FetoGnost® Kit RHD

CE IVD

FetoGnost® Kit RHD			
Order no.	**Reactions**	**Exon 5, 7, 10**	**Internal positive control**
HUFG100	100	VIC+FAM+NED channel	Cy5 channel
HUFG500	500	VIC+FAM+NED channel	Cy5 channel

Kit contents:

- Detection assay for the human RHD gene exon 5, 7 and 10 gene and for the IPC (internal positive control)
- Target for DNA internal positive control (DNA IPC, control of PCR amplification and/or DNA extraction)
- DNA reaction mix for real-time PCR (contains a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs, ROX™ dye (passive reference) and buffer components – additives optimized to handle PCR inhibitors)
- DNA Positive control for exons 5, 7 and 10

Background: Rhesus factor D (RhD) or RhD antigen is the most common of the five main Rhesus antigens (C, c, D, E and e) out of 54 antigens on the surface of red blood cells. The dominant RHD gene determines whether a person is RhD-positive or -negative. Approximately 85 % of the European population is RhD-positive, around 95 % in sub-Saharan Africa and greater than 99.5 % in eastern Asia. The majority of RhD-negative Caucasians have a complete deletion of the RHD gene. In other populations such as Asians, Japanese and black Africans, the negative phenotype can also be associated with smaller genetic variations (e.g. point mutations, insertions, gene-rearrangements) resulting in non-functional RHD genes.
The prediction of the fetal RHD status is significant for the prevention of fetal hemolytic disease, where a RhD-negative mother becomes sensitized to an RHD-positive fetus causing a maternal immune response to produce IgG anti-D antibodies.

PCR-platforms: FetoGnost® Kit RHD has been validated with the ABI 7500® instrument and QuantStudio™ 7 Pro (Thermo Fisher Scientific), but is also compatible with other real-time PCR instruments capable of measuring and differentiating fluorescence in the FAM, VIC, NED, and Cy5 channels.

Description: FetoGnost® Kit RHD allows rapid, sensitive and non-invasive fetal RHD genotyping of samples purified from maternal plasma of RhD-negative pregnant women, based on real-time PCR technology (non-invasive prenatal determination of fetal RHD status, NIPT-RHD).
This test is suitable for women of all ages with gestation age ≥11+0 with singleton or multiple pregnancies.
The test can be used both in a first pregnancy and in subsequent pregnancies. It allows targeted anti-D prophylaxis in RhD-negative pregnant women without anti-D alloimmunization.

Contraindications:

- Pregnant women with anti-D alloimmunization. The immunization status of the pregnant woman should be known before starting the test.
- The test is not suitable for samples taken before gestation age 11+0. The limited performance of the test prior to gestation age ≥11+0 must be indicated on the report.
- The test is not intended for Rhesus D determination of transfusion recipients and blood donors.

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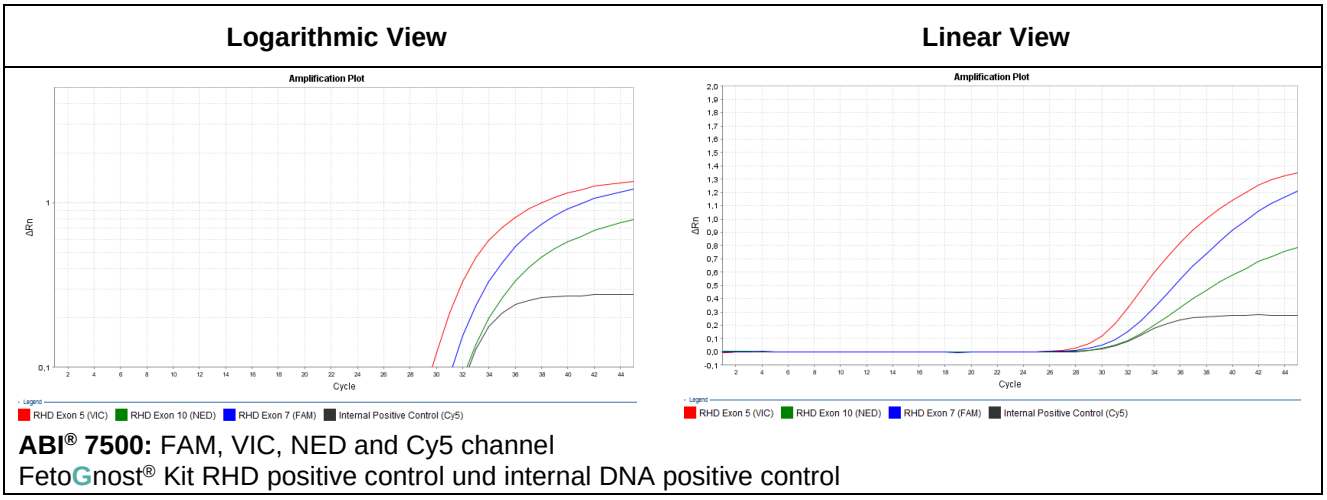
Three probe-specific amplification-curves at in VIC, FAM and NED channel indicate the amplification of exon 5, exon 7 and exon 10 of the RHD gene, respectively. In addition, an internal positive control (IPC) with detection in Cy5 channel monitors the integrity of kit reagents, serves as a control for DNA extraction and excludes false-negative interpretation of results due to inhibition of real-time PCR. The target for the IPC is added during DNA extraction of maternal plasma samples.
The sensitive and robust multiplex test format for the detection of three exons of the RHD gene in triplicates minimizes false-negative results. The sampling shall be after gestation age ≥11+0.

Sensitivity and specificity: The detection limit (LoD95: number of copies, which are positively detected in 95% of cases) for exon 5, 7, and 10 detection is 13, 8, and 7 target copies/reaction, respectively. The test is 100% specific for human RHD gene exon 5, 7 and 10. The diagnostic sensitivity is 99.93% and the diagnostic specificity is 99.61%.



ABI® 7500: FAM, VIC, NED and Cy5 channel
FetoGnost® Kit RHD positive control und internal DNA positive control

Figure 1 Performance of FetoGnost® Kit RHD

References:

- Legler TJ.; Müller SP.; Haverkamp A.; Grill S.; Hahn S. 2009. Prenatal RhD Testing: A Review of Studies Published from 2006 to 2008. Transfus Med Hemother. 36:189-198
- Legler, T.J., Lührig, S., Korschineck, I. and Schwartz, D. 2021. Diagnostic performance of the noninvasive prenatal FetoGnost RhD assay for the prediction of the fetal RhD blood group status. Archives of Gynecology and Obstetrics. 2021 Apr 9 (doi:10.1007/s00404-021-06055-1. Epub ahead of print)
- Müller SP, Bartels I, Stein W, Emons G, Gutensohn K, Köhler M, Legler TJ. 2008. The determination of the fetal D status from maternal plasma for decision making on Rh prophylaxis is feasible. Transfusion. 48:2292-301.

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