LIMITATIONS OF THE TEST

- Only possible for single fetus pregnancy, not suitable for twin pregnancies
- Where the result is unclear (around 1%), anti-D prophylaxis is recommended
- Rare genetic rhesus variants can lead to false-positive results in 0.2-0.3% of cases
- False-negative results can be caused by a low level of fetal cell-free DNA, degradation of the cell-fee DNA or by hemolysis in the specimen tube

INFORMATION ABOUT THE TEST PROCEDURE

- Test material: 9-10ml EDTA tube labeled with surname, first name and date of birth
- Pregnant woman must give informed and written consent
- Specimen storage and transport: between +2°C and +25°C, max. 48 hours
- Processing time: 5-8 working days after sample receipt

WHY US

- A network of laboratories and medical institutions makes us **a leader in genetic testing** in Germany with foundations dating back to 1998
- A clinical team comprised of scientists, physicians and medical geneticists, several with **>20 years of experience** in genetic testing, assuring meaningful and comprehensive genetic tests
- **Up-to-date diagnostic algorithms**
- Expertise in gene variant analysis ensuring **"no variant left behind"**
- Cutting-edge technology in sequencing and laboratory methods allows for **short turnaround times**
- **Quality** assessed by several certifying bodies, including EFI, DIN EN ISO 15189 accreditation for medical laboratories, DIN EN ISO/IEC 17025 accreditation for testing and calibration laboratories and a generally valid GMP (Good Medical Practice) certificate
- **Data privacy** is your right and our priority

CONTACT

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NON-INVASIVE FETAL RhD DETERMINATION

Targeted anti-D prophylaxis through determination of the fetal RhD status

PHYSICIAN INFORMATION

MEDICOVER GENETICS

Your logo goes here

WHAT IS NON-INVASIVE FETAL RhD DETERMINATION?

With non-invasive fetal Rhesus factor (RhD) determination, RhD negative pregnant women can have their blood tested to determine the RhD of their unborn child. Most people possess the RHD gene and are therefore RhD positive. About 17% of pregnant women are RhD negative.

IMPORTANCE OF THE TEST

RhD negative women are at risk of RhD sensitization during pregnancy if the maternal immune system comes into contact with RhD positive erythrocytes.

Transfer of fetal erythrocytes into the maternal bloodstream occurs in every pregnancy, either without any external influence or through interventions such as amniocentesis. Due to the increase in the amount of erythrocytes during pregnancy, the risk of RhD sensitization increases from the 3rd trimester.

There is no risk of RhD sensitization if the father is RhD negative. There is a 50% probability that heterozygous carriers will pass on the RhD trait. This results in a total of approximately 35-40% of the RhD negative pregnant women giving birth to an RhD negative child and thus receiving unnecessary rhesus prophylaxis without a fetal RhD determination test. Following amendments to the maternity guidelines of August 2020, **every RhD negative pregnant woman with a single fetus pregnancy should be offered fetal Rhesus factor determination** from maternal blood.

FOR WHOM IS THE TEST RELEVANT?

RhD negative pregnant women who want to know whether they require anti-D prophylaxis (with a RhD positive fetus)

RhD negative pregnant women with evidence of anti-D antibodies (RhD sensitization)

METHOD

- Detection of cell-free fetal DNA from maternal plasma
- Analysis of the RHD sequences using real-time PCR with three target regions (exons) to detect as many variants of the RHD gene as possible
- Test (CE-IVD product) with high diagnostic sensitivity (>99%) and specificity (>98%)

WHEN IS THE TEST PERFORMED?

The test can be performed from the 12th week of pregnancy at the earliest. However, we recommend fetal RhD determination **from the 19th week of pregnancy** to reduce the possibility of a false-negative result.

An RhD negative result obtained before the 19th week of pregnancy must be confirmed by repeating the analysis after week 17. An RhD positive result can be considered definitive from as early as the 12th week of pregnancy.

RESULT OF THE TEST

Positive result: RHD sequences detected and the fetus is RhD positive. A positive result (positive RHD genotype) is to be considered definitive. Anti-D prophylaxis should be administered in the 28th-30th week of pregnancy.

Negative result: No RHD sequences 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 must be confirmed at least two weeks later and after the 17th week of pregnancy. Anti-D prophylaxis is not necessary if the fetus is RhD negative.

Regardless of the result of the non-invasive fetal RhD determination test, 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 will be given a standard dose of anti-D immunoglobulin (300µg) within 72 hours of birth.