

Devyser RHD

Devyser RHD is a real-time PCR assay designed for the noninvasive determination of fetal RHD status. This high-sensitivity test simplifies workflows and allows clinicians to provide targeted anti-D prophylaxis.

IVDR

risk class D

10th

week of pregnancy

12 years

in use

100,000+

people tested

High diagnostic sensitivity and specificity

Proven sensitivity of 99.99%¹ from gestation week 10. Demonstrated accuracy and robustness across diverse populations and clinical settings².

Unique single-exon design

Simplified workflow optimized for high-throughput screening—fewer ambiguous or contradictory results, and low rerun rates.

Easy implementation

Compatible with multiple PCR platforms and suitable for automation, minimizing hands-on time and enabling seamless integration.

The single-exon design results in high sensitivity and simple response algorithms.

Prof. Agneta Wikman, M.D., PhD.
Karolinska University Hospital, Stockholm

Modern screening for targeted treatment

$\geq 99.9\%$

Diagnostic sensitivity

$\geq 99.8\%$

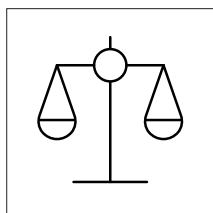
Diagnostic specificity

$\geq 99.8\%$

Correlation to Rhesus serology of the newborn

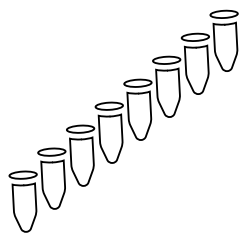
Data from our large validation study confirming compliance with strict safety, performance, and quality criteria.

Ethical and resource-conscious



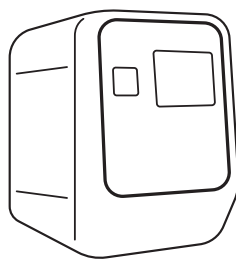
Continuing to administer RhIG unnecessarily, when RHD genotyping offers a reliable alternative, is increasingly seen as ethically problematic. Because RhIG is derived from a limited pool of human donors and subject to global shortages, targeted use through genotyping helps preserve this critical resource for patients who truly need it.

Simple workflow



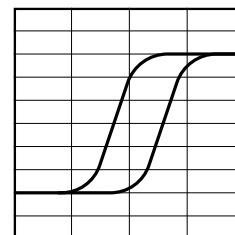
Devyser RHD assay setup

Mix DNA extracted from maternal plasma with kit components



Real-time PCR run

Clinical samples are run and amplification data displayed in real time



Data analysis

Analysis of raw data and determination of fetal RHD status

Devyser products are distributed worldwide. Not all intended uses and applications mentioned here are available in every country. Please consult your local sales representative for details

References

1. Isakson, P., & Pardi, C. (2023). Evaluation of an automated platform for non-invasive single-exon fetal RHD genotyping early in pregnancy. *Blood Transfus*, 21, 472-478.
2. Uzunel, M., Tiblad, E., Mörtberg, A., & Wikman, A. (2022). Single-exon approach to non-invasive fetal RHD screening in early pregnancy: An update after 10 years' experience. *Vox Sanguinis*, 117(11), 1296-1301.

Article numbers

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| Devyser RHD IVDR kit
78 tests (8-R060-78)
390 tests (8-R060-390) | Devyser RHD RUO kit
78 tests (8-A406)
390 tests (8-A460-390) |
| Devyser RHD IVDD kit
78 tests (8-A060)
390 tests (8-A060-390) | Devyser RHD IVD CA kit
78 tests (8-A060-78-CA)
390 tests (8-A060-390-CA) |

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