INSTITUT DE BIOTECHNOLOGIES JACQUES BOY

REFERENCE : 502080533

Free DNA Fetal Kit RhD - Duplex

Reliable, non-invasive fetal *RHD* genotyping

An essential solution for optimise the care of RhD-negative pregnant women .

The Free DNA Fetal Kit RhD - Duplex is a fetal *RHD* genotyping test performed on a single maternal blood sample. It is used to determine the RhD status (RH: 1 or RH: -1) of the fetus as early as the 11th week of amenorrhoea.

This test is essential for the diagnosis of feto-maternal RhD incompatibility, making it possible to optimise management of pregnant women who are RhD-negative (RH: -1) and to limit the administration of anti-D immunoglobulins to RhD-negative (RH: -1) women carrying an RhD-positive (RH: 1) fetus.

Safety and compliance

Non-invasive method

A simple maternal blood test is all that's needed.

Compliance with European standards

CE-IVD certified, meets the requirements of Regulation (EU) 2017/746, guarantees the safety and reliability of the test.

Validation by an independent laboratory

All batches undergo an external performance assessment before being released to market.

Used by accredited laboratories

Many laboratories have already obtained COFRAC ISO 15189 accreditation.

Recommended by the CNGOF and the HAS

Since 2006, this test has been recommended for better management of pregnancies in RhD-negative women.

Test covered by your health insurance

Contact the public or private organisation responsible for reimbursing healthcare costs in your area. This test may: not be reimbursed, be reimbursed at 100% or be partially reimbursed.

CE IVD · ISO 15189 ACCREDITATION · HAS HAUTE AUTORITÉ DE SANTÉ · CNGOF

Easy to use and time-saving

Designed to be simple and effective to use, this test enables early management of pregnancies at risk of anti-D alloimmunisation.

Thanks to a standardised protocol, **it can be easily integrated into laboratory workflows** without the need for adaptation, offering significant time savings.

Its flexible capacity, **with a kit enabling perform up to 96 tests divided into 1 to 6 series**, meets the varied needs of medical facilities, guaranteeing optimised organisation and greater responsiveness to the demands of monitoring requirements.

Storage conditions

Box divisible into 2 parts:

Part with primers and probes:
Temperature ≤ -18°C, protected from light and in the room dedicated to PCR preparation.

Part with controls:
Temperature ≤ -18°C and in an extraction room.
extraction room.

Reliability and precision

Optimised detection
The test amplifies three key exons of the RHD gene (exons 5, 7 and 10), ensuring maximum specificity and enabling the identification of numerous genetic variants as early as the 11th week of amenorrhoea.

Sensitivity and specificity
Sensitivity rate: 100%
Specificity rate: 99.2%

Accurate, reproducible results
Test based on a real-time PCR technique easy to use.

Integrated quality control
The kit includes positive and negative controls, as well as an internal control to check the integrity of the results.

The first fetal *RHD* genotyping kit to have obtained CE-IVD marking in 2007
Developed in IBJB's laboratories, it is certified as class D according to the CE IVDR regulation 2017/746 since 2023, guaranteeing a high level of control and quality.

Associated quality control

IJB-*RHD* DNA Control

A specific IQC (Internal Quality Control) to check each stage of the analytical fetal *RHD* genotyping process.

Compliance with the European standard Regulation (EU) 2017/746.

Contains 4 human plasma samples mimicking an RhD-negative patient (RH: -1) pregnant with an RhD-positive (Rh: 1) fetus in early pregnancy.

Developed with quality requirements guaranteeing reliable control.

Why choose *Free DNA Fetal Kit RhD -Duplex ?*

A reliable, non-invasive and approved method for prenatal diagnosis.

Full compliance with the following regulations in force

In Europe: CE-IVD certification under Regulation (EU) 2017/746 for Class D devices.

In Australia: Assessment under the Therapeutic Goods (Medical Devices.) Regulations 2002 (TG(MD) R 2002) and registration with the Therapeutic Goods Administration (TGA).

In Switzerland: Registration with Swissmedic in collaboration with a Swiss agent (CH-REP).

In the United Kingdom: Registration with the Medicines and Healthcare products Regulatory Agency (MHRA) in collaboration with a UK agent (UK-REP).

Maximum sensitivity and specificity, including management of genetic variants of the RH system.

A solution that can be easily integrated into laboratory workflow.

INSTITUT DE BIOTECHNOLOGIES JACQUES BOY

Developed and manufactured by :
Institut de Biotechnologies Jacques Boy

Carefully read the instructions provided in the product's IFU.

03 26 79 72 72 • contact@ibjb.fr • www.ibjb.fr
Pôle technologique Henri Farman - 4, Allée Albert Caquot - 51100 REIMS

bpifrance EXCELLENCE

La FRENCH FAB