Luminex®

Luminex® 100™ and Luminex® 200™

39 TARGETS 71 TARGETS

xTAG® Cystic Fibrosis (CFTR) 39 Kit v2 and 71 Kit v2

Your Choice for Cystic Fibrosis Testing

The benefits of xTAG® Cystic Fibrosis Kits include:

- **Comprehensive** - Choose the mutation coverage you need.
- **Flexibility** - Mutation panel selection through the TDAS software (included with the assay kit).
- **Confidence** - Second generation of an IVD assay with 100% overall accuracy and >99% precision, after allowable re-run. No reflex testing necessary.*
- **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) 71 Kit v2‡

Broad Ethnic Coverage			
CFTRdele2,3	G330X	3791delC	935delA
E60X	R352Q	Q890X	ΔF311
R75X	S364P	2869insG	2143delT
405+3A>C	G480C	3120G>A	K710X
406-1G>A	Q493X	3199del6	S1196X
444delA	1677delTA	R1066C	L206W
R117C	1812-1G>A	W1089X	2055del9>A
G178R	G622D	D1152H	R1158X

[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.*

‡ *xTAG Cystic Fibrosis 71 Kit v2 may be used to identify all the mutations or variants targeted by the xTAG Cystic Fibrosis 39 Kit v2 in addition to the list above.*

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), plus 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.

See Package Insert for additional details.[1,2]

Ordering Information[++]

Product Name	Part Number
xTAG® Cystic Fibrosis (CFTR) 39 Kit v2	I027C0232
xTAG® Cystic Fibrosis (CFTR) 71 Kit v2	I024C0185

[++]*Products are CE Marked and Health Canada licensed for IVD Use.*

References:

1. Luminex Corporation | xTAG Cystic Fibrosis (CFTR) 39 Kit v2 (CE-IVD) Package Insert
2. Luminex Corporation | xTAG Cystic Fibrosis (CFTR) 71 Kit v2 (CE-IVD) Package Insert

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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. Luminex 100/200 is a Class 1(I) laser product.

FOR OUTSIDE THE US ONLY

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