Luminex

Luminex® 100™ and Luminex® 200™ Systems

39 TARGETS 60 TARGETS

xTAG® Cystic Fibrosis (CFTR) 39 kit v2 and 60 kit v2

Your Choice for Cystic Fibrosis Testing

The benefits of xTAG® Cystic Fibrosis Kits include:

- **Comprehensive** - Mutation coverage, including ACMG/ACOG recommended panel. Multiplex genotyping - no reflex testing necessary.
- **Flexibility** - Mutation panel selection through the software.
- **Confidence** - Second generation IVD assay with 100% overall accuracy* and >99% precision after allowable re-runs.
- **Ease of Use** - Streamlined protocol with minimal hands-on time.

** Accuracy of 100% for genotyping information used for carrier and newborn screening.*

CFTR Mutation Detection—Choose your assay. Choose your coverage.

xTAG® Cystic Fibrosis (CFTR) 39 kit v2

ACMG Recommended Mutations[1]			16 Most Common Additional Mutations**	
ΔF508	A455E	R1162X	1078delT	1898+5G>T
ΔI507	1717-1G>A	3659delC	394delTT	2183AA>G
G542X	R560T	3849+10kbC>T	Y122X	2307insA
G85E	R553X	W1282X	R347H	Y1092X
R117H	G551D	N1303K	V520F	M1101K
621+1G>T	1898+1G>A	5/7/9T	A559T	S1255X
711+1G>T	2184delA	F508C	S549N	3876delA
R334W	2789+5G>A	I507V	S549R	3905insT
R347P	3120+1G>A	I506V		

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xTAG® Cystic Fibrosis (CFTR) 60 kit v2

Broad Ethnic Coverage		
CFTRdel2,3	G330X	L206W
E60X	Q890X	2055del9>A
R75X	K710X	R1158X
2143delT	S1196X	935delA
406-1G>A	3199del6	3791delC
Q493X	R1066C	
1677delTA	W1089X	
G178R	D1152H	

[1] *Genet Med. 2004 Sep-Oct; 6(5):387-91.*

*** List of mutations or variants identified in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.*

CF Mutation Detection Rate (%) [§]

Ethnic Group	Incidence of CF	Carrier Frequency	ACMG Recommended Mutation Only	xTAG® Cystic Fibrosis (CFTR) 39 kit v2	xTAG® Cystic Fibrosis (CFTR) 60 kit v2
Caucasian	1 in 3,200	1 in 25	88.3	89.7	90.6
Hispanic Americans	1 in 9,500	1 in 46	71.7	73.4	83.7
African Americans	1 in 15,300	1 in 65	64.5	68.6	72.5
Ashkenazi Jewish	1 in 3,300	1 in 25	94.0	94.0	95.9
Asian Americans	1 in 32,100	1 in 90	48.9	54.5	54.5

§ Data collected from the following references: Watson et al. Genet Med 2004;6(5):387-91, Richards et al. Genet Med 2002;4(5):379-391, Bobadilla et al. Human Mutat 2002;19:575-606, Heim et al. Genet Med 2001;3:168-76, Sugarman et al. Genet Med 2004;6:392-99, Organ et al. Genet Testing 2001;5:47-52, Wong et al. Human Mutat 2001;18:296-307, Alder et al. Human Mutat 2004 MIB #752, and Shriver et al. JMD 2005;7:289-99.

Assay Description

The xTAG Cystic Fibrosis kits are used to simultaneously detect and identify a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens. The panels include mutations and variants recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG), as well as some of the world's most common and North American-prevalent mutations. The kits are qualitative genotyping tests which provide information intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.

The kits are not indicated for use in fetal diagnostic or pre-implantation testing. The kits are also not indicated for stand-alone diagnostic purposes.

Ordering Information

Product Name	Part Number
xTAG® Cystic Fibrosis (CFTR) 39 kit v2	I027C0231
xTAG® Cystic Fibrosis (CFTR) 60 kit v2	I024C0181

Products are FDA Cleared for IVD use.

References:

1. Luminex Corporation | xTAG Cystic Fibrosis (CFTR) 39 kit v2 (US-IVD) Package Insert
2. Luminex Corporation | xTAG Cystic Fibrosis (CFTR) 60 kit v2 (US-IVD) Package Insert

Luminex®
A DiaSorin Company

orders@luminexcorp.com or support@luminexcorp.com

For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions. Please contact Luminex at support@luminexcorp.com to obtain the appropriate product information for your country of residence. For a complete list of warnings and precautions, consult the package insert. The Luminex 100/200 is a class 1(I) laser product.

www.luminexcorp.com/cf

HEADQUARTERS
UNITED STATES
+1 512 219 8020
info@luminexcorp.com

EUROPE
+31 73 800 1900
europe@luminexcorp.com

CANADA
+1 416 593 4323
info@luminexcorp.com

CHINA
+86 21 802 31150
infocn@luminexcorp.com

JAPAN
+81 3 5545 7440
infojp@luminexcorp.com

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