

Certificate of Analysis

Quan-Plex™ Patient-Like ctDNA Panel

Manufacturing Quality

ISO 9001:2015

ISO 13485:2016

Product Information

Catalog Number	Lot Number		Volume		
ARF-1003CT	ARF1003CT291725-5		7.5 µL		
	ARF1003CT291725-1		7.5 µL		
	ARF1003CT291725-01		7.5 µL		
	ARF1003CT291725-0		7.5 µL		
Expiration Date	6/13/2020				
Mutation	Gene	Nucleotide Change	Amino Acid Change	Cosmic ID	Variant Type
	EGFR	c. 2155G>A	p.G719S	6252	Substitution
	EGFR*	c.2307_2308insGCCAGCGTG	p.V769_D770insASV	12376	Insertion
	EGFR	c.2369C>T	p.T790M	6240	Substitution
	EGFR	c.2573T>G	p.L858R	6224	Substitution
	KRAS	c.35G>A	p.G12D	521	Substitution
	PIK3CA	c.1633G>A	p.E545K	763	Substitution
	NRAS	c.181C>A	p.Q61K	580	Substitution
*Mutation is detected by NGS only at 5% allelic frequency and not detected by dPCR.					
Long Term Storage	-20°C				
Short Term Storage	2-8°C (2 months shelf-life up to 3 freeze/thaw cycles)				
Shipping Condition	Cold Pack				
Instructions for Use	Refer to product Datasheet (Available www.accuref.com)				
Intended Use	For research use only. Not intended for human or animal diagnostic or therapeutic use.				

Quality Control

Test	Method	Acceptance Criteria	Result
Genotype	Sanger Sequencing	Locus Specific PCR	Pass
Allelic Frequency	Digital PCR	0.0%-0.2% 1%-5% ± 30% >20% ± 10%	Pass
Quantification	Qubit 4.0 Fluorometer	40 ng/µL ± 10%	Pass
Fragment Size	Bio Analyzer DNA 1000 Chip	150-166 bp	Pass

Applied StemCell, Inc. certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date when stored unopened as recommended.

<i>Deepika Temam</i>	<i>10/18/2018</i>
Quality Assurance	Date