Quan-Plex

Quan-Plex™ EGFR FFPE Cell Scroll Reference Standard

Cancer is a heterogeneous disease in which hundreds of genes, and many thousands of mutations, have been implicated in oncogenesis. As we enter an era of precision tumor profiling, there is a significant need for molecular reference standards that can be employed for assay development and quality assurance in order to validate assay performance, and understand cross-site and inter-operator reproducibility. The Quan-Plex™ EGFR FFPE Cell Reference Standard is a highly-characterized, quantitative multigene, formalin-fixed paraffin embedded (FFPE) cell section for use as a quality standard, thus enabling researchers to assess pre-analytical sample processing efficiency and consistency in a laboratory workflow. EGFR C797S mutation is an emerging resistance marker to EGFR T790M-targeted tyrosine kinase inhibitor therapeutics.

Powered by CRISPR/cas9 gene-editing technology, our foot-print free ONCOREF™ engineered mutation cell line are the basis for preparing a FFPE cell block. The Quan-Plex™ EGFR FFPE Cell is prepared by mixing a mutation cell line containing two engineered mutations C797S(+/+) and T790M(+/+) [Cis position] with the wild-type (RKO) parental cell line at pre-defined target allelic frequencies (1% or 5%) and then verifiying the allelic frequency with digital PCR. In addition to the EGFR mutations, the Quan-Plex™ EGFR FFPE Cell Scroll contains approximately >1,000 variants endogenous to the isogenic parental cell lines, derived from a male colorectal cancer patient.

Quan-Plex™ EGFR FFPE Cell Reference Standard is a reliable, consistent, and renewable source of genetic material, without trade-off in sample complexity. Our FFPE Cell Scroll will provide you with the added confidence when transitioning testing from research into clinically-relevant sample testing.

Applications:

- FFPE sample workflow and assay optimization
- Monitor sample-to-sample or batch-to-batch variability
- Evaluation and refine bioinformatics analysis pipelines for FFPE effects
- Perform inter-operator and cross-site variability studies
- Compatible with NGS or dPCR workflows

Key Features & Benefits:

- Digital PCR-verified allelic frequencies at 1% and 5%
- Two EGFR actionable somatic co-mutations (Cis and homozygous)
- > 1,000 endogenous variants in the parental cell line
- Highly-characterized, biologically-relevant quality control material

Digital PCR Verified Mutations:

Gene	Nucleotide Change	Amino Acid Change	Cosmic ID	Variant Type
EGFR	c. 2369C>T	p. T790M	COSM6240	Substitution
EGFR	c. 2389T>A	p. C797S	COSM6493937	Substitution

AccuRef

Technical Information:

Genes Covered	EGFR
Verified Mutations	2
Allelic Frequency	0% (wt), 1% and 5%
Cell Line	RKO (colorectal cancer, male)

General:

Storage	- 20˚C (long)
Shipping	Room temperature
Stability	24 months/Exp Date
FFPE Processing	10% buffered formalin solution (4% formaldehyde), 24 hrs, room temperature

Ordering:

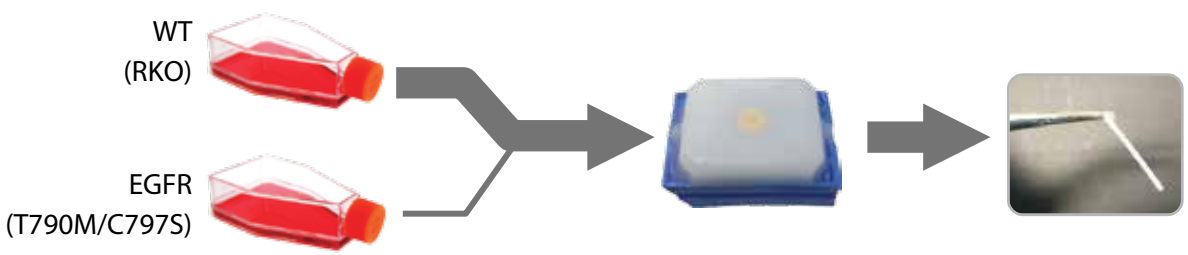
Quan-Plex™ EGFR C797S/T790M (cis) c.2389T>A/c.2369C>T ID:6493937/6240 FFPE Cell Scroll 1%	Catalog # ARF-1004S-1
Quan-Plex™ EGFR C797S/T790M (cis) c.2389T>A/c.2369C>T ID:6493937/6240 FFPE Cell Scroll 5%	Catalog # ARF- 1004S-5
Onco-Ref™ FFPE Cell Scroll RKO wt (0%)	Catalog # ASO-5051

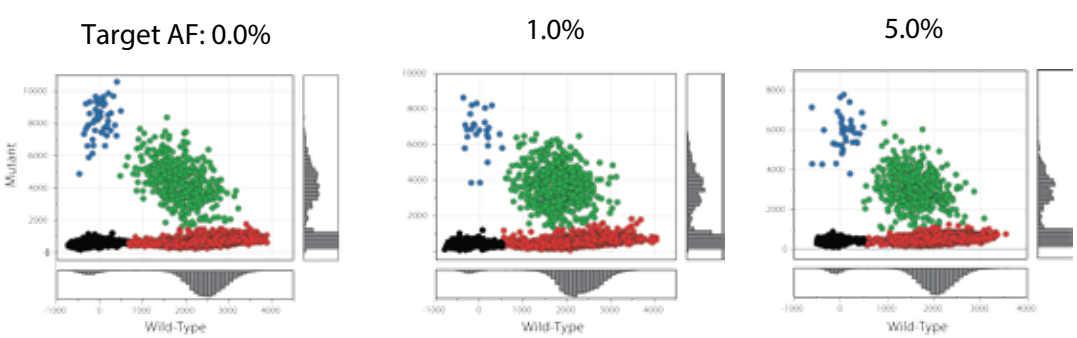
Quality Control:

Genotype	Sanger sequencing of locus specific PCR (cell line)
Quality	> 60% cell density based on H&E staining of 5µm section
Quantification	Digital PCR (mutation allelic frequency). Tested with NGS (Ion AmpliSeq™ Hotspot Cancer Panel v2) data not used for QC release.
Manufacturing	ISO 9001:2015 and 13485:2016 certified

Format:

Unit Size	1 FFPE cell scroll
Quantity	20 µm thick x 7.0 mm cell pellet core diameter
Concentration	> 400ng of FFPE gDNA/ scroll
Intended Use	Assessment of FFPE extraction and detection on the laboratory workflow





EGFR C797S mutant cell lines were mixed with WT parental cells (RKO) and then formalin-fixed to obtain targeted allelic frequencies of 1.0%, and 5.0%.

For Research Use Only. Not intended for animal or human diagnostics, or therapeutic use.

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