

AmplideX[®]

PCR/CE CFTR Kit*



Providing the broadest coverage of the U.S. population[†] of any commercially available, targeted CFTR testing kit

The AmplideX[®] PCR/CE CFTR Kit* brings the simplicity and scalability of AmplideX technology to CFTR variant detection. Offering the streamlined detection of 67 pathogenic variants, and covering approximately 93%[†] of the U.S. population, the assay provides the broadest coverage of any commercially available, targeted testing kit. The assay is optimized for use on widely established laboratory equipment and delivers genotype results from DNA in under five hours.

REDUCED COMPLEXITY

- Broad coverage[†] provided using only PCR/CE workflow
- Similar testing process to AmplideX PCR/CE FMR1* and SMN1/2 Plus* kits eases implementation
- Streamlined data analysis via AmplideX Reporter software

OPTIMIZED WORKFLOW

- Easy-to-use workflow with fewer hands on steps than most competitor assays
- Flexible use on widely installed CE equipment
- <5 hrs from DNA to data

QUALITY RESULTS

- Built on the latest prevalence data to provide the best coverage[†] for all U.S. ethnicities
- Detects complex yet key CFTR mutations (CNVs, STRs, SNPs, INDELs) and resolves zygosity
- Excellent concordance with other methods



Figure 1. AmplideX PCR/CE CFTR Kit* workflow.

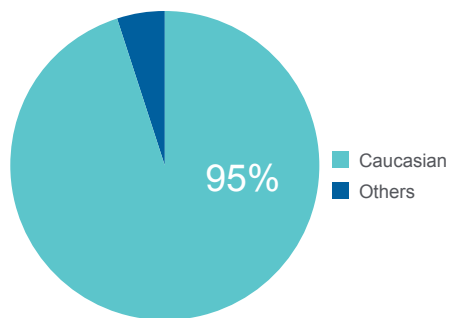


Figure 2A. Ethnic diversity of 89K patients in CFTR2 database.

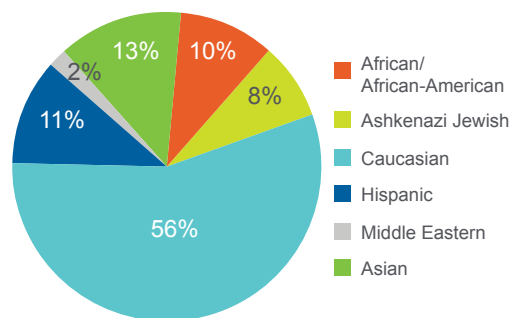


Figure 2B. Ethnic diversity of 115K subjects in U.S. study.[†]

Commercial Kit Manufacturer/Panel	Full Product Name	# of Variants Detected	% Coverage, CFTR2	% Coverage, U.S.	% Coverage Difference, U.S.
Asuragen	Amplidex PCR/CE CFTR Kit	67	92.1%	93.0%	-
Luminex 97	xTAG Cystic Fibrosis (CFTR) 97 kit (Custom)	97	92.2%	88.2%	4.8%
Illumina	MiSeqDx Cystic Fibrosis 139 Variant Assay	139	94.3%	87.7%	5.3%
Agena	iPLEXPro CFTR Panel	74	91.5%	86.9%	6.1%
Elucigene	CF-EU2v1	50	90.5%	86.2%	6.8%
Luminex 60	xTAG Cystic Fibrosis (CFTR) 60 kit v2	60	91.2%	86.1%	6.9%
Luminex 39	xTAG Cystic Fibrosis (CFTR) 39 kit v2	39	89.1%	80.7%	12.3%

Table 1. Percent coverage of variants detected by commercially available kits based on frequencies observed in the CFTR2 database** and the U.S. population.

76 Cell Lines from Coriell Repository					
Sample Agreement with Reference Assay		Sanger Sequencing			Overall Sample Agreement
		WT/WT	MUT/MUT	MUT/WT	
CFTR PCR/CE Assay	WT/WT	22	0	0	22/22 (100%)
	MUT/MUT	0	24	0	24/24 (100%)
	MUT/WT	0	0	27	27/27 (100%)

Table 2A. Mutations in Cell Lines Detected by Prototype PCR/CE CFTR Kit and Sanger Sequencing.

102 Clinical Samples Across 3 Sites					
Sample Agreement with Reference Assay		xTAG® Cystic Fibrosis (CFTR) 60 kit v2 or Sanger Sequencing			Overall Sample Agreement
		WT/WT	MUT/MUT	MUT/WT	
CFTR PCR/CE Assay	WT/WT	34	0	0	34/34 (100%)
	MUT/MUT	0	19	0	19/19 (100%)
	MUT/WT	0	0	49	49/49 (100%)

Table 2B. Mutations in Clinical Samples Detected by Prototype PCR/CE CFTR Kit and Either xTAG® Cystic Fibrosis (CFTR) 60 Kit v2 or Sanger Sequencing.

ORDERING INFORMATION

Part Number	Product Description	Number of Reactions
A00076	Amplidex PCR/CE CFTR Kit	50
A00077	Amplidex PCR/CE CFTR Kit	100

For more information please contact asuragen.com

*For Research Use Only. Not for use in diagnostic procedures.

**The Clinical and Functional Translation of CFTR (CFTR2); available at <http://cftr2.org>

[†]Beauchamp, et al. Genet Med. 2019 Nov;21(11):2569-2576.