

# Cystic Fibrosis Screening

## Yourgene® Cystic Fibrosis Range



### Cystic Fibrosis *Base*: Pair with our *Plus* range for comprehensive Cystic Fibrosis screening

A range of Cystic Fibrosis tests for newborn screening and carrier screening utilising **ARMS (Amplification-Refractory Mutation System)** technology. Our range of *Base*, *Plus* and *Lite* tests can be used in combination to cover a wide range of mutations grouped by relevance for named regions of European descent.

#### Key Benefits

##### Carrier testing and newborn screening for CFTR gene mutations

##### CE-IVDR certified

- High quality, fully validated and regulated product requires minimal validation to fit into your workflow

##### Rapid Workflow

- Fast workflow enables rapid delivery of results, enabling laboratories to maintain best service TAT
- Patients receive results quickly, permitting timely downstream management

##### Single Tube Assay

- Simple to use; just add DNA
- Fewer reagents to improve economies of testing

##### Reliable Performance

- Optically balanced primers to maximise ease-of-interpretation and reduce analysis burden

##### Compatible with ABI 3130/3500/SeqStudio Genetic Analyser Platform

- Developed for maximum compatibility with existing workflow

##### Aligned to clinical guidelines and pathways

- Meaningful results for appropriate clinical management

The Yourgene® Cystic Fibrosis *Base* assay has received IVDR certification!

A product with IVDR certification enables clinician and patient confidence in a high quality test - where accuracy matters

Yourgene®  
Cystic Fibrosis  
*Base*

#### Clinical Performance

Performance you can rely on

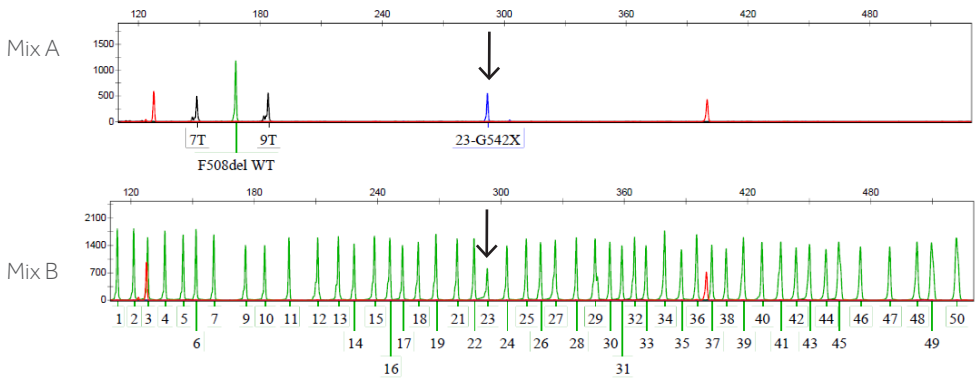
# 100%

Accuracy, Repeatability & Reproducibility



## Data Interpretation

Figure 1. Example Result – Heterozygous G542X result (G542X/+)



Scan the QR code to view the mutations covered by Yourgene® Cystic Fibrosis Base



- Green peaks represent wild type alleles for each screened position in Mix B (except for F508del in Mix A).
- Blue peaks appear when a mutation is present in Mix A.
- Black peaks indicate intron 9 polyT status (Mix A).
- In this example, the presence of both green and blue peaks at position 23 for G542X indicates a heterozygote status for the patient. PolyT status is 7T/9T.

## Ordering Information

## Cystic Fibrosis Base: Pair with our *Plus* range

| Product Name                           | Part Code | Description   | Pack Size |
|--|-----------|---|-----------|
| Yourgene® Cystic Fibrosis Base (IVDR)  | CFEU2B2   | Yourgene® Cystic Fibrosis Base for qualitative detection of 50 Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations, common in European populations.                               | 50 Tests  |
| Yourgene® Cystic Fibrosis Lite         | CF4HTB1   | Yourgene® Cystic Fibrosis Base Lite for qualitative detection of 4 Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations, common in European populations                            | 25 Tests  |
| Yourgene® Cystic Fibrosis Base France  | CF030B1   | Yourgene® Cystic Fibrosis Base France for qualitative detection of 29 Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations, common in French populations                           | 25 Tests  |
| Yourgene® Cystic Fibrosis Base Germany | CF1DEB2   | Yourgene® Cystic Fibrosis Base Germany for qualitative detection of 31 Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations, outlined by the G-BA for newborn screening in Germany | 50 Tests  |
| Yourgene® Cystic Fibrosis Plus UK      | CF1UKB1   | Yourgene® Cystic Fibrosis Plus UK can be used with Yourgene Cystic Fibrosis Base to increase mutation coverage for an additional 11 mutations common in British populations                             | 25 Tests  |
| Yourgene® Cystic Fibrosis Plus Iberian | CFIBNB1   | Yourgene® Cystic Fibrosis Plus Iberian can be used with Yourgene Cystic Fibrosis Base to increase mutation coverage for an additional 12 mutations common in Iberian populations                        | 25 Tests  |
| Yourgene® Cystic Fibrosis Plus Italian | CFITAB1   | Yourgene® Cystic Fibrosis Plus Italian can be used with Yourgene Cystic Fibrosis Base to increase mutation coverage for an additional 14 mutations common in Italian populations                        | 25 Tests  |

The Yourgene® Cystic Fibrosis Base assay is CE marked in accordance with the IVDR.  
The other assays in the Yourgene® Cystic Fibrosis Range are CE marked in accordance with IVDD.

Yourgene® Cystic Fibrosis Base and Yourgene® Cystic Fibrosis Plus Iberian is also available as Research Use Only (RUO)

### For further information

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Yourgene Health

Check out our Reproductive Health portfolio:

- Male Factor Infertility
- Rapid Aneuploidy Analysis
- Pregnancy Loss
- Thrombosis Risk Panel



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