# INNO-LiPA™ *CFTR*iage\*

A simpler, more powerful concept for CFTR testing





# INNO-LiPA™ CFTRiage

## **Detects 88 mutations for Cystic Fibrosis**

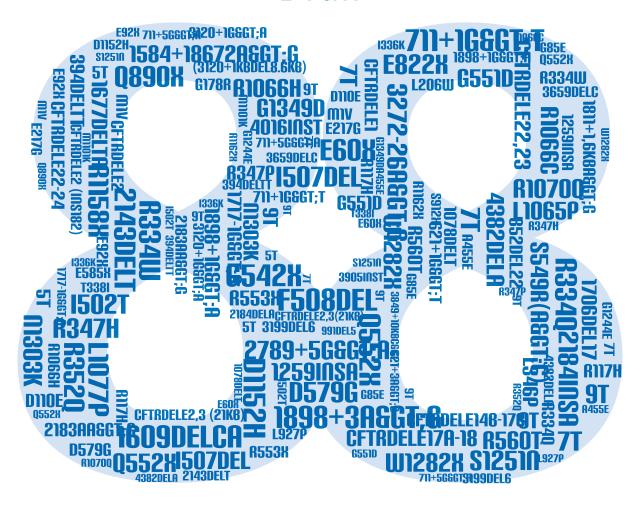
For nearly 30 years, Fujirebio has been developing tests for genetic testing of Cystic Fibrosis.

Thousands of couples and patients have been screened with the help of Fujirebio INNO-LiPA CFTR products, improving their prognosis for this life-threatening inherited disease.

Early diagnosis is important and labs look for easy and cost-effective solutions for fast and high-quality results. To meet these demands Fujirebio developed INNO-LiPA *CFTR*iage. This patented approach, uses only **one amplification** in a **single run**, while covering 88 of the world's most frequent mutations with a **detection rate of > 91,7%**¹.

The ideal solution for easy, routine genetic testing in a multi-ethnic world.

# 1 amplification 1 run



### BENEFITS OF THE PRODUCT

### UNIQUE AND PATENTED ALL-IN-ONE PRINCIPLE

- Simultaneous detection of 88 mutations and rearrangements
- Mutant and wild type sequences for frequent mutations
- Differentiation between homozygous and heterozygous results
- 5T/7T/9T testing

### **CONFORMS WITH CURRENT REGULATIONS AND LOCAL GUIDELINES**

- More than 91,7% detection rate1
- All mutations > 1% frequency included
- Frequent European mutations included
- · ACMG recommended mutations included

#### **EASY AND EFFICIENT**

- Validated for whole blood, dried blood spots, and buccal brushes
- A single amplification reduces hands-on time
- Automated or manual processing available
- LiRAS™ for LiPA™ Cystic Fibrosis v5 software automates interpretation and archives results
- More than 95% conclusive results with a single analysis

| CFTRiage           |              |                  |                      |                  |  |
|--------------------|--------------|------------------|----------------------|------------------|--|
| 19                 | 17 + Tn      | Italian Regional | Deletions + 6        | Extra            |  |
| F508del*           | 621+1G>T*    | 1259insA         | CFTRdele1            | M <sub>1</sub> V |  |
| G542X*             | 3849+10kbC>T | 4016insT         | CFTRdele2 (ins182)   | E92X             |  |
| N1303K*            | 2183AA>G     | 4382delA         | CFTRdele2            | D110E            |  |
| W1282X*            | 394delTT     | 852del22         | CFTRdele2,3 (21kb)** | G178R            |  |
| G551D*             | 2789+5G>A*   | D579G            | CFTRdele14b-17b      | 712-1G>T         |  |
| 1717-1G>A*         | R1162X       | G1244E           | CFTRdele17a-18       | L206W            |  |
| R553X              | 3659delC     | G1349D           | (3120+1kbdel8.6kb)   | 1336K            |  |
| CFTRdele2,3(21kb)* | R117H*       | 1502T            | CFTRdele22.23        | L346P            |  |
| 1507del            | R334W        | L1065P           | CFTRdele22-24        | R352Q            |  |
| 711+1G>T           | R347P        | R1158X           | 1677delTA            | 1609delCA        |  |
| 3272-26A>G         | G85E         | T338I            | 1706del17            | 1584+18672A>G    |  |
| 3905insT           | 1078delT     | S549R(A>C)       | E585X                | 1811+1,6kbA>G    |  |
| R560T              | A455E*       | 991del5          | L1077P               | 2184insA         |  |
| 1898+1G>A          | 2143delT     | D1152H           | R1066C               | E822X            |  |
| S1251N             | E60X         | 1898+3A>G        | S912X                | Q890X            |  |
| 3199del6           | 2184delA     | R1070Q           |                      | Y1092X(C>A)      |  |
| 3120+1G>A          | 711+5G>A     | R1066H           |                      | M1101K           |  |
| Q552X              |              | R347H            |                      | 4374+1G>A        |  |
|                    | 5T           | 621+3A>G         |                      | Additional       |  |
|                    | 7T           | E217G            |                      | Additional       |  |
|                    | 9T           | R334Q            |                      | L927P*           |  |

<sup>\*</sup> For the 12 most frequent mutations, INNO-LiPA *CFTR*iage detects both the mutation and the wild type, allowing for immediate discrimination between heterozygous and homozygous results.

<sup>\*\*</sup> CFTRdele2,3 (21kb) is both present on CFTR19 Strip and on CFTR Deletions + 6 Strip.

<sup>1.</sup> Based on the CFTR2 database March 2019 (www.CFTR2.org).

## **ORDERING INFORMATION**

| Product                                 | Product description        | Article No |  |  |
|---|----------------------------|------------|--|--|
| INNO-LiPA <i>CFTR</i> iage OneAmp Kit*  | 20 tests/kit               | 80596      |  |  |
| INNO-LiPA <i>CFTR</i> iage Strips*      | 20 tests/kit               | 80577      |  |  |
| INNO-LiPA CFTRiage Buffer Kit*          | 20 tests/kit               | 80595      |  |  |
| INNO-LiPA CFTR19 Strips*                | 20 tests/kit               | 80580      |  |  |
| INNO-LiPA <i>CFTR</i> 17 + Tn Strips*   | 20 tests/kit               | 80581      |  |  |
| INNO-LiPA CFTR Italian Regional Strips* | 10 tests/kit               | 80579      |  |  |
| INNO-LiPA CFTR Deletions + 6 Strips*    | 10 tests/kit               | 80578      |  |  |
| INNO-LiPA CFTR Extra Strips*            | 10 tests/kit               | 80582      |  |  |
| Software                                |                            |            |  |  |
| LiRAS™ for LiPA™ Cystic Fibrosis v5*    | CD-ROM                     | 80535      |  |  |
| Automation                              |                            |            |  |  |
| Auto-LiPA™ 48                           | Strip Processor (up to 48) | 80628      |  |  |
| TENDIGO™                                | Strip Processor (up to 10) | 80412      |  |  |

 $<sup>^{\</sup>star}$  All INNO-LiPA  $\textit{CFTR}\xspace$  products are not yet available as CE marked products

