENT, PROOF OF CONSULTATION AND CONSENT

I, ……., a doctor/midwife,

Attest to the fact that I consulted with **the patient indicated above whose blood group is rhesus D negative** in compliance with Article R.162-16-67 in decree number 95-559 from 6 May 1995 in order to provide her with the following information:

- During the pregnancy, certain events can promote blood flow from the foetus to the maternal bloodstream. If your foetus is rhesus D negative like you, there is no risk; however, if it is rhesus D positive and no precautionary measures are taken during the pregnancy, you are at risk of developing antibodies against these red blood cells. This is called Rhesus alloimmunization.
- You may receive one or more injections of a product (anti-D immunoglobulin) to eliminate the foetal red blood cells that may have entered your bloodstream to prevent this alloimmunization. This injection will be given if you have to undergo chorionic villus sampling (CVS) or amniocentesis, or in any other potentially risky situation. According to the recommendations of the French National College of Gynaecologists and Obstetricians, you will systematically be offered an injection on the 28th week of your pregnancy. When you give birth, your baby's blood group will be determined. If it is RhD positive, you will once again receive one or more injections of anti-D immunoglobulin.
- Anti-D immunoglobulin is a human blood product obtained from blood donations. The risk of an infectious agent being transmitted is low because of the preventive measures that are taken, but it can never be completely eliminated. If your baby is RhD negative (which occurs about 1/3 of the time in our experience), you are not at risk of RhD alloimmunization and therefore do not have to receive any anti-D immunoglobulin injections. If you are already alloimmunized, there is no risk for your current pregnancy.
- Determining the foetus' RhD group is now possible through genetic analysis (RhD genotyping) of the foetal DNA circulating in your bloodstream. The French National Authority for Health (HAS) recommends conducting this test at the 11th or 12th week of amenorrhoea as a preventive measure to define care for RhD-negative women pregnant with RhD-positive babies and as part of treatment plans to determine which RhD-negative pregnant women with RhD-positive babies are already immunized as they must receive specific, specialised care.
- Foetal RhD genotyping as it is performedby our laboratory is based on detecting sequences of nucleotides derived from the RhD gene in the mother's blood. The results are interpreted based on the fact that most RhD-negative individuals lack the RhD gene and the presence of the gene generally means the person is RhD positive. The test is therefore relevant for patients in the RhD negative group who completely lack the RhD gene in their genome; in our experience (having conducted over 5,000 tests to date), this is the case for over 99% of Caucasian women, but only 18% of black women and less than 1% of Asian women.
- In about 3% of cases, the foetal genotype cannot be determined. Most of the patients in these cases are non-Caucasian (~48%) or Caucasians with the Cde or cdE phenotype (~32%). In less than 1% of cases, a difference in the prenatal phenotype and the phenotype at birth was observed in connection with variants of the RhD gene (sensitivity and clinical specificity of the test >99%). .

I, the undersigned, Ms. ……

consent to the sampling and analysis which will be performed by a laboratory authorised by the Regional Health Agency (Agence Régionale de Santé) to perform this analysis. The test simply involves taking a small amount of blood and presents no risk to my baby.
I understand that negative or indeterminate results may have to be confirmed using a second blood sample.

The results of the test will be given and explained to me by the doctor or midwife who prescribed it.

Signed in , on

Signature (patient)
MANDATORY

Signature (prescriber)
MANDATORY