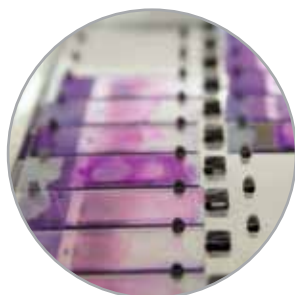


Quan-Plex™ Molecular CytoPath Reference Slides

In collaboration with multinational clinical research laboratories, AccuRef Diagnostics has developed the Quan-Plex™ Molecular CytoPath Reference Slide Panel – a validated, multigene cytopathology panel, that is the first and only reference standard panel to mimic fine needle aspirates (FNAs). The panel consists of four mutations in the MAPK pathway at dPCR-validated allelic frequencies of 0% (wild-type), 1%, 5%, or 10%. These slides are ideal for proficiency testing or clinical laboratory workflow training, thus saving precious clinical specimens for final validation.



Key Feature & Benefits:

- Quantitative multigene cytopathology molecular reference slides
- Designed for proficiency testing (PT) or routine clinical laboratory workflow training
- Set of four slides containing three PCR-validated mutations at 0% (wt), 1%, 5% or 10% MAF
- Approximately 200,000 cells/slide mimics low cell counts in clinical samples
- Proprietary Kwik-Diff™ compatible slides for low cell loss during staining and DNA extraction
- Biologically-relevant, and reproducible quality controls for NGS, dPCR and MALDI-TOF analysis

Digital PCR Verified Mutations:

Slide	Gene	Nucleotide Change	Amino Acid Change	Cosmic ID	Mutation Allele Frequency Target	Mutation Allele Frequency Observed
10%	EGFR	c.2235_2249del15	p. E746-A750del	6223	10%	11.52%
	EGFR	c.2369C>T	p. T790M	6240	10%	12.36%
	KRAS	c. 38 G>A	p. G13D	532	10%	11.89%
5%	EGFR	c.2235_2249del15	p. E746-A750del	6223	5%	6.57%
	EGFR	c.2369C>T	p. T790M	6240	5%	5.59%
	KRAS	c. 38 G>A	p. G13D	532	5%	5.65%
1%	EGFR	c.2235_2249del15	p. E746-A750del	6223	1%	1.17%
	EGFR	c.2369C>T	p. T790M	6240	1%	1.38%
	KRAS	c. 38 G>A	p. G13D	532	1%	1.33%

Fine-Needle Aspirates for Molecular Characterization

Most lung cancer patients are currently diagnosed using fresh cytological smears, rather than formalin-fixed, paraffin-embedded (FFPE) cell blocks.¹ In such a case, a fine needle aspirate (FNA) specimen is smeared directly onto a glass slide for analysis, or deposited onto a slide using a Cytospin™ centrifuge. If residual cellular material remains, it is processed into an FFPE cell block. Due to the low quantity of cytological specimen obtained from an aspirate, and in the absence of a cell block preparation, direct smears are the only source of tumorigenic material for molecular characterization in lung cancer.¹

A New Paradigm in FNA Proficiency Testing Reference Materials

Performing proficiency testing (PT) with cytological smears is particularly challenging, since clinical FNA samples are not reproducible or replaceable. Our Onco-Ref™ engineered cell lines allow us to generate a consistent and renewable source of FNA mimetic slides, thereby enabling the development of the first FNA reference standard product on the market.

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

Technical Information:

Genes Covered	EGFR and KRAS. (BRAF V600E & BRAF V600K may be detected in background but not dPCR verified.)
Verified Mutations	3 mutations per slide (concurrent)
Allelic Frequency	0% slide (wild-type), 1% slide, 5% slide, 10% slide
Fixation Process	70% methanol, 4 hours at room temperature

Ordering:

Quan-Plex™ Molecular CytoPath Reference Slides	Catalog# ARF-1002F
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Format:

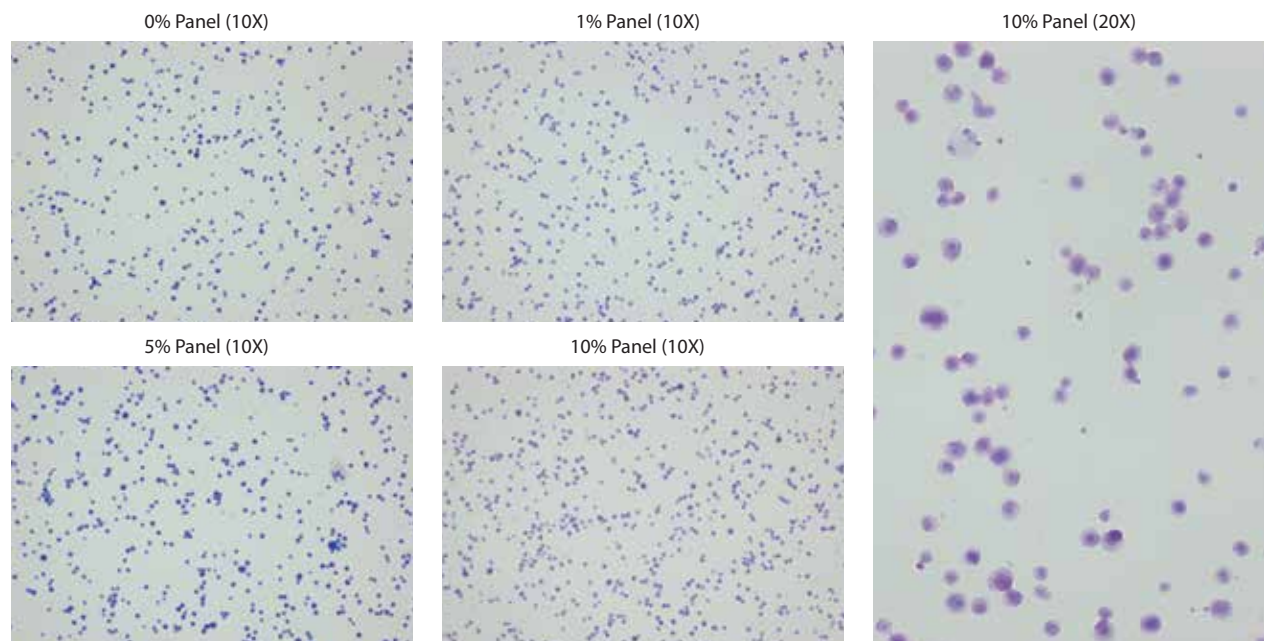
Unit Size	1 panel (4 cytology slides)
Quantity	200,000 cells per slide (typically, >50ng/ slide gDNA post-extraction)
Intended Use	Fine Needle Aspirate (FNA) molecular cytopathology proficiency testing with NGS, digital PCR, and mass spec.

General:

Storage	-20°C (long term)
Shipping	Room temperature
Cell Line Background	RKO

Quality Control:

Genotype	Sanger sequencing of locus specific PCR (cell line)
Quality	Kwik-Diff™ stain (slides)
Quantification	Cell counter (cells) and digital PCR (mutation allele frequency determination from extracted gDNA)
Manufacturing	ISO 9001:2015 and 13485:2016 certified



Kwik-Diff™ stained images of Quan-Plex™ Molecular CytoPath Reference Slides at 10x and 20x magnification.

References: 1. Belleveicine C, Vita GD, Malapelle U, Troncone G. Applications and limitations of oncogene mutation testing in clinical cytopathology. Semin Diagn Pathol. 2013;30:284-297.

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DS-ARF-1002F-v3