

NIPD-RhD – Rhesus test

Fact sheet

- Non-invasive prenatal RhD genotyping from maternal blood
- For RhD negative pregnant women with singleton pregnancy
- Between gestational weeks 11 + 0 and 25 + 0 (recommended)
- CE-marked IVD^{1,2} – reimbursed in France
- Test performed by Eurofins Biomnis, France
- Delivery time 10 working days per analysis (Monday to Friday, without holidays)

100%³

Sensitivity

95.1%³

Specificity

Limitations

- False-positive results are possible in case of a rare genotype, non-functional RhD variant⁴ or bone marrow donation⁵
- A test result cannot be reported if the mother is carrier of the RhD gene
- In general, false-negative results are possible^{6,7}

Exemplary diagnostic strategy for RhD negative pregnant women

Non-immunised patient

Blood sampling & express delivery
(responsible doctor)

Test result
(generally 10 working days)

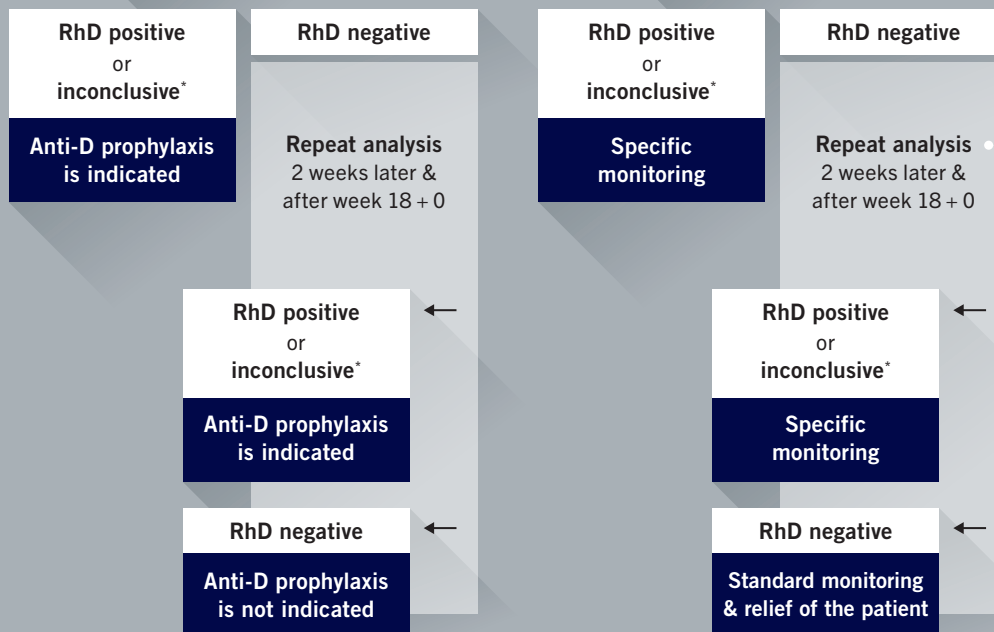
Immunised patient

Blood sampling & express delivery
(responsible doctor)

Test result
(generally 10 working days)

Timeframe for blood sampling

We recommend blood sampling latest in gestational week 25 + 0. This will ensure a test result latest in gestational week 29 – including a repetition, if necessary.



Repeat analysis to confirm a negative test result

- You will receive a special blood collection set for the repeat analysis.
- Fill both blood tubes
- Tick „repeat blood sample (if 1st analysis failed)“ on the form
- Send both blood samples together with the completed form

* due to biological limitations

1 Rouillac-Le Sciellour C et al. (2007). Noninvasive fetal RHD genotyping from maternal plasma. Use of a new developed Free DNA Fetal Kit RhDR. *Transfus Clin Biol*, 2007 Dec;14(6):572-7. doi: 10.1016/j.trcli.2008.01.003.

2 Mackie FL et al. (2017). The accuracy of cell-free fetal DNA-based non-invasive prenatal testing in singleton pregnancies: a systematic review and bivariate meta-analysis. *BJOG*, 2017 Jan;124(1): 32-46. doi: 10.1111/1471-0528.14050.

3 Instruction manual: Institut de Biotechnologies Jaques Boy. Free DNA Fetal KitR RhD. Noninvasive fetal RHD genotyping from free fetal DNA in maternal RhD-Negative pregnant women blood (Real-Time PCR). Product identification: 502080233. Manual version 16/03/2018.

4 Flegel WA (2007). Genetik des Rhesus-Blutgruppensystems. *Dtsch Arztebl* 2007, 104(10): A-651-657/B-573/C-549.

5 Thurik FF et al. (2016). Fetal RHD genotyping after bone marrow transplantation. *Transfusion*, 56: 2122-2126. doi:10.1111/trf.13669.

6 Clausen FB et al. (2014). Routine noninvasive prenatal screening for fetal RHD in plasma of RhD-negative pregnant women – 2 years of screening experience from Denmark. *Prenat Diagn*, 34:1000-1005. doi: 10.1002/pd.4419.

7 de Haas, M et al. (2012). A nation-wide fetal RHD screening programme for targeted antenatal and postnatal anti-D. *ISBT Science Series*, 7: 164-167. doi:10.1111/j.1751-2824.2012.01600.x.



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