



Applied StemCell



# Certificate of Analysis

## Quan-Plex™ NGS FFPE Block Reference Standard

Manufacturing Quality

ISO 9001:2015

ISO 13485:2016


### Product Information

<b>Catalog Number</b>	ARF-1001S		
<b>Lot Number</b>	F1001S291814		
<b>Kit Component</b>	<b>Gene</b>	<b>Mutation</b>	<b>Panel Frequency</b>
	KIT	D816V	10%
	EGFR	L858R	8%
	EGFR	T790M	1%
	EGFR	G719S	5%
	KRAS	G12D	2%
	HRAS	Q61R	3%
	HRAS	Q61K	5%
	PIK3CA	H1047L	6%
PIK3CA	E545K	7%	
<b>Expiration Date</b>	07/02/2021		
<b>Long Term Storage</b>	-20°C		
<b>Short Term Storage</b>	2-8°C (2 months shelf-life up to 3 freeze/thaw cycles)		
<b>Shipping Condition</b>	Cold Pack		
<b>Instructions for Use</b>	Refer to product Datasheet (Available <a href="http://www.accuref.com">www.accuref.com</a> )		
<b>Intended Use</b>	For research use only. Not intended for human or animal diagnostic or therapeutic use.		

### Quality Control

Test	Method	Result	Result
Allelic Frequency	Digital PCR	0.1% - $\geq 2\% \pm 60\%$ $> 2\% - < 10\% \pm 30\%$ 10% - 20% $\pm 20\%$ 20% $\pm 10\%$	Pass
Quantification	Qubit 4.0	$> 50\text{ng}/\text{scroll}$	Pass
Cell Density	H&E staining	$> 60\%$	Pass
NGS sequence validation	Ampliseq Cancer hotspot v2	0.1% - $\geq 2\% \geq \pm 60\%$ $> 2\% - < 10\% \geq \pm 30\%$ 10% - 20% $\geq \pm 20\%$ 20% $\geq \pm 10\%$	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.

	12/18/19
<b>Quality Assurance</b>	<b>Date</b>