



INTROL CF Panel I Control v.02

INTENDED USE:

INTROL[®] CF Panel I Control v.02 is intended for use as reference material to monitor analytical performance of the extraction, amplification and detection steps of diagnostic assays used in the detection of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations and variants. This product is intended to be extracted and analyzed routinely with each CFTR assay run.

The INTROL[®] CF Panel I Control v.02 is designed to monitor the detection of 38 CFTR mutations associated with cystic fibrosis, including the 23 mutations recommended for testing by American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG). The INTROL[™] CF Panel I Control also monitors 3 polymorphisms (I506V, I507V, F508C) and the 5/7/9T variants.

PRODUCT DESCRIPTION:

INTROL[®] CF Panel I Control v.02 consists of synthetic CFTR DNA suspended in a matrix of carrier DNA of non-human species, preservatives, dye, and stabilizers. The synthetic DNA contains all 27 CFTR gene exons plus intronic borders, and contains specific mutations and polymorphisms which are divided among 3 bottles (bottles a, b, and c). The specific mutations present in each bottle are listed in Table 1; all other CFTR sequence is wild type. CFTR mutations that are not listed cannot be detected in the INTROL[®] CF Panel I Control v.02.

CFTR DNA is stabilized in the matrix and released when processed through common extraction methods as if it were a whole blood specimen. Following extraction, the released DNA can be used in common amplification based molecular assays techniques. Because INTROL[®] CF Panel I Control v.02 is designed to mimic the whole blood sample, the resulting copy number of the artificial CFTR segment, after extraction, will be similar to that found in a processed human whole blood sample (v/v).

INSTRUCTIONS FOR USE:

Extract and analyze INTROL[®] CF Panel I Control v.02 as you would a whole blood specimen:

1. Allow INTROL[®] CF Panel I Control v.02 to reach room temperature (18° – 25°C).
2. Thoroughly mix the controls prior to opening by inverting the bottle several times immediately before use, or by placing on an automated mixer.
3. Extract INTROL[®] CF Panel I Control v.02 in the same manner as a whole blood clinical specimen. Use the same volume of INTROL[®] CF Panel I Control v.02 that would be used for a patient sample in your lab.

Note 1: Certain extraction 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 with 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 I Control v.02 DNA according to your standard laboratory protocol.
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 running the control material will depend on individual laboratory practice and may vary according to the analytical system being used.

STORAGE and STABILITY:

Upon receipt and after opening, the material should be stored at 2° – 8°C. Do not freeze. Unopened INTROL[®] CF Panel I Control v.02 material is stable through the expiration date printed on each bottle when stored refrigerated (2° – 8°C). Opened material returned to the refrigerator (2° – 8°C) shortly after use is stable for thirty (30) days from the date of opening. Contact MMQCI if control material was inadvertently frozen or exposed to high temperatures.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Interferences and cross-reactions may occur with some detection methods and confound interpretation of the test. Please refer to the kit manufacturers package insert to review possible cross-reactions and near neighbor interferences identified in the method.
- Recoveries may vary depending on extraction method, instrumentation, cycle time / temperature, reagents, method variation, and systematic or random errors.
- This product contains 23% ethanol (v/v) and could be flammable. Keep away from open flames.
- This product does not contain any biological material of human origin.
- The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL[™] CF Panel I in demonstrating adequate system performance.
- MMQCI CF products are not intended to be frozen and are shipped with a DO NOT FREEZE label. MMQCI CF products are not intended to be frozen and are shipped with a DO NOT FREEZE label.
- INTROL[®] CF Panel I Control v.02 is protected by patents. It cannot be cloned, sold, or transferred to other laboratories without the explicit written consent of MMQCI.

EXPECTED VALUES:

Table 1. Composition of INTROL[®] CF Panel I Control v.02 includes the following combinations of CFTR mutations and polymorphisms (plus wild type sequence covering 27 CFTR exons). Polymorphisms are in parentheses ().

Allele	Genotype
Bottle a	
7T*	7T / 7T
(I507V)*	I507V / WT
(F508C)*	F508C / WT
S549N/ S549R	Heterozygous
S1251N	Heterozygous
Bottle b	
E60X	Homozygous mutant
G85E*	Homozygous mutant
I148T	Homozygous mutant
621+1G>T*	Homozygous mutant
711+1G>T*	Homozygous mutant
1078delT	Homozygous mutant
R334W*	Homozygous mutant
R347P*	Homozygous mutant
9T*	9T / 9T
A455E*	Homozygous mutant
del F508*	Homozygous mutant
V520F	Homozygous mutant
1717-1G>A*	Homozygous mutant
G542X*	Homozygous mutant
G551D*	Homozygous mutant
2184delA*	Homozygous mutant
2789+5G>A*	Homozygous mutant
3120+1G>A*	Homozygous mutant
3199del6	Homozygous mutant
D1152H	Homozygous mutant
R1162X*	Homozygous mutant
3659delC*	Homozygous mutant
3849+10kbC>T*	Homozygous mutant
3876delA	Homozygous mutant
3905insT	Homozygous mutant
W1282X*	Homozygous mutant
N1303K*	Homozygous mutant
Bottle c	
394delTT	Heterozygous
R117H*	Heterozygous
R347H	Heterozygous
5T* / 7T*	Heterozygous
(I506V)*	I506V / WT
del I507*	Heterozygous
R553X*	Heterozygous
2183AA>G	Heterozygous

*ACMG / ACOG Panel

ORDERING INFORMATION:

INTROL[®] Cystic Fibrosis Panel I Control v.02

Part Number: G106ac-OUS
 Kit Contains: 3 bottles x 2mL
 1 each G106a, G106b, and G106c

Part Number: G106ac-1-OUS
 Kit Contains: 3 bottles x 1mL
 1 each G106a-1, G106b-1, and G106c-1