INSTITUT DE BIOTECHNOLOGIES JACQUES BOY

PRENATAL DIAGNOSIS KIT

Fetal RHD genotyping

from a maternal blood sample collected from the 11th GW.

IBJB produces in its laboratories in Reims-France the only IVD MD for fetal RhD genotyping responding the European regulatory requirements and French Public Health Code[1]. Aimed at diagnosing fœto-maternal incompatibility for *RhD* negative mothers-to-be, it is used by approved laboratories[2]: by using this CE-marked kit, many of them have already received the accreditation in accordance with ISO 15189.

All of our batches are checked before release by an independent expert laboratory (Annex II List A).

CE 0459 IVD

100% MADE IN FRANCE

SENSITIVE AND SPECIFIC

Amplification of exons 5,7 & 10 of the ***RHD*** gene ensures **maximum sensitivity**[3] including for future mothers with silent ***RHD*** genes.

A COMPLETE KIT

The kit **includes all the necessary elements**[4]. It is exclusively dedicated to the determination of ***RHD*** fetal genotype.

AN IQC AVAILABLE[5]

Developed with the same requirements as the box, the **IQC «IJB-RHD DNA CONTROL»** contains 4 identical samples of human plasma acting like the plasma of an ***RhD* negative** patient carrying ***RhD*-positive** fetus with DNA present in low quantities.

CE 0459 IVD

REFERENCE:502080233

Free DNA Fetal Kit RhD « Simplex »

REFERENCE:502080533

Free DNA Fetal Kit RhD « Duplex »*

REFERENCE:508020154

IJB-RHD DNA CONTROL

* Suitable for the laboratories carrying out the greatest number of tests, the duplex version makes it possible to carry out twice as many patients per microplate and to save consumables.

[1] Recommended in France since 2006 by the national syndicate of gynecologists and by the national health authorities since 2011, the prenatal determination of the fetal RhD genotype on maternal blood is reimbursed since July 13, 2017. Accessible to all RhD negative patients, this tests consists of a simple and non-invasive biologic act prescribed by gynecologists and midwives.

[2] In France, the laboratories using this kit must be authorised by their Regional Health Agency to perform molecular genetical tests in prenatal diagnosis and / or genetical tests on cell free fetal DNA circulating in maternal blood.

[3] See paragraph «Performances» of the IFU

[4] Only the Taq is not included in this kit.

[5] Internal quality control is part of good laboratory practices. It allows a corrective type quality approach aimed at regularly monitoring the interactive analytical process «material - technical - reactive» and detecting anomalies in real time in order to remedy them immediately.

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More information on **our website**

Read carefully the instructions in the IFU.

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Entreprise membre de bpifrance EXCELLENCE 2019 FRENCH FAB G MED

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