

T-Cell Receptor Gamma Rearrangement 2.0 Assay Performance Summary

Twelve (12) cell lines containing clonal T-cell rearrangements were assessed using the *TCRG* Gene Clonality Assay (BIOMED-2 Tubes A and B) and the T-Cell Receptor Gamma Gene Rearrangement 2.0 Assay (*TCRG*-6FAM, single tube). The data shown below was generated using dilutions of DNA from each of the 12 positive cell lines in polyclonal DNA. Following PCR amplification, the products were run on an ABI capillary electrophoresis instrument. For each master mix the clonal amplicon size, signal strength (RFUs), and relative peak ratios (RPRs) are listed.

The RPR of a clonal peak detected with the BIOMED-2 master mixes was determined using the following calculation: the height of the clonal peak divided by the height of the second highest peak in the associated Gaussian distribution. The RPR of the clonal peak generated with the new *TCRG*-6FAM assay was calculated by dividing the height of the clonal peak by the height of the smallest adjacent peak. When assessing the sensitivity of an assay, both the signal strength in RFUs and the sensitivity as defined by the RPRs must be considered.

	TCRG Gene Clonality Assay (BIOMED-2 Tube A and B)			T Cell Receptor Gamma Gene Rearrangement 2.0 Assay (TCRG-6FAM)		
	Product Size (base pairs)	RPR	RFU	Product Size (base pairs)	RPR	RFU
5% IVS-0004	211	40.5	910	179 188	97.5 18.4	2534 2191
5% IVS-0005	221	3.3	477	173 197	44.1 4.3	2072 934
5% IVS-0006	212	4.5	206	188	2.5	632
5% IVS-0008	218 229	2.0 3.8	105 196	195 207	3.2 28.9	1029 1241
5% IVS-0009	211	2.1	103	187 190	2.8 3.6	427 1258
5% IVS-0014	187	23.7	1552	185 204	18.4 12.1	1469 909
5% IVS-0016	225 240	3.5 3.1	2244 1496	169 193	111.5 5.6	1227 1014
5% IVS-0021	165 210	6.2 38.9	336 1896	183 188	18.5 4.3	1110 710
5% IVS-0022	158	46.9	5166	159 192	29.8 8.4	2114 3202
5% IVS-0026	156 222	25.9 4.5	4028 1025	191 200	6.4 9.1	1911 1369
5% IVS-0036	235	7.6	328	187 190	4.6 4.0	761 1755
5% TCRG Positive Control	161	20.9	1338	193 196	3.8 7.7	1081 1679

The results show that six (6) of the cell lines tested, the *TCRG*-6FAM master mix generated two clonal products, whereas the BIOMED-2 master mixes only generated one. This is because *TCRG*-6FAM includes primers for all known TCR gamma variable regions and joining regions that are involved in gene rearrangements, which leads to more inclusive testing of these target sequences. Products generated with the *TCRG*-6FAM master mix exhibited significantly higher fluorescent signal strength which can facilitate interpretation of ambiguous peaks. Additionally, the clonal products generated with the *TCRG*-6FAM master mix fall within the comparatively tighter, single contiguous size range of 159 bp to 207 bp, whereas the products generated using the BIOMED-2 master mixes fall into four different size ranges from 156 bp to 240 bp.

Ordering Information

Part #	Description	Quantity
92070101*	IdentiClone T-Cell Receptor Gamma Gene Rearrangement Assay 2.0 - ABI Fluorescence Detection	33 Reactions
92070111*	IdentiClone T-Cell Receptor Gamma Gene Rearrangement Assay 2.0 MegaKit - ABI Fluorescence Detection	330 Reactions

*These are *in vitro* diagnostic products and available in regions that accept CE-IVD products.