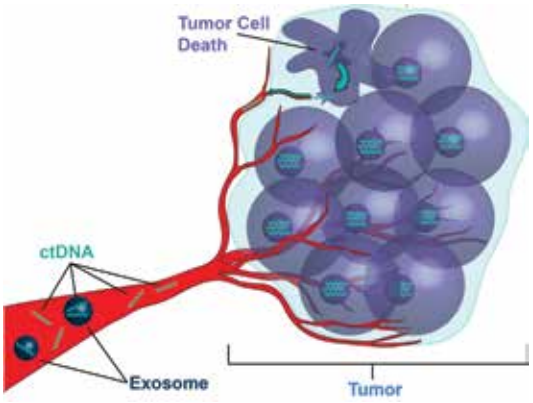
Quan-Plex

Quan-Plex™ Patient-Like ctDNA Reference Standard



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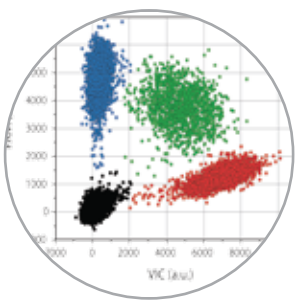
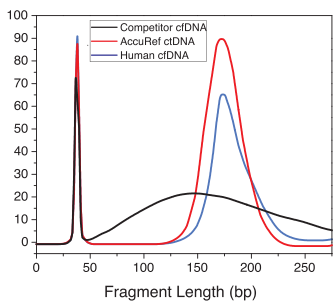
Recent advances in Next-Generation Sequencing (NGS) and digital PCR (dPCR) have enabled the development of quantitative assays that can detect low amounts of mutant DNA. The high sensitivity of these new technologies, often down to 1 in 1000 mutant alleles (i.e. 0.1%) or lower, has enabled non-invasive cancer profiling through what have become known as "liquid biopsies", or the detection of cancer-associated somatic variants from circulating tumor DNA (ctDNA) in blood specimens. Examples of applications where ctDNA testing has shown promise are: blood screening for early cancer detection, therapy selection, routine monitoring of cancer to assess minimal residual disease, and resistance monitoring during therapy.

The Quan-Plex™ Patient-like ctDNA Reference Standard is a highly-characterized, quantitative multiplex quality control that allows researchers to develop their own assays, and assess limits of detection (LODs) for eight cancer-associated solid tumor mutations. This panel can also be used to monitor the quality of their NGS or dPCR oncology-based workflow for routine quality assessment. The standards have been engineered to mimic the fragmentation profile of nucleosomal ctDNA (~166 bp) as observed in patient samples.



Key Feature & Benefits:

- Highly-characterized ctDNA mimetic reference standard
- 166 bp average length mimics true ctDNA samples
- 8 cancer-associated mutations in EGFR, PIK3CA, NRAS and KRAS
- Available at 0%, 0.1%, 1.0% and 5.0% mutant allele frequencies
- Cancer cell lines provides a true biologically-relevant control
- Pre-validated by digital PCR



Digital PCR Verified Mutations*:

Gene	Nucleotide Change	Amino Acid Change	Cosmic ID	Variant Type
EGFR	c. 2155G>A	p. G719S	6252	Substitution
EGFR	c. 2573T>G	p. L858R	6224	Substitution
EGFR	c. 2369C>T	p. T790M	6240	Substitution
PIK3CA	c.1633G>A	p. E545K	763	Substitution
NRAS	c.181C>A	p. Q61K	580	Substitution
EGFR**	c. 2307_2308insGCCAGCGTG	p. V769_D770insASV	12376	Insertion
KRAS	c. 35G>A	p. G12D	521	Substitution
EGFR	c. 2235_2249del15	p. E746_A750del	6223	Deletion

*For dPCR verified mutations please refer to lot specific certificate of analysis (CoA) available in the product page at www.accuref.com

Technical Information:

Genes Covered	EGFR, KRAS, NRAS, PIK3CA
Verified Mutations	8
Allelic Frequency Range	0%, 0.1%, 1% and 5%
Fragment Size	150-166 bp

AccuRef

Ordering:

Catalog # ARF-1003CT	Quan-Plex™ Patient-like ctDNA Panel
Catalog # ARF-1003CTP	Quan-Plex™ Patient-like ctDNA Panel - in Synthetic Plasma

Format:

Unit Size	1 Panel
Quantity	4 vials of 7.5µl ctDNA mimetic (300ng/vial for ARF-1003CT), or 4 vials of 500µl each of ctDNA mimetic in synthetic plasma (300ng/vial for ARF-1003CTP)
Concentration	40 ng/µl (ARF-1003CT); 0.6 ng/µl (ARF-1003CTP)
Intended Use	For routine NGS performance monitoring and assess limit of detection of ctDNA with NGS or dPCR assays

General:

Storage	-20˚C (long term) 2 years Exp Date
Freeze/Thaw	No more than 3 freeze/thaw cycles
Shipping	4˚C (gel packs)
Cell Line Background	RKO/HCT116
Buffer	Tris-EDTA (10mM Tris-HCl, 1mM EDTA), pH 8.0 (ARF-1003CT) Synthetic Plasma pH 8.5 (ARF-1003CTP)
Regulatory	For Reseach Use Only. Not intended for human or animal diagnostics or therapeutic use.

Quality Control:

Genotype	Sanger sequencing of locus specific PCR (cell line)
Quality	BioAnalyzer™ DNA1000 Chip and Next-generation sequencing: Ion AmpliSeq™ Hotspot Cancer Panel v2 on Illumina
Quantification	Qubit 4.0™ Fluorometer Mutation allele frequency: digital PCR **Quantified with NGS. Note: allele frequency of the insertion will be observed with NGS.
Manufacturing	ISO 9001:2015 and ISO 13485:2016 certified

Sample	Target	Ratio
5% Target	KRAS-G12D	4.41%
	EGFR-E746-A750del	4.95%
	EGFR-T790M	5.02%
	EGFR-L858R	4.52%
	PIK3CA-E545K	4.27%
	NRAS-Q61K	3.46%
	EGFR p.V769_D770insASV	4.58%

Sample	Target	Ratio
1% Target	KRAS-G12D	1.11%
	EGFR-E746-A750del	0.98%
	EGFR-T790M	0.89%
	EGFR-L858R	1.39%
	PIK3CA-E545K	0.87%
	NRAS-Q61K	1.27%
	EGFR p.V769_D770insASV	0.95%

Sample	Target	Ratio
0.1% Target	KRAS-G12D	0.08%
	EGFR-E746-A750del	0.10%
	EGFR-T790M	0.13%
	EGFR-L858R	0.20%
	PIK3CA-E545K	0.13%
	NRAS-Q61K	0.14%
	EGFR p.V769_D770insASV	0.12%

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