



## CAR-T Release Testing

CAR-T (Chimeric Antigen Receptor T-cell) therapy represents a groundbreaking advancement in cancer treatment, as it harnesses the power of genetically modified T-cells to specifically target and eliminate cancer cells. This innovative approach offers remarkable efficacy in treating certain types of refractory or relapsed cancers, providing new hope for patients who have exhausted conventional treatment options.

At Avance Biosciences, we understand the critical nature of providing fast quality control of your CAR-T drug product. We have comprehensive Quality Control (QC) solutions tailored to ensure the highest standards of product safety, efficacy, and consistency to support in the following areas:

### Key CAR-T Services:

Critical Quality Attributes	Assay	Description
Identity	CAR+ expression	Confirm CAR expression on T-cell surface using flow cytometry
	CAR transgene integration site analysis	Verify the CAR transgene sequence within the T-cells using PCR and Sanger sequencing or NGS
Purity	Immunophenotyping	Determine % of immune cell subsets in the DP by flow cytometry
	CAR+ T cell percentage	Determine the % of CAR+ T cells by flow cytometry
Potency	Vector Copy Number (VCN) Analysis	Confirm the presence and copy number of the CAR transgene in the CAR-T cell drug product using QPCR or ddPCR
	Transduction Efficiency Analysis	Determine the % of transduced cells using flow cytometry or QPCR/ddPCR
	Cell-based Potency Assays	Assess the ability of CAR-T cells to elicit an antitumor response, typically by measuring their cytotoxicity against target cells or evaluating other effector functions. Requires development of assay specific to target
	Viability and Cell Counting	Determine the viability and concentration of CAR-T cells in the final product using NC-200 or flow cytometry

## Key CAR-T Services (Cont.):

Critical Quality Attributes	Assay	Description
Safety	Replication Competent Lentivirus (RCL) Testing	Perform a rapid QPCR-based assay to verify CAR-T drug product is free from RCL
	Sterility Testing	USP <71>
	Endotoxin Testing	USP <85>
	Mycoplasma Testing	QPCR-based rapid mycoplasma test covering 17 Mycoplasma species.
Other	pH	USP <791>
	Osmolality	USP <785>

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