



INTROL® CF Panel III Control

INTENDED USE:

INTROL® CF Panel III Control is intended for *in vitro* use as a quality control to monitor analytical performance of the extraction, amplification and detection steps of systems used in the qualitative measurement of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. This product is intended to be extracted and analyzed routinely with each cystic fibrosis (CF) test run.

INTROL CF Panel III is designed to monitor the detection of 79 CFTR mutations, genetic risk factors associated with cystic fibrosis, including the 23 mutations recommended by ACMG and ACOG. **INTROL CF Panel III Control** also monitors variants I506V, I507V, F508C, 5/7/9/11T and I148T.

INTROL CF Panel III is provided for Research Use Only (RUO). It cannot be cloned, sold, or transferred without the explicit written consent of MMQCI. Patents issued.

PRODUCT SUMMARY:

INTROL CF Panel III Control consists of synthetic CFTR DNA suspended in a non-infectious, blood-like matrix containing carrier DNA, preservatives and stabilizers. The synthetic DNA contains all 27 CFTR gene exons plus intronic borders, and contains specific mutations and variants which are divided among 4 bottles (Bottles a, b, c, d). Specific mutations and variants present are described in Table 1. The DNA should be extracted and purified from its matrix before analysis.

Analysis of **INTROL CF Panel III** test results can be valuable in the detection and troubleshooting of errors associated with the sample extraction, amplification, and signal measurement phases of CF test systems.

PRECAUTIONS AND WARNINGS:

This product contains 23% ethanol (v/v) and could be flammable. Keep away from open flames.

This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures. This product does not contain any biological material of human origin.

INSTRUCTIONS FOR USE:

Extract and analyze **INTROL CF Panel III Control** as you would a whole blood specimen:

1. Allow **INTROL CF Panel III** to come to room temperature (18° – 25°C).
2. Thoroughly mix the solution prior to opening by inverting the bottle several times or placing on an automated mixer immediately before use.
3. Extract **INTROL CF Panel III** in the same manner as a whole blood specimen. Use the same volume that would be used for a patient sample in your lab.
 - Note 1: Certain test methods may require additional processing of control material, such as dilution prior to analysis.
 - Note 2: The level of CFTR DNA present in the extracted control may not be detectable by certain quantitation methods and is not quantifiable by spectrophotometer measurements.
4. Analyze the extracted DNA as you would genomic DNA. If dilutions or other preparations of the extracted DNA are required as part of the testing procedure, handle the **INTROL CF Panel III** DNA in the same manner as clinical specimens.
5. Tightly recap each bottle after use and store refrigerated (2° - 8°C).
6. Controls should be tested routinely as a matter of Good Laboratory Practice and according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. The frequency of analysis will depend on individual laboratory policies for control use and may vary according to the analyte being measured or the analytical system being used.

STORAGE:

Upon receipt and after opening, the material should be stored at 2° – 8°C. Do not freeze.

STABILITY:

Unopened **INTROL CF Panel III Control** material is stable through the expiration date printed on each bottle when stored refrigerated (2° – 8°C). Opened material tightly capped and returned to the refrigerator (2° – 8°C) shortly after use is stable for thirty (30) days from the date of opening.

EXPECTED VALUES:

The genotype for each mutant / variant allele is listed in Table 1 below. The sequence of **INTROL CF Panel III** DNA has been confirmed by bi-directional sequencing. In some CF test systems, neighboring mutations interfere with expected test results. Such interferences occur with the **INTROL CF Panel III** just as they occur with patient samples. Thus, **INTROL CF Panel III** can assist the lab by demonstrating interference results to ensure correct interpretation of results.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for **INTROL CF Panel III** in demonstrating adequate system performance. Recoveries may vary depending on extraction method, instrumentation, cycle time / temperature, reagents, method variation, and other systematic or random errors.

Table 1.
INTROL® CF Panel III Control Mutations and Variants [in parentheses ()].

Allele	Genotype	Allele	Genotype	Allele	Genotype
Bottle a		Bottle b		Bottle d	
CFTRdele2,3	HET	E60X	HET	R75X	HET
Y122X	HET	G85E*	HET	405+3A>C	HET
(7T*/11T)	7T/11T	(I148T)	I148T/WT	406-1G>A	HET
Q493X	HET	621+1G>T*	HET	444delA	HET
(I507V)*	I507V/WT	711+1G>T*	HET	R117C	HET
(F508C)*	F508C/WT	1078delT	HET	G178R	HET
S549RT>G	HET	R334W*	HET	L206W	HET
A559T	HET	R347P*	HET	935delA	HET
1898+5G>T	HET	(7T*/9T*)	7T/9T	delF311	HET
2307insA	HET	A455E*	HET	G330X	HET
Y1092XC>A	HET	del F508*	HET	R352Q	HET
M1101K	HET	V520F	HET	S364P	HET
3849+4A>G	HET	1717-1G>A*	HET	(5T*/9T*)	5T/9T
S1251N	HET	G542X*	HET	G480C	HET
Bottle c		S549N	HET	del I507*	HET
394delTT	HET	G551D*	HET	1677delTA	HET
R117H*	HET	R560T*	HET	S549N	HET
711+5G>A	HET	1898+1G>A*	HET	1812-1G>A	HET
R347H	HET	2143delT	HET	G622D	HET
(5T*/7T*)	5T/7T	2184delA*	HET	2055del9>A	HET
del I507*	HET	2789+5G>A*	HET	K710X	HET
(I506V)*	I506V/WT	3120+1G>A*	HET	Q890X	HET
1677delTA	HET	3199del6	HET	2869insG	HET
S549RA>C	HET	D1152H	HET	3120G>A	HET
R553X*	HET	R1162X*	HET	R1066C	HET
2183AA>G	HET	3659delC*	HET	W1089X	HET
3272-26A>G	HET	3849+10KbC>T	HET	R1158X	HET
Y1092XC>G	HET	3876delA	HET	S1196X	HET
S1255XA>G	HET	3905insT	HET	3791delC	HET
S1255XC>A	HET	W1282X*	HET	D1270N	HET
		N1303K*	HET		

*ACMG / ACOG Panel

ORDERING INFORMATION:

INTROL® Cystic Fibrosis Panel III Control

Order Number:

G115-1 contains: 4 bottles, 1 milliliter each

G115 contains: 4 bottles, 2 milliliters each