

Cystic fibrosis

# Devyser CFTR Core

## Discover the advantages

- 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 every 2,000-3,000 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, enabling clinicians to determine if an abnormal diagnostic result is due to a mutation within the CFTR gene. Other disorders related to CFTR dysfunction include male infertility caused by CBAVD and acute recurrent or chronic pancreatitis.

## Cystic fibrosis molecular diagnostics

More than 2,000 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.

## A complete CFTR kit for first level mutation screening

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 poly-thymidine 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 analyzed by capillary electrophoresis on a Genetic Analyzer instrument. Amplified fragments are identified based on size and fluorescent labels.

**Devyser. Results for life.**

*Devyser is specialized in the development, manufacture and sales of diagnostic kits for complex DNA testing within Oncology, Reproductive Health and Hereditary Diseases. The products are used to guide targeted cancer therapies, to enable rapid prenatal diagnostics as well as in a wide array of genetic tests. Devyser's product development focuses on simplifying and streamlining complex testing processes to improve throughput, reduce hands-on time and produce accurate and trusted results.*



## Technical specifications

### Intended use:

Qualitative genotyping of a panel of normal and mutated alleles in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human genomic DNA

### GE-labelled for IVD use

### Compatible Genetic Analysers:

Thermo Fisher's capillary electrophoresis instruments: ABI 310, ABI 3130, ABI 3500, ABI 3730

### Ready to use for PCR

### Kit size:

48 tests

### Article number:

8-A031

### DNA Size marker:

560 SIZER ORANGE

### Mutations detected:

711+1G>T, 3120+1G>A, 621+1G>T, 1717-1G>A, CFTR-dele2,3(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

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