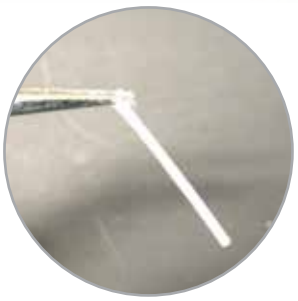
Quan-Plex

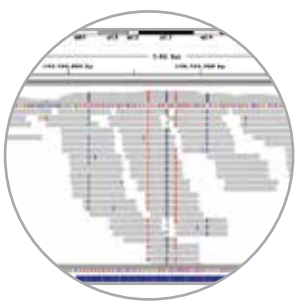
Quan-Plex™ NGS FFPE Reference Standard

The Quan-Plex™ FFPE NGS Reference Standard is a highly-characterized, quantitative multiplex, reference standard that allows researchers to accurately assess the quality of an oncology-based next-generation sequencing (NGS), digital PCR, and/or real-time PCR workflow with using CRISPR/cas9 genome-edited cancer cell lines that were prepared into either a formalin-fixed paraffin-embedded (FFPE) mimetic cell block sectioned into 20µm scrolls or gDNA extracted from 10% formalin-compromised cells. These reference standard panel spans a broad range of actionable mutations at digital PCR and NGS-verified mutation allelic frequencies (%MAF) ranging from 1% to 10%. In addition, the Quan-Plex™ NGS FFPE Reference Standard contains > 1,500 variants that are endogenous to the isogenic parental cancer cell lines (RKO and HCT116). This convenient and easy-to-use panel includes nine (9) actionable somatic mutations across six oncogenes (KIT, EGFR, NRAS, HRAS, KRAS and PIK3CA).

Applications:

- Evaluate your FFPE specimen processing/extraction workflow
- Monitoring of inter-and intra-operator variability
- Routine assessment of sample-to-sample or batch-to-batch variability
- Evaluate and refine a bioinformatics pipelines for FFPE sample analysis





Key Features & Benefits:

- 9 actionable somatic mutations at dPCR and NGS-verified mutation allelic frequencies
- Highly-characterized, biologically-relevant quality control material
- > 1,500 endogenous variants in a background of parental cancer cell lines
- Available in two formats: FFPE Cell Scroll (cat# ARF-1001S) and 10% formalin-compromised gDNA (cat# ARF-1001FC-1)

Digital PCR Verified Mutations*:

Gene	Chromosome	Nucleotide Change	Amino Acid Change	COSMIC ID	Variant Type	Nominal Mutation Allele Frequency, %
KIT	4q11-q12	c.2447A>T	p. D816V	COSM1314	Substitution	10.0%
EGFR	7p12	c.2573T>G	p. L858R	COSM6224	Substitution	8.0%
EGFR**	7p12	c.2369C>T	p. T790M	COSM6240	Substitution	1.0%
EGFR	7p12	2155G>A	p. G719S	COSM6252	Substitution	5.0%
KRAS	12p12.1	35G>A	p. G12D	COSM521	Substitution	2.0%
HRAS	11p15.5	c.182A>G	p. Q61R	COSM499	Substitution	3.0%
NRAS	1p13.2	c.181C>A	p. Q61K	COSM580	Substitution	5.0%
PIK3CA	3q26.3	c.3140A>T	p. H1047L	COSM776	Substitution	6.0%
PIK3CA	3q26.3	c.1633G>A	p. E545K	COSM763	Substitution	7.0%

*Please refer to lot specific certificate of analysis (CoA) available on the product page at www.accuref.com.
**This mutation is verified only with NGS.

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

AccuRef

The Quan-Plex™ NGS FFPE Reference Standards is an ideal solution for researchers who do not have the resources or time to develop their own in-house reference material. It can be easily integrated into the daily workflow for platform assessment, especially if poor or inconsistent NGS data quality is observed, or to assist in assay validation of a targeted gene panel in a translational genomics laboratory workflow.

Examples of Variants Confirmed in Background of Parental Cell Lines:

Gene	Chromosome	COSMIC ID	Position	Reference Allele	Variant Allele	Estimated Allelic Frequency
CTNNB1	chr3	COSM33668	41266133	CTT	C	46.8 %
PIK3CA	chr3	COSM775	178952085	A	G	50.6 %
APC	chr5	COSM3760869	112175770	G	A	99.9 %
RET	chr10	COSM4418405	43613843	G	T	99.9 %
KRAS	chr12	COSM1140132	25398281	C	T	49.8 %

Platform Compatibility:

The Quan-Plex™ FFPE NGS Reference Standards is compatible with all next-generation sequencing platform (e.g. Illumina's MiSeq™ , ThermoFisher's PGM™), or with any DNA sequencing application such as targeted amplicon (Ion AmpliSeq™ or TruSeq Amplicon™), exome and whole genome. This product is available in two FFPE formats: FFPE Cell Scroll and 10% formalin-compromised genomic DNA, which can be used to generate challenging data sets for bioinformatic analysis pipeline optimization. In addition, a non-fixed genomic DNA format is also available for assay development and system set-up in a laboratory (e.g. IQ/OQ/PQ)***.

Technical Information:

Genes Covered	KIT, EGFR, KRAS, HRAS, NRAS and PIK3CA
COSMIC	1,500+ (background parental cell lines)
Verified Mutations	9 dPCR and 1 NGS
Allelic Frequency Range	1% - 10% (ARF-1001S and ARF-1001FC-1)

General:

Storage	-20°C (long)
Shipping	Ambient temperature
Stability	36 months/ Exp Date
Cell Line Background	RKO/ HCT116
Fixation Conditions	10% buffered formalin solution (4% formaldehyde) for 24 hours at room temperature

Ordering:

Quan-Plex™ NGS FFPE Cell Scroll Reference Standard	Catalog # ARF- 1001S (10% formalin)
Quan-Plex™ NGS Formalin-Compromised Genomic DNA Reference Standard	Catalog # ARF- 1001FC-1 (10% formalin)

Format:

Unit Size	1 FFPE cell scroll (20µm for ARF-1001S); 1 vial (ARF-1001FC-1 and ARF-1001G-1)
Quantity	400 ng FFPE gDNA (ARF-1001S); 1 µg gDNA (ARF-1001FC-1)
Concentration	25ng/µl (ARF-1001FC-1)

Quality Control:

Genotype	Sanger sequencing of locus-specific PCR (mutation cell lines)
Quality	≥ 60% cell density assessed by digital image of H&E staining of a 5µm slide (ARF 1001-S) ≥ 400 ng/scroll DNA per 20µm section (Promega Maxwell LEV Plus FFPE DNA Extraction Kit) (ARF 1001-S)
Quantification	Qubit™ 4.0 Fluorometer Digital PCR for mutation allele frequency Sequence verification and % MAF: NGS (AmpliSeq™ Cancer HotSpot Panel v2 for Illumina®)
Manufacturing	ISO 9001:2015 and 13485:2016 certified

***Please see Quan-Plex™ NGS Reference Standard datasheet for specifications.

rev. DS-ARF-1001-FFPE-v2

Accuref Diagnostics
A Division of Applied StemCell, Inc.
521 Cottonwood Drive, Suite 111
Milpitas, CA 95035 (SF Bay Area)
info@accuref.com

ISO 9001 & 13485 Certified

www.accuref.com
1.408.773.8007