MEDICOVER GENETICS

FETAL RHESUS FACTOR DETERMINATION ORDER FORM

BARCODE

SENDER INFORMATION (PRACTICE/CLINIC STAMP) / [ADD TRANSLATION IN LOCAL LANGUAGE]

Practice/Clinic / [Add translation in local language]

Street / [Add translation in local language]

Post Code/City / [Add translation in local language]

Tel./Fax/E-mail / [Add translation in local language]

Responsible Medical Person / [Add translation in local language]

Stamp (if necessary) / [Add translation in local language]

PATIENT INFORMATION / [ADD TRANSLATION IN LOCAL LANGUAGE]

First Name / [Add translation in local language]

Last Name / [Add translation in local language]

Date of Birth (DD/MM/YYYY) / [Add translation in local language]

Gender (male/female/other - specify karyotype) / [Add translation in local language]

Address (street name, no., city, post code, country) / [Add translation in local language]

Telephone Number (country code & number) / [Add translation in local language]

Personal Identification No. / [Add translation in local language]

Sample Collection Date (DD/MM/YYYY) / [Add translation in local language]

NON-INVASIVE FETAL RhD TESTING/DETERMINATION

SPECIMEN

1 large collection tube with venous EDTA blood (9-10ml)

Collection date

Collection time

Repeat investigation: Yes ☐ No ☐

Note: The specimen should only be stored at room temperature until collection. The specimen should arrive at the laboratory within 48 hours of sampling.
Tubes of blood without a barcode label must be discarded!

Declaration of consent on the reverse side

CLINICAL INFORMATION AND INDICATIONS FOR EXAMINATION

(The information below is mandatory and incomplete order forms cannot be processed!)

Week of pregnancy/gestational age (week + day) ☐☐+☐ Weight (before pregnancy): ☐☐☐ kg Height: ☐.☐☐ m

☐ 1 fetus (only possible for a single fetus pregnancy) ☐ Patient's blood group: _____

POSSIBLE RESULTS OF THE NON-INVASIVE FETAL RHD DETERMINATION

Positive result: RHD sequences were detected and the fetus is RhD positive. A positive result (positive RHD genotype) is to be considered final. Anti-D prophylaxis is recommended in this case.

Negative result: no RHD sequences could be detected. The fetus is RhD negative or the amount of fetal DNA was too low. A negative result before the 19th week of pregnancy is to be considered provisional and should be confirmed at least two weeks later and after the 17th week of pregnancy. In this case, anti-D prophylaxis is not necessary.

Limitations of the non-invasive fetal RhD determination test: the test is only possible for **single fetus pregnancies**. In approximately 1% of cases, the result is not clear. In this case, anti-D prophylaxis is recommended. Furthermore, in 0.2-0.3% of cases, rare genetic variants can lead to a positive RHD result even though the fetus is serologically RhD negative. Nevertheless, anti-D prophylaxis is still recommended in this case. Despite high sensitivity (>99%) and specificity (>98%), false-negative and false-positive results cannot be excluded with absolute certainty.
Regardless of the result of the non-invasive fetal Rhesus factor (RhD) determination, the RhD trait is determined immediately after birth from umbilical cord blood for every baby born to a RhD negative mother in order to exclude rare false-negative results. If the baby is RhD positive, the RhD negative mother is given a standard dose of anti-D immunoglobulin (300µg) within 72 hours of birth.

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INFORMATION PART OF CONSENT FORM

BARCODE

PATIENT INFORMED CONSENT

With non-invasive fetal Rhesus factor (RhD) determination, pregnant women with negative RhD can have the blood of their unborn child tested in order to obtain targeted information about necessary anti-D prophylaxis (rhesus prophylaxis). Approximately 35-40% of RhD negative pregnant women will have a RhD negative child. In this case, rhesus prophylaxis during pregnancy is not necessary since there is no rhesus incompatibility between mother and child. Thus, in the case of a negative test result, unnecessary rhesus prophylaxis in RhD negative pregnant women can be avoided. Only if the test result shows that the child is RhD positive, is rhesus prophylaxis necessary.

One tube of EDTA blood (9-10ml) is necessary for the test. During pregnancy, maternal blood contains genetic material from the fetus which is ideal for use to determine the unborn child's Rhesus factor. The test enables the Rhesus factor of the unborn child to be determined **from the 12th week of pregnancy at the earliest**. The test is not suitable for a multiple fetus pregnancy. Rare genetic rhesus variants can lead to false-positive results and unnecessary rhesus prophylaxis. False-negative results are caused by too little fetal DNA in the bloodstream of the mother. As the proportion of fetal DNA increases throughout the pregnancy, we recommend the investigation **from the 19th week of pregnancy**. Regardless of the result of the prenatal test, the Rhesus factor of every baby born to an RhD negative mother is determined immediately after birth in order to give rhesus prophylaxis after birth in case of a rare false-negative result.

Current data show that the test has no discernible disadvantages for either the pregnant woman or the unborn child. With the test, RhD negative pregnant women expecting an RhD negative baby can be spared rhesus prophylaxis.

DECLARATION OF CONSENT ACCORDING TO THE GENETIC DIAGNOSTICS ACT (GENDG)

The GenDG requires a detailed explanation and written consent for all genetic examinations. Please read the declaration of consent carefully and cross out any statements you do not agree with.

By signing the form below, I confirm that I

- have been fully informed about the type, purpose, scope and significance of the examination
- have been given sufficient opportunity to discuss open questions
- agree to the collection of samples for the examination
- agree with the **determination of fetal Rhesus factor from maternal blood**
- agree that the remaining sample material may be stored after the examination is completed, yet not claiming storage
- agree that my sample material may be made available anonymously for quality management and scientific purposes
- agree that the examination results may be stored for a longer time than the statutory period of 10 years, yet not claiming storage of results
- agree that the examination order form, or parts thereof, may be forwarded to collaborating medical laboratories if necessary

In addition, I have been informed that

- I may stop the investigation at any time and ask for the results available until that time to be destroyed
- I may withdraw my consent at any time, entirely or in part, without giving reasons
- I will only be charged for the costs incurred up to the time of withdrawal of consent
- I may choose not to be informed about the test results (right not to know)
- the genetic examination and evaluation is limited to the requested indication and no statements will be made about other diseases

Place, Date

Patient Signature

INFORMATION AND GENETIC COUNSELING FOR THE NON-INVASIVE DETERMINATION OF THE FETAL RHESUS FACTOR (RhD) ACCORDING TO THE GENDG

With my signature below I declare that

- the pregnant woman was informed about the non-invasive determination of fetal Rhesus factor
- the pregnant women received genetic counselling

Place, Date

Signature of Responsible Medical Person

Insert your logo here

Address:
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

E-mail: xxxxxxxxxxxxxxxxxxxx
Website: xxxxxxxxxxxxxxxxxx

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