



Quality Controls for Cystic Fibrosis Testing

Cystic fibrosis (CF) is a genetic disease caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, leading to a buildup of thick, sticky mucus causing damage to the lungs, digestive system and other organs. Symptoms can vary and early diagnosis and treatments are critical for improving quality of life, preventing complications, and increasing life expectancy.

PATIENT-LIKE



Designed to resemble characteristics of a human specimen, resulting copy numbers of the artificial CFTR segment will be similar to that found in a patient sample.

MULTI-PURPOSE



Can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures.

PROTECT



Assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system.

REPRODUCIBLE



Manufactured according to current Good Manufacturing Practice (cGMP) designed to provide your lab with controls that are reproducible lot to lot.



Cystic Fibrosis Extractable Controls

INTROL® CF Panel I Control v.02 (38 CFTR mutations)

Catalog No.: G106ac-1

Kit Contains: 3 bottles, 1 each of a, b, c x 1 mL

Catalog No.: G106ac

Kit Contains: 3 bottles, 1 each of a, b, c x 2 mL

INTROL® CF Panel II Control (54 CFTR mutations)

Catalog No.: G110-1

Kit Contains: 3 bottles, 1 each of a, b, c x 1 mL

Catalog No.: G110

Kit Contains: 3 bottles, 1 each of a, b, c x 2 mL

INTROL® CF Panel III Control (79 CFTR mutations)

Catalog No.: G115-1

Kit Contains: 4 bottles, 1 each of a, b, c, d x 1 mL

Catalog No.: G115

Kit Contains: 4 bottles, 1 each of a, b, c, d x 2 mL

Please contact MMQCI to ask about compatibility with your CFTR assay.



Extractable Controls

These products are intended to be extracted and analyzed routinely with each Cystic Fibrosis test run.



Process Monitoring


Uniquely designed to be carried through the entire testing process, including extraction, amplification, and detection.


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Cystic Fibrosis Non-Extractable Controls (NGS)

NGS CF Control Panel G211 v1.1 (188 variants)

Catalog No.: G211v1.1

Kit Contains: 6 tubes, 1 of each Av1.1, Bv1.1, Cv1.1, Dv1.1, Ev1.1, Fv1.1 x 50 µL

NGS CF Control Panel G211plus (211 variants)

Contains all 100 ACMG recommended variants for carrier screening!

Catalog No.: G211plus

Kit Contains: 6 tubes, 1 of each Aplus, Bv1.1, Cplus, Dv1.1, Eplus, Fplus x 50 µL



Please contact MMQCI to ask about compatibility with your CFTR assay.



High Quality Controls

Highly multiplexed and well-characterized, all sequences have been validated by bi-directional Sanger sequencing.



Variety of Variants

Contain a variety of variants ensuring that all clinically-relevant variant types (such as SNVs, INDELs, or rearrangements) can be detected.



Methods Evaluation

Can be used to evaluate sequencing platforms, library prep methods, and sensitivity & specificity of various bioinformatics pipelines.



Performance Monitoring


Monitor the analytical performance of your library preps, sequencing, and data analysis in the identification of variants within CFTR.


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Differences between

NGS CF Control Panel G211 v1.1 & NGS CF Control Panel G211*plus*

Table 1: Twenty-eight variants were added in NGS CF Control Panel G211*plus* compared to the NGS CF Control Panel G211 v1.1 to account for the new recommendations from ACMG.

Kit Tube	CFTR Variants	cDNA Name (HGVS)
Cplus	Q2X	c.4C>T
Fplus	G91R	c.271G>A
Cplus	Q98R	c.293A>G
Cplus	F191V	c.571T>G
Aplus	L218X	c.653T>A
Cplus	V232D	c.695T>A
Aplus	Q290X	c.868C>T
Cplus	1161delC	c.1029del
Cplus	V456A	c.1367T>C
Aplus	1504delG	c.1373del
Cplus	C524X	c.1572C>A
Eplus	1716+1G->A	c.1584+1G>A
Aplus	G551S	c.1651G>A
Cplus	1811+1G->A	c.1679+1G>A
Aplus	R560S	c.1680A>C
Cplus	A561E	c.1682C>A
Eplus	1824delA	c.1692del
Aplus	A613T	c.1837G>A
Aplus	G628R	c.1882G>A
Aplus	R785X	c.2353C>T
Eplus	R792X	c.2374C>T
Aplus	Y913X	c.2739T>A
Aplus	G970D	c.2909G>A
Aplus	T1036N	c.3107C>A
Fplus	W1098C	c.3294G>C
Fplus	S1118F	c.3353C>T
Aplus	3849+5G->A	c.3717+5G>A
Aplus	3940delG	c.3808del

Table 2: Seven variants with varying clinical significance, present in the NGS CF Control Panel G211 v1.1, are not included in the NGS CF Control Panel G211*plus*.

Kit Tube	CFTR Variants	cDNA Name (HGVS)
Fv1.1	R74W	c.220C>T
Ev1.1	I506T (T>C)	c.1517T>C
Ev1.1	D579G	c.1736A>G
Fv1.1	F1052V	c.3154T>G
Fv1.1	G1069R	c.3205G>A
Ev1.1	Q1238X	c.3712C>T
Av1.1	1949del84	c.1820_1903del84

For the complete lists of variants in each panel, please see our Package Inserts.