



Free DNA Fetal Kit® RhD

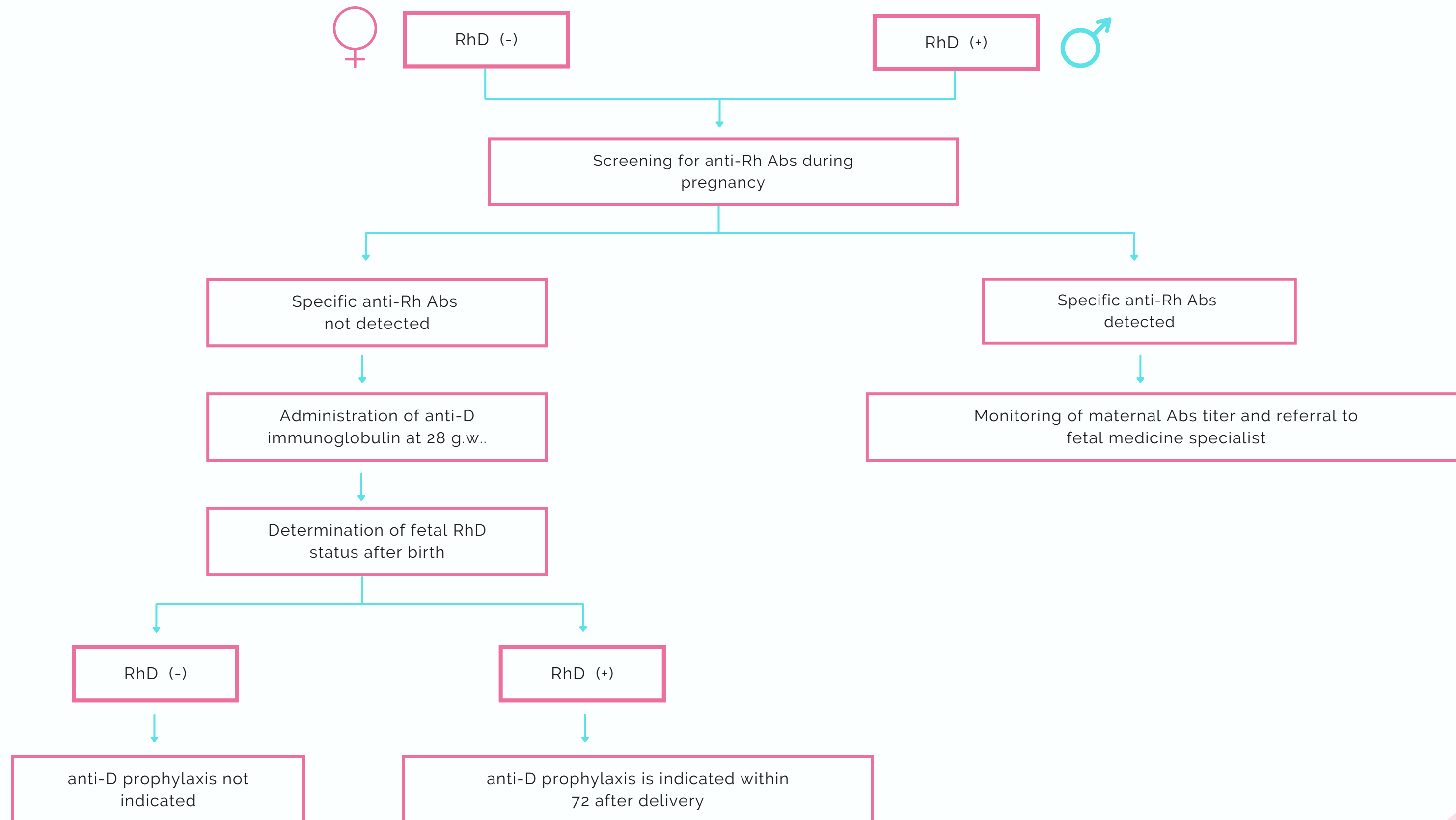
Non-invasive prenatal RhD genotyping

RhD fetal-maternal incompatibility

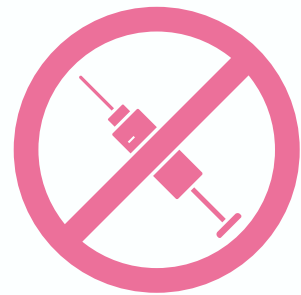
- **RhD isoimmunization** is the process of formation of antibodies in pregnant woman against antigens expressed on the surface of fetal erythrocytes. These antigens are not present on the surface of maternal's erythrocytes
- These maternally-derived antibodies can cross the placenta and enter into the fetal blood circulation thus causing **hemolysis of fetal erythrocytes** and leading to development of **fetal anemia** and **hemolytic disease of the fetus and newborn**



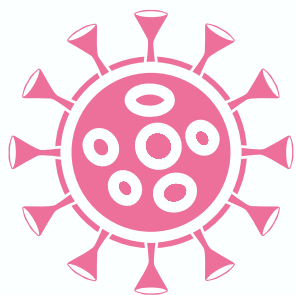
Diagnostic Algorithm



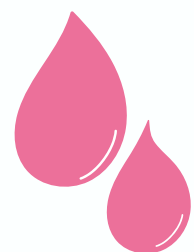
Facts and precautions on the use of anti-D immunoprophylaxis



About 40% of all RhD (-) women are carrying RhD (-) fetus and anti-D immunoprophylaxis is **not necessary** for those women



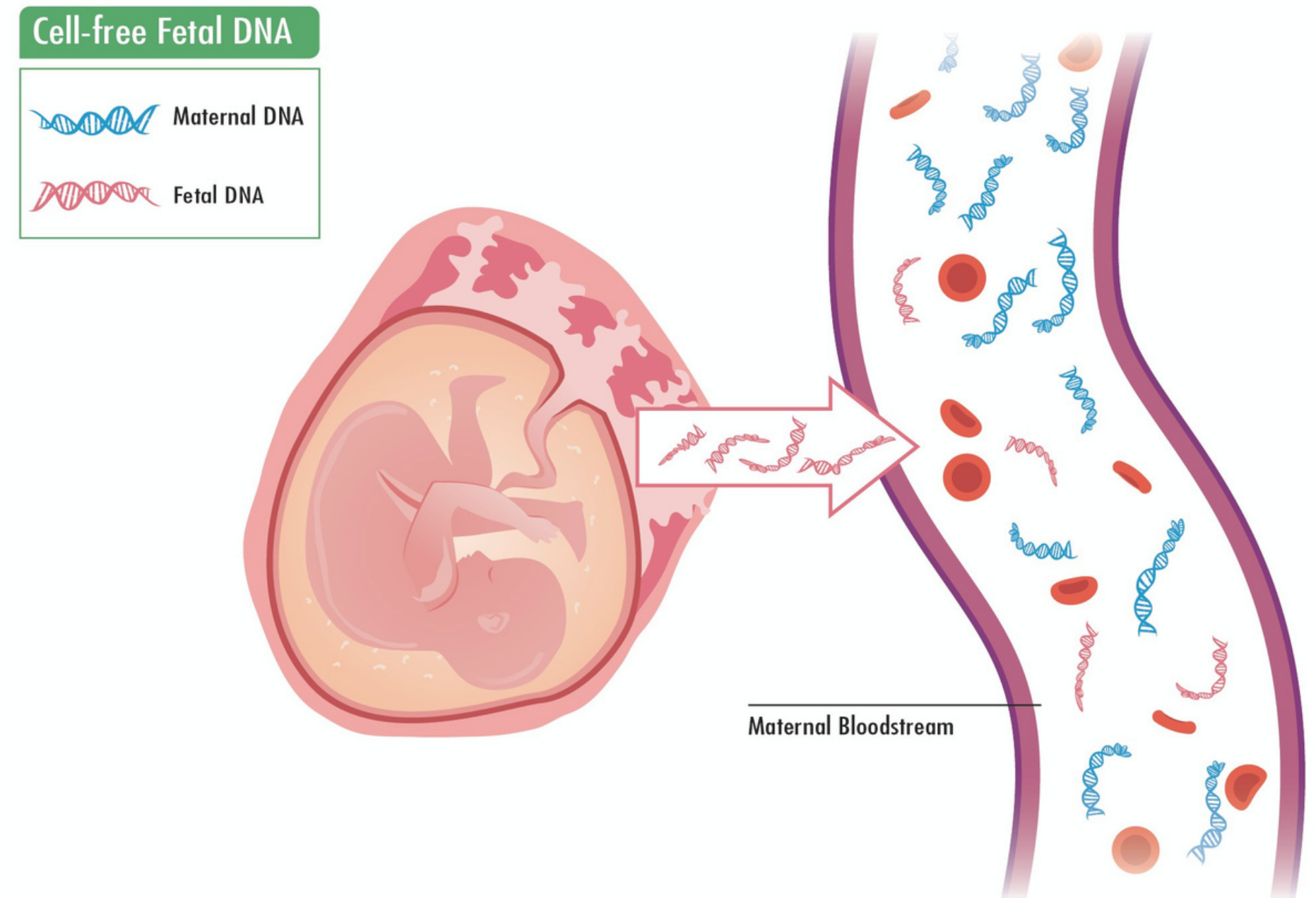
Anti-D immunoglobulin is a blood-derived product with a potential risk for transmission of **blood-borne infections (HCV, HBV, HIV and etc.)**, as well as a risk of causing **allergic reactions**



Anti-D immunoglobulin is a **limited resource** due to the decreasing number of volunteer blood donors

Non-invasive prenatal testing using cffDNA

- **cffDNA** - reaches 10-30% of the total circulating cfDNA in maternal plasma
- RhD gene cannot be detected in women with RhD **negative** status
- In these cases, the detection of RhD gene in maternal blood samples is an indication for RhD **positive** fetus



Free DNA Fetal Kit® RhD

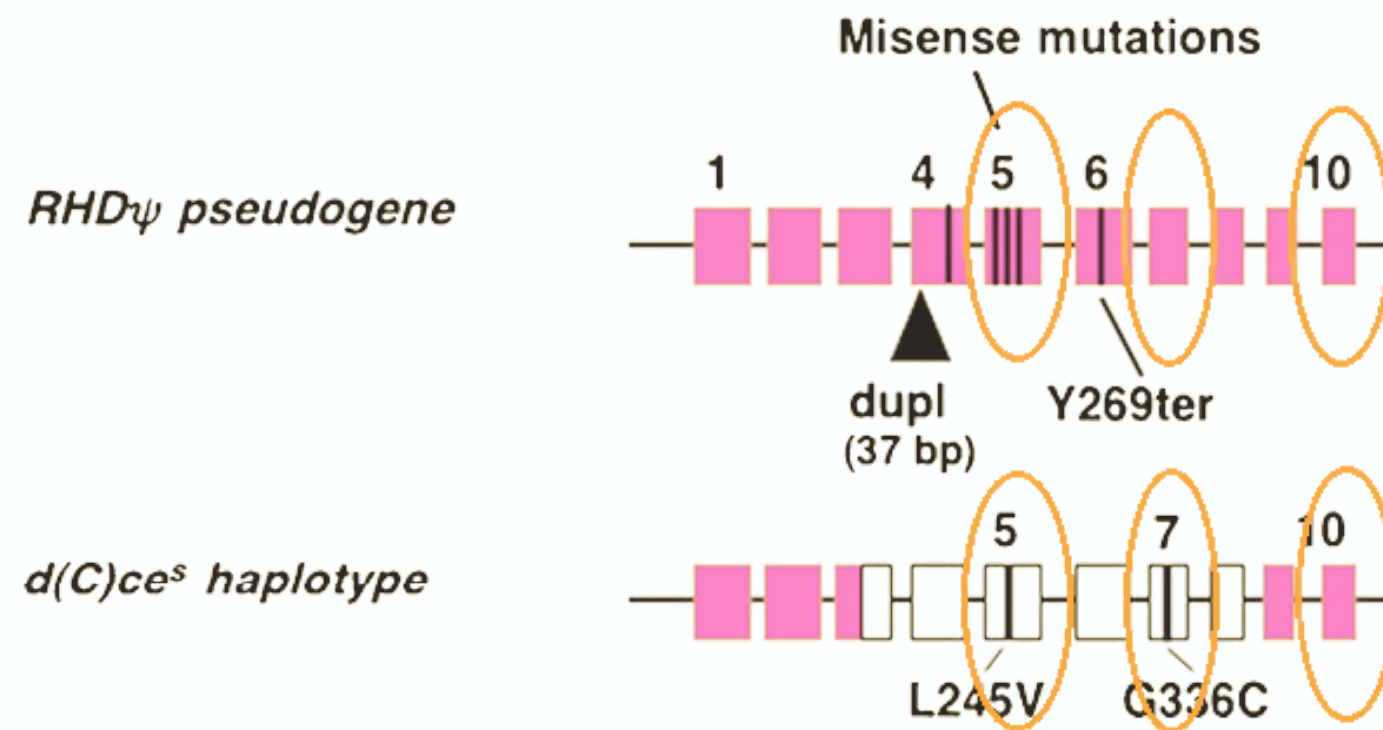
- **Non-invasive** prenatal RhD determination from a **maternal blood sample**
- **Early screening** - starting from 11 g.w.
- Detection of **3 exons** in the RhD gene - **5, 7 and 10**
- **Real-Time PCR**
- Made in **France**
- **CE-IVD** certified



Free DNA Fetal Kit® RhD

Detection of 3 RhD exons - 5, 7 and 10:

- ensures maximum sensitivity and specificity of the analysis
- allows discrimination between the most prevalent RhD variants



Free DNA Fetal Kit® RhD

Simple procedure for sampling and storage:

- Sample: venous blood sampled with EDTA tubes
- Transport and storage: at +2°C to +25°C for up to 48 h.
- Plasma is separated upon sample receipt and is aliquoted in individual 1.5/2.0 ml tubes
- Separated plasma can be stored at <-18°C for 8 months
- For **maximum diagnostic sensitivity** it is recommended to perform the sampling and analysis **during 24-28 g.w.**

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Results interpretation:

Results			Interpretation
Exon 5	Exon 7	Exon 10	
✓	✓	✓	Positive fetal RhD genotype
✗	✗	✗	Negative fetal RhD genotype
1 or 2 positive exons			Undetermined fetal RhD genotype

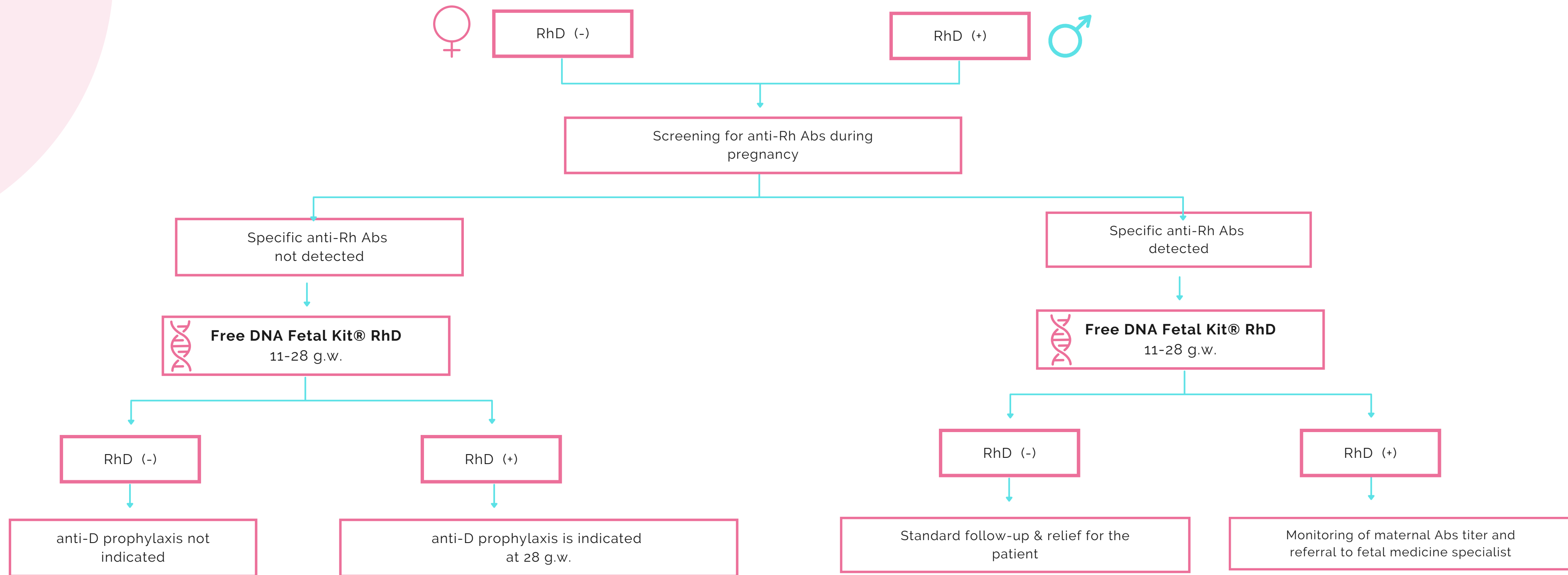
- Ct values ranging from 35 to 41 cycles are considered positive for amplification of fetal RhD gene regions
- Earlier Ct values are indication for prescence of maternal DNA in the sample, twins pregnancy or sampling at advanced gestational age

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Detection of 1 or 2 exons only is a possible indication for RhD variant

Results			Interpretation
Exon 5	Exon 7	Exon 10	
×	✓	✓	DΨ, DV, DBS, DVI
✓	×	×	DHAR
✓	×	✓	DIV
×	×	✓	dCe, DBT

Free DNA Fetal Kit® RhD - Diagnostic Strategy



Free DNA Fetal Kit® RhD - Performance characteristics

- Performance characteristics were assessed by analyzing fetal RhD genotype in **2109 pregnant women**
- All results were compared with results from RhD phenotyping test after delivery

Performance characteristics		
True positive	1450	PPV: 99.18 %
False positive	12	NPV: 100 %
True negative	609	Sensitivity: 100 %
False negative	0	Specificity: 98.07 %

Free DNA Fetal Kit® RhD - Advantages

- **Targeted anti-D immunoprophylaxis** - administration of anti-D IgG only in RhD (-) women with confirmed RhD (+) fetus
- In patients with **RhD sensibilisation** and **confirmed RhD (+) fetus** allows for identification of **high-risk pregnancies** and **the need for their careful follow up**
- Patients with **RhD sensibilisation** and **confirmed RhD (-) fetus** do not need frequent follow up and **they can have a smooth pregnancy**
- Reduces the unnecessary administration of anti-D immunoglobulin and its associated health risks and side effects

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