Allogeneic Cell Therapy

Allogeneic therapies use cells from healthy donors that are expanded and may be modified before they are used to treat patients. In addition to human donor screening, additional GMP biosafety testing must be performed after the GMP cell-processing activities have been completed.

Why Choose Eurofins BioPharma Product Testing?

In addition to the final Certificate of Analysis, we also provide raw data results as a deliverable.

Our industry leading online data portal, LabAccess, provides customers access to our LIMS system, allowing 24-hour access to data.

Our dedicated Project Management team focuses on biosafety, rapid testing, and client communications to assure on time delivery in a GMP environment.

Our PhD scientists and Quality Assurance teams work together to provide expertise that ensures sound scientific approaches and GMP adherence.

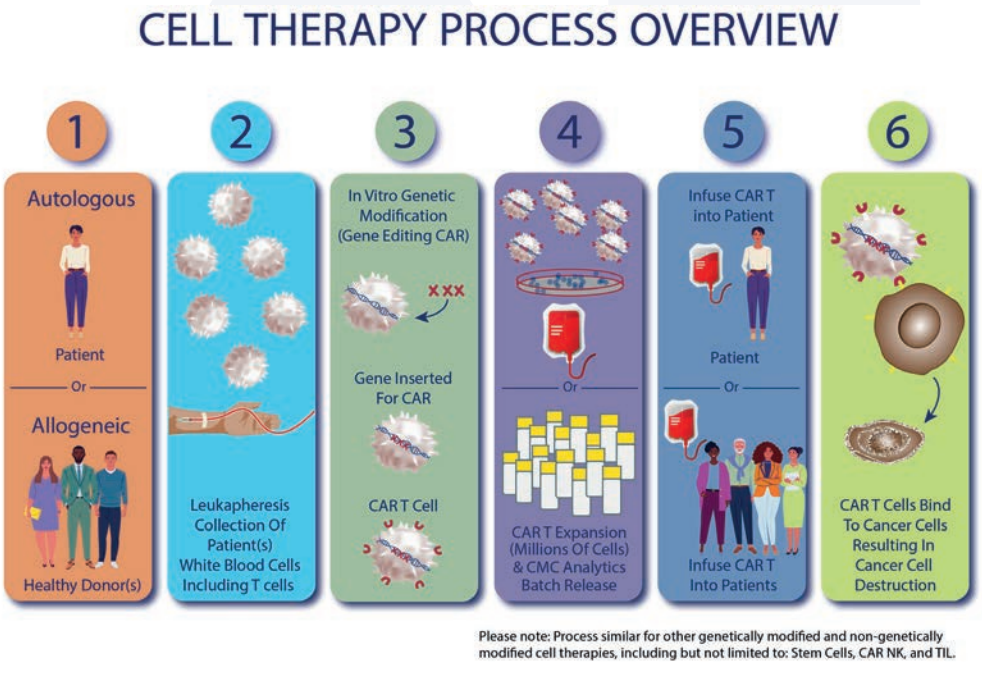
Testing Performed

GMP biosafety testing, such as sterility, mycoplasma, in vitro adventitious agent, etc. should be considered to confirm the product has not been contaminated.

A critical item to consider are the raw material inputs. If the human cells are exposed to any reagents or materials derived from animals, targeted species-specific viral testing may be needed. Manufacturing may utilize retroviruses which means that downstream virology testing may also be required If viral vectors are used for gene editing, replication competent testing may be needed.

Sample Considerations

Sample harvest for these individual test methods may vary during the cellular processing and can vary based upon your cellular processing approach. Appropriate sample planning and assessment of the manufacturing process should be considered to determine the most appropriate time to take a sample for a particular biosafety test method. Sampling plans and GMP release testing should always be discussed with your regulatory reviewer to be sure the approach is satisfactory and will yield the most accurate information prior to administering the cellular product to a patient. If appropriate, Eurofins can provide cell expansion to generate enough material to run the various GMP release test methods.



Please note: Process similar for other genetically modified and non-genetically modified cell therapies, including but not limited to: Stem Cells, CAR NK, and TIL.

Allogeneic Testing Requirements			
Test Method	**US Test Code**	**US TAT**	**US Sample Requirement**
Cell Expansion	GPMSX	Varies	2 Vials
Sterility Suitability B&F	QL1C2	25 Days	7 Vials
Sterility	QL23J	25 Days	1% of Cell Bank (minimum of 2 vials)
Mycoplasmastasis	GPMYK, GPMYL	35 Days	2x25mL, 4x1.5mL > 1x10e^6 cells/mL
Mycoplasma Analysis	GPMYM, GPMYN	35 Days	2x12mL, 2x1.5mL > 1x10e^6 cells/mL
Identity via CO1	QL0CJ	14 Days	2x10e^7 cells
Karyology	QL121	6-8 Weeks	Cyropreserved Cells
Short Tandem Repeat (STR)	QL6X0	35 Days	1x10e^8 Cell Pellet
in vitro Adventitious Agent - MRC-5	QL07V	35 Days	7mL Cell Lysate at 1x10e^7 cells/mL
in vitro Adventitious Agent - Vero	QL07W	35 Days	7mL Cell Lysate at 1x10e^7 cells/mL
in vitro Adventitious Agent - HeLa	QL09G	35 Days	7mL Cell Lysate at 1x10e^7 cells/mL
Bovine 9CFR*	QL089	35 Days	6mL Cell Lysate at 1x10e^7 cells/mL
Porcine 9CFR*	QL0B6	35 Days	8mL Cell Lysate at 1x10e^7 cells/mL
Human PCR Panel HIV I/II, HAV, HBV, HCV, HTLV I/II, EBV, CMV, HHV 6/7/8, HPV 16/18, & B19	QL0FM	21 Days	1x10e^6 cell pellet
	QL0FR	21 Days	1x10e^6 cell pellet
	QL0FT	21 Days	1x10e^6 cell pellet
	QL0FV	21 Days	1x10e^6 cell pellet
	QL0FY	21 Days	1x10e^6 cell pellet
	QL0G0	21 Days	1x10e^6 cell pellet
	QL0G4	21 Days	1x10e^6 cell pellet
	QL0G6	21 Days	1x10e^6 cell pellet
	QL0G8	21 Days	1x10e^6 cell pellet
	QL0GB	21 Days	1x10e^6 cell pellet
	QL0GD	21 Days	1x10e^6 cell pellet
	QL0GF	21 Days	1x10e^6 cell pellet
	QL0GH	21 Days	1x10e^6 cell pellet
	QL0GJ	21 Days	1x10e^6 cell pellet
TEM	QL4YU	40 Days	Unprocessed Bulk (inquire about volume)
F-PERT	QL0BV	10 Days	2x5 mL Supernatant, 2x5 mL of fresh media (if available)
Endotoxin Suitability	GPMA8	14 Days	10mL
Endotoxin Routine	GPMA5	14 Days	10mL
Mycobacterium PCR	QL4YE	10 Days	2x2mL (1x10e^7 cells)

*These tests may not be needed and can depend upon your process inputs.

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