HEREDITARY

Cystic fibrosis

# Devyser CFTR for NGS

## Discover the advantages

- Detect all mutations in the CFTR gene
- One tube per sample means no need for sample splitting
- Reduce hands-on time from days to under 45 minutes
- Direct detection of frequent CNVs
- Determination of poly-T and TG repeats
- Choice of several validated software options, including CNV analysis

## Designed for routine NGS diagnostics

The Devyser CFTR kit is easy to implement and highly cost-effective, making it a good match for laboratories of any size. With ready-to-use reagents and a user-friendly workflow, it suites both manual and automated workflows. Devyser's unique single-tube approach simplifies the workflow, reduces hands-on time and minimizes the risk of sample mix-up and contamination. The proprietary multiplex PCR primer chemistry provides full and uniform coverage of the CFTR gene. Coverage includes all exons and exon/intron junctions, the promoter region and several clinically relevant deep intronic mutations. Overlapping primer design is used to ascertain superior INDEL and primer site mutation coverage as well as downstream CNV analysis. In addition, the kit also allows analysis of poly-T variants along with the upstream TG-repeat region.

## Analytical software options

Laboratories have a choice of fully validated analytical software solutions, locally deployed or cloud-based. Both include our validated level1 mutation filter based on CFTR2. We also support integration with other analytical software solutions.

## Complete CFTR gene characterization by NGS

CFTR mutation testing can be used to guide targeted therapies, in newborn screening, CF diagnosis, male infertility caused by CBAVD, and acute recurrent or chronic pancreatitis. More than 2,000 mutations and variants in the CFTR gene have been described. The vast majority of these mutations have a population frequency below 0.1 % with high heterogeneity of mutation distribution between different ethnic groups. Devyser's CFTR NGS kit enables the detection of all mutations, known and unknown, in a single test.

Watch video at www.devyser.com/ngs

## Technical specifications

**Intended use:**
The Devyser CFTR kit is an in vitro diagnostic product for detection of mutations in the CFTR gene.

**Assay procedure:**
Targeted sample library preparation. Standardized sample barcoding and sample pooling for NGS.

**Compatible NGS instruments:**
Illumina NGS instruments

**DNA input:**
10 ng/sample. From whole blood or DBS punch

**Article number:**
8-A101-8: Devyser CFTR 8-test
8-A101-24: Devyser CFTR 24-test

**Procedures included in assay:**

- Targeted library preparation
- Sample indexing/molecular barcoding
- Sample clean-up and pooling

## Contact

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*Devyser. Results for life.*

*We're specialists in diagnostic kits for complex DNA testing within oncology, reproductive health and hereditary diseases. Our products are used to guide targeted cancer therapies, to enable rapid prenatal diagnostics, as well as in a wide array of genetic tests. We have a guiding principle when it comes to developing products that are ideal for routine diagnostics: make the technology simple, reproducible and less prone to user-generated errors. And this is precisely what our customers appreciate about us, which is why routine diagnostic laboratories in more than 50 countries worldwide use our products.*

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# DEVYSER CFTR NGS

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|---|---|
| 100 % Bases covered | <5 Time required in hours |
| 100 % Coverage uniformity >20% mean | <45 000 Recommended # of reads per library |
| ≥94 % Coverage uniformity >50 % mean | 188 bp Average target amplicon length |
| 100 % CFTR2 mutations covered | 10 ng Input DNA required |
| ≥95 % On-target reads | <45 Hands-on time in minutes |
| 10 kB Total target size | Illumina® Platform |

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