

# ctDNA Reference Standard

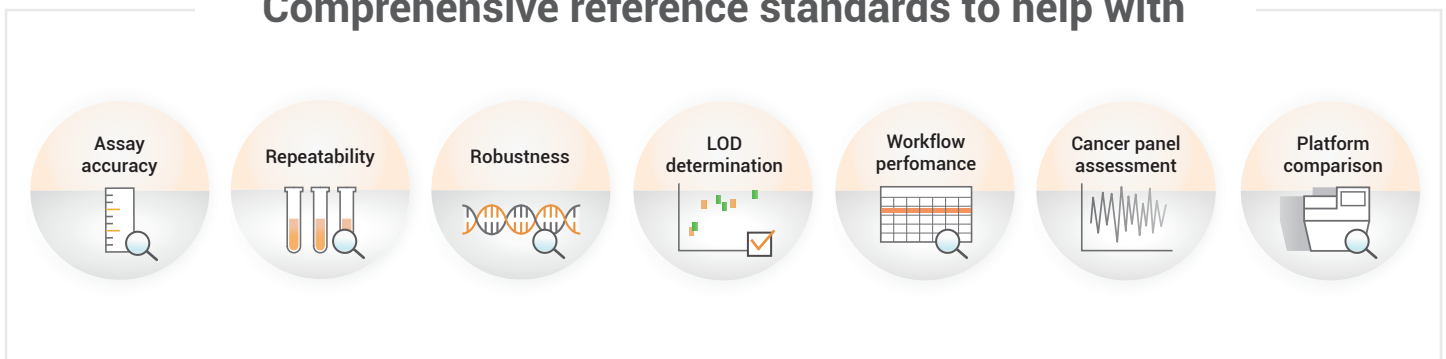
 **Contribute to the confidency, consistency and accuracy of liquid biopsy**








## Product List

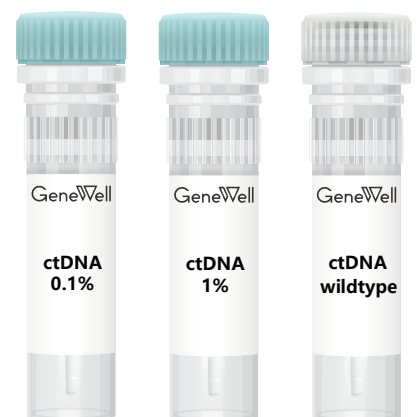
Product Code	Product Name	Format	Specification	Shelf Life
IB-GW-OCTM009	Onco SNV Multiplex ctDNA Reference Standard Set	ctDNA	3 tubes * 0.5µg/tube	36 months (2-8°C)
IB-GW-OCTM001	Onco Structural Multiplex 5% ctDNA Reference Standard	ctDNA	0.5µg/tube	36 months (2-8°C)
IB-GW-OCTM005	Onco Wildtype ctDNA Reference Standard	ctDNA	0.5µg/tube	36 months (2-8°C)

## Comprehensive reference standards to help with



## Key Features

-  Cell line-derived products to better mimic clinical patient samples
-  Fragmented to around 160bp, similar to the nature of cell-free DNA (cfDNA)
-  A wide range of allelic frequencies are offered with cancer-related variants, as well as matched wildtype
-  Variants are precisely verified by ddPCR with multiple repeats, especially for those with low AFs
-  Multi fragmentation methods are also available upon requests



## GW-OCTM009 Onco SNV Multiplex ctDNA Reference Standard Set

Variants	Variant Type	Expected Allelic Frequency, %
PIK3CA E545K	SNV	0%, 0.1%, 1%
KRAS G12D	SNV	0%, 0.1%, 1%
KRAS A146T	SNV	0%, 0.1%, 1%
NRAS Q61K	SNV	0%, 0.1%, 1%
EGFR L858R	SNV	0%, 0.1%, 1%
EGFR T790M	SNV	0%, 0.1%, 1%
EGFR A767_V769dup	Insertion	0%, 0.1%, 1%
EGFR E746_A750del	Deletion	0%, 0.1%, 1%

## GW-OCTM001 Onco Structural Multiplex 5% ctDNA Reference Standard

Variants	Variant Type	Expected Allelic Frequency, %
AKT1 E17K	SNV	5%
PIK3CA E545K	SNV	5%
EGFR A767_V769dup	Insertion	5%
EGFR E746_A750del	Deletion	5%
ROS1 CD74(6)-ROS1(34)	Fusion	5%
ALK EML4(6)-ALK(20)	Fusion	5%
MET Amplification	CNV	3.5 copies
ERBB2 Amplification	CNV	7.0 copies

## GW-OCTM005 Onco Wildtype ctDNA Reference Standard

Verified Mutations as Wildtypes			
EGFR L858R	PIK3CA E545K	BRAF V600E	MET Amplification
EGFR T790M	PIK3CA H1047R	NRAS Q61K	ERBB2 Amplification
EGFR E746_A750del	KRAS G12D	AKT1 E17K	
EGFR G719S	KRAS G13D	ROS1 CD74(6)-ROS1(34)	
EGFR A767_V769dup	KRAS A146T	ALK EML4(6)-ALK(20)	

## Quality Control

Testing Items	TEST METHOD	ACCEPTANCE CRITERIA
Allelic Frequency and Copy Number	Droplet Digital PCR	AF = 0%, accepted range = $\leq 0.1\%$ ; AF < 1%, accepted range = $\pm 50\%$ (AF=0.1% accepted range $\geq 0.05\%$ + wildtype); 1% $\leq$ AF < 5%, accepted range = $\pm 40\%$ ; 5% $\leq$ AF < 10%, accepted range = $\pm 30\%$ ; 10% $\leq$ AF, accepted range = $\pm 20\%$ ; Copy number < 5, accepted range = $\pm 40\%$ ; 5 $\leq$ Copy number < 10, accepted range = $\pm 30\%$
Concentration	Qubit dsDNA BR Assay	20 $\pm$ 15% ng/ $\mu$ L
Fragments Size	D1000 DNA ScreenTape Assay	160bp $\pm$ 10%



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