FetoGnost® Kit Control

For research use only

FetoGnost® Kit Control		
Order no.	**Reactions**	**Maternal and Fetal marker**
HUFG050	50	VIC+FAM+NED channel

Kit contents:

- Detection assay for one maternal und two fetal marker genes
- 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 maternal und fetal marker genes

Background: Cell-free fetal DNA (cffDNA) is highly fragmented genetic material of the fetus (< 300 bp), that crosses the placenta and circulates in the maternal blood. DNA from fetal sources comprises only a small portion of total circulating cell-free DNA (ccfDNA) rising from 3 % in early to 12 % in late pregnancy. In plasma samples taken during the second trimester of pregnancy the concentration of cffDNA can range from 50–200 genome equivalents of cffDNA/ml of blood. Methods in molecular biology enable the detection of minute amounts of circulating cffDNA (Lo et al., 1998).

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

Description: FetoGnost® Kit Control allows the non-invasive detection of fetal cell-free DNA (cffDNA) in samples purified from maternal plasma of pregnant women, based on multiplex real-time PCR technology. The test is exclusively intended for the validation of suitable extraction methods for the purification of cffDNA from maternal plasma. The sampling shall be after gestation age ≥11+0.
The detection of cffDNA by FetoGnost® Kit Control depends on a restriction enzyme digest of an aliquot of sample eluate to remove maternal DNA. The digested DNA sample is subsequently tested with real-time PCR. Probe-specific amplification curves in fluorescence channels for FAM, NED and VIC detect the amplification of two fetal markers and maternal marker, respectively.
When testing plasma samples in triplicates and controls in duplicates, the content of one kit allows the analysis of 15 plasma samples.

Sensitivity: The detection limit (LoD95: number of copies, which are positively detected in 95% of cases) for the maternal marker and the two fetal markers is 15, 20 and 8 target copies/reaction, respectively.

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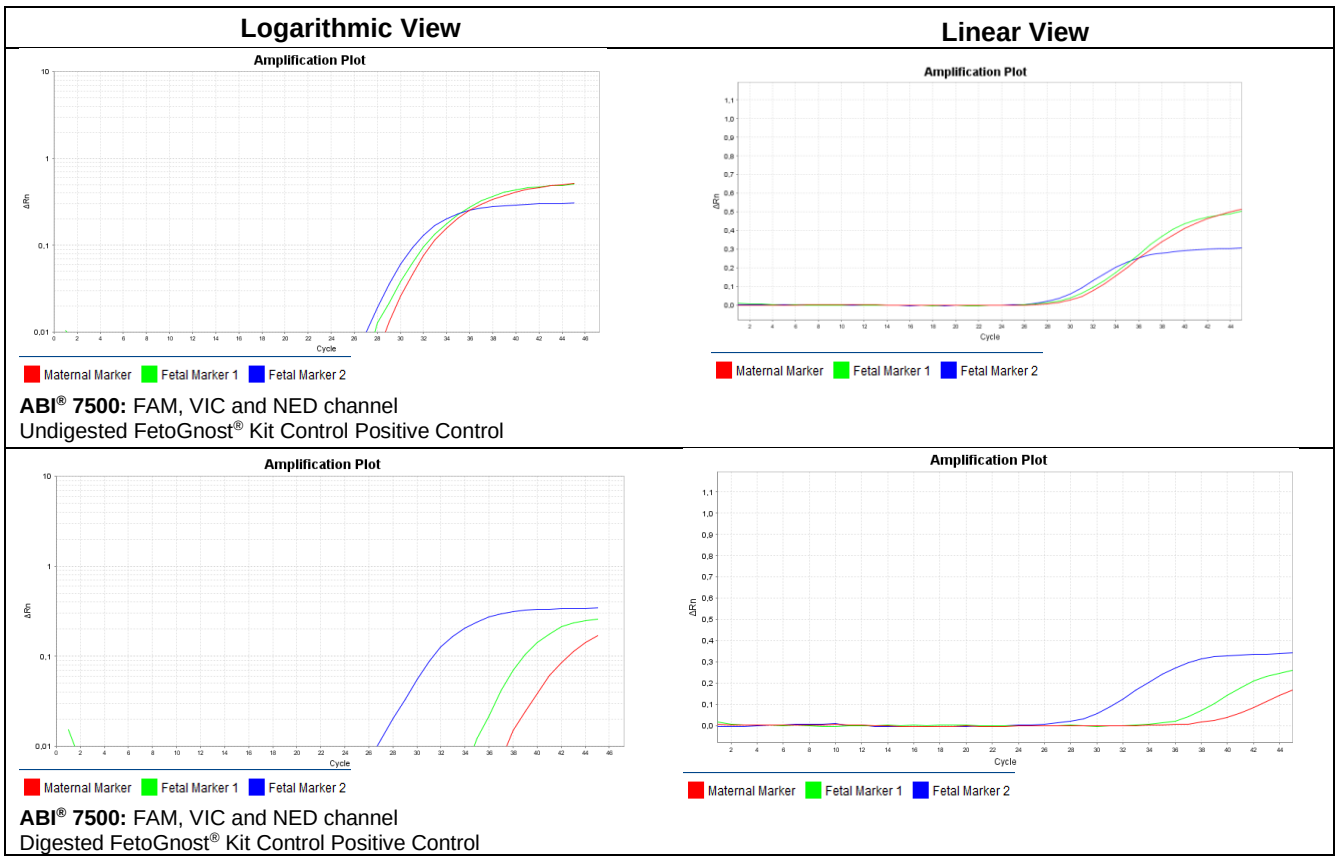
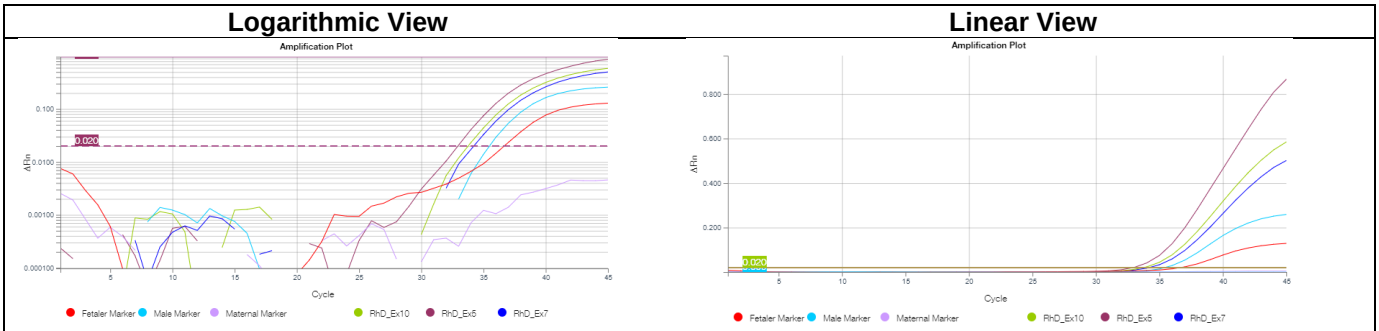


ABI® 7500: FAM, VIC and NED channel
Undigested FetoGnost® Kit Control Positive Control

ABI® 7500: FAM, VIC and NED channel
Digested FetoGnost® Kit Control Positive Control

Figure 1



QuantStudio™ 7 Pro: FAM, VIC and NED channel
Example for analysis of maternal plasma positive with fetal RHD cffDNA with FetoGnost® Kit Control and FetoGnost® Kit RHD

Figure 2

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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