

SPECIFICATION SHEET

Product:	pAMC_Pack
Sterility:	0.2 µm filtered
Storage Temperature:	-80 °C

The quality attributes and performance of this product are tested using the following assays:

TEST	METHOD	SPECIFICATION
Appearance	Visual evaluation	Clear no visible particle
pH	Potentiometric Measurement	Report
Concentration	UV/Vis Spectrometry	1 mg/mL
Purity	Spectrometry A260/A280	1.8 - 2.0
Identity	Restriction enzymes and AGE	Conform to reference
Identity	Sanger Sequencing	100% alignment to reference
Residual RNA	Visual inspection after AGE	< 5%
Residual genomic DNA	Visual inspection after AGE	< 5%
Residual genomic DNA	qPCR	< 5%
Residual proteins	BCA assay	< 2% w/w
DNA homogeneity (ccc content)	HPLCs	≥ 80%

TEST	METHOD	SPECIFICATION
Bacterial Endotoxins	LAL test	< 10 EU/mg DNA
Bacteriophages	Microbial method (direct inoculum)	No visible plaques
TAMC&TYMC	Microbial count	< 1 UFC/mL
Sterility	Ph.Eur 2.6.1	Sterile
Mycoplasma	Ph.Eur 2.6.7	Negative