Devyser Extend v2

Designed for accuracy, speed and ease of use

Key advantages of the Devyser Extend v2:

- Forty-two (42) genetic markers for analysis of chromosomes 13, 15, 16, 18, 21, 22, X and Y
- No tissue culture needed
- Built-in ID marker enables cross-mix sample identity confirmation
- No misdiagnosis due to maternal contamination and cell overgrowth
- Cost-effective solution with less hands-on time required
- Proven QF-PCR technology

Early pregnancy loss

Early pregnancy losses affect up to 15% of clinically recognized pregnancies. Many factors can cause embryo loss, but it is well recognized that a majority of early spontaneous abortions result from chromosomal abnormalities and that up to 96% of these are numerical chromosome abnormalities. The most frequently observed numerical chromosomal abnormalities involve chromosomes 13, 15, 16, 18, 21, 22 and X.

Women who have undergone one or more spontaneous abortions caused by chromosomal abnormalities are at increased risk for chromosomal abnormalities in future pregnancies. Cytogenetic studies of miscarriages are highly recommended even in the case of the first spontaneous abortion. Identification of the possible cause of fetal loss significantly reduces longterm psychological distress in women with a miscarriage and enables improved genetic counseling for those couples in future pregnancies.

The Devyser Extend v2 diagnostic kit

Conventional cytogenetic studies (karyotyping or FISH) are expensive and need a long period of time in order to obtain results. Moreover, they result in high rates of culture failure, misdiagnosis due to maternal contamination and cell overgrowth as as well as insufficient quality of chromosome preparations. Cell culture may selectively yield normal karyotypes or selected abnormal karyotypes that survive in-vitro cell proliferation.

Recent studies have shown that QF-PCR can serve as a complementary method in cytogenetic studies of spontaneous abortions. The QF-PCR technology is also proven to be a fast, reliable and cost-efficient technique for diagnosis of chromosomal aneuploidies in prenatal samples. QF-PCR does not require cell culture, requires very small amounts of tissue material and allows the lab to obtain results within one working day.

The Devyser Extend v2 kit includes 42 genetic markers for aneuploidy analysis by QF-PCR of chromosomes 13, 15, 16, 18, 21, 22, X and Y.

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Technical Specification

Intended Use	The Devyser Extend v2 kit is an in vitro diagnostic product for detection of whole chromosome aneuploidies of chromosomes 13, 15, 16, 18, 21, 22, X and Y
CE -labelled for IVD use	Yes
Detection format	ABI Prism 310, 3100, 3130, 3500, 3730
Complies with Best Practice guidelines for QF-PCR	Yes
Total number of markers	42 genetic markers in two multiplex PCR reactions (Full kit: 8-A015.2) or 15 markers for chromosomes 15, 16 and 22 in one mix (Devyser Extend M1 v2 kit: 8-A015.2-M1)
Reaction volume	25 µL
DNA input	10 – 20 ng / PCR reaction is recommended for optimal results
Ready to use for PCR	Yes
Kit size	25 test
Article id	**Devyser Extend v2 (8-A015.2):** For detection of chromosomes 13, 15, 16, 18, 21, 22, X and Y. **Devyser Extend M1 v2 (8-A015.2-M1)**: For detection of chromosomes 15, 16 and 22.

About Devyser

Devyser AB is specialized in the development, manufacturing and sales of diagnostic kits and reagents based on DNA analytical procedures, including PCR.

Devyser AB operates under strict quality control protocols and has an ISO13485:2003 (medical device) certification. Products are CE-labelled according to IVDD 98/79/EC for use in in-vitro diagnostic procedures. The main areas of application for our products are prenatal diagnostics and clinical genetics.

Devyser
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