Devyser

Devyser CFTR Core

Designed for accuracy, speed and ease of use

Key benefits of Devyser CFTR Core

- Designed for testing European populations
- Detects normal and mutant alleles
- Determination of intron 9 (IVS8) poly-T and TG repeat number
- Built-in ID marker enables cross-mix sample identity confirmation
- Cost-effective solution with less hands-on time required

Cystic Fibrosis and CFTR

Mutations in the CFTR gene may cause Cystic Fibrosis (CF). One in 25 people of European descent carries a mutated CFTR allele and 1 in 2000–3000 newborns is found to be affected by CF. CFTR mutation testing can be used as an aid in newborn screening, CF diagnosis, and reproductive decisions, allowing clinicians to determine if an abnormal diagnostic result is due to a mutation within the CFTR gene. Other disorders caused by CFTR dysfunction include male infertility caused by CBAVD and acute recurrent or chronic pancreatitis.

Cystic Fibrosis Molecular Diagnostics

More than 1900 mutations and variants in the CFTR gene have been described. The vast majority of mutations have a population frequency below 0,1 % with high heterogeneity of mutation distribution between different ethnic groups. The Devyser CFTR Core kit has been designed to detect the most common mutations found across populations of European origin.

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The Devyser CFTR-Core kit is designed to genotype the normal and mutant alleles at 33 loci of the CFTR gene using purified human genomic DNA. Genotype coverage includes a panel of 36 mutations to support genetic diversity of multiethnic European populations. The assay also detects polythymidine variants (5T/7T/9T) within intron 9 (IVS8) of the CFTR gene. In case of a 5T allele, the TG repeat number upstream of the poly-T region can also be determined.

The Devyser CFTR Core kit is based on multiplex allele specific PCR amplification for detection of normal, non-mutated, and mutated alleles in the CFTR gene. Allele specific PCR amplification generates fluorescently labelled fragments that are analysed by capillary electrophoresis on a Genetic Analyzer instrument. Amplified fragments are identified based on size and fluorescent labels.

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Technical Specification

Intended Use	The Devyser CFTR Core kit is intended for qualitative genotyping of a panel of normal and mutated alleles in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human genomic DNA.
CE - labelled for IVD use	Yes
Compatible Genetic Analysers:	ABI 310, 3100, 3130, 3500, and 3730
Ready to use for PCR	Yes
Kit size	48 test
Article No.	8-A031
Accessories	DNA Size marker: 560 SIZER ORANGE (Art. No.: 8-A402)
Mutations detected	711+1G>T, 3120+1G>A, 621+1G>T, 1717-1G>A, CFTRdele2,3(21kb), 3849+10kbC>T, 2789+5G>A, 1898+1G>A, G542X, G85E, Y1092X(C>A), G551D, R553X, 3659delC, N1303K, R560T, R117H, R1162X, L1077P, R117C, R1066C, L1065P, W1282X, R347H, R347P, I507del, T338I, F508del, I336K, 1677delTA, R334W, 3272-26A>G, 1078delT, 2183AA>G, 2184insA, 2143delT, IVS8: 5T (TG9-13), 7T, 9T

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 ISO13485:2012 (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 genetic testing.

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