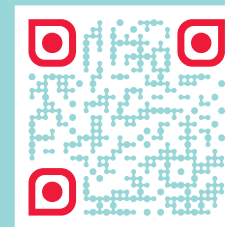


# For a true cell therapy manufacturing partnership, the CDMO of choice is SCTbio



**sctbio**

Member of PPF Group



**14 years**

in cell  
and gene  
therapy field



**70+**

employees



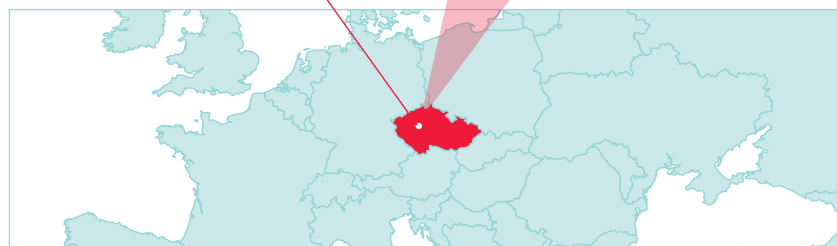
**2,000 m<sup>2</sup>**

facility area  
including 420 m<sup>2</sup>  
of clean rooms

SCTbio is the leader in services, development and cGMP production of cell-based therapies as well as viral vectors. The team provides a full range of services ensuring GMP compliance for the entire life cycle of drug development, including analytical services such as cell-, flow cytometry-, molecular biology- and microbiology-based methods.

Based in Central  
Europe, Prague, CZ

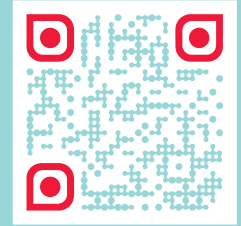
**sctbio**



## Full scope of analytical capability

Microbiology	Sterility test (direct inoculation, rapid BACTEC, membrane filtration or GRAM stain)	Safety first! On the top of the standard safety tests, we can provide rapid and modern approach of sterility testing (BACTEC™) and endotoxin (Endosafe®)
	Endotoxin test (LAL assay or Endosafe®)	
	Mycoplasma test (PCR)	
	Microorganism determination	
d/q PCR	Residual plasmid assay	Detection or precise absolute or relative quantification allows for the identity testing of viral vector samples or ATMPs as well as for impurities detection
	Viral particle quantification	
	Vector copy number	
	Gene expression quantification	
ELISA	PERT Assay	ELISA tests allow to determine the state of impurities (residual reagents, host cell proteins, viral particles) in the samples. Additionally, the p24 ELISA provides accurate quantification of viral particles
	Benzonase	
	BSA	
	HEK293 HCP	
Flow cytometry	p24	Our flow cytometers allow for the testing of up to 12 colors at once. Highly experienced team can help you to design the panel that will fit unique requirements
	Identification of various cell populations in whole blood, leukapheresis products and cell cultures	
	Quasi-quantitative or quantitative enumeration of cell populations	
	Viability and apoptosis assessment	
Hematology analyzer	Evaluation of activation, exhaustion and senescence of T cells	Donor/patient starting materials are highly variable. Extensive analysis at the beginning of the production is useful information before processing any further steps of production
	Cell cycle testing	
	Complete blood counting	
	5 populations differential	
Others	Viability	Monitoring of cell culture growth and physicochemical tests of the drug product
	Fast characterization of CD markers in unmanipulated sample	
	Lactate measurement	
	Glucose measurement	
Custom-made methods	Turbidity measurement	Contact us @ <a href="mailto:partnering@sctbio.com">partnering@sctbio.com</a> to discuss your needs in detail
	pH measurement	
	Potency test	
	Culture-based methods	
	Clonogenic assays	

# Study case: In-house analytical assays for CAR-T product



sctbio

Member of PPF Group

Starting material

First expansion

Transduction

Second expansion

Product



## Leukapheresis /PBMC

- Lactate
- Hematological analysis / CELL-DYN Sapphire
- Cell population and viability / Flow cytometry (BD LSRFortessa™)



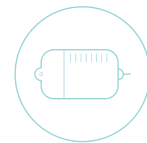
## In-process

- Cell counting and viability / Nucleocounter® NC-200™



## Post-transduction

- T-cell population, viability, CAR expression / Flow cytometry



## Expansion

- Customizable flow cytometry panel
- Cell counting and viability / NC-200™



## Drug substance / Drug product

### Safety:

- Sterility
- Endotoxin
- Mycoplasma
- RCL / RCR / cultivation test\* or / PCR
- Viral vector copy number / q/d PCR

### Impurities:

- BSA / ELISA
- Benzonase / ELISA
- Residual plasmid / q/d PCR

### Identity:

- Gene of interest copy number / q/d PCR
- Expression of the CAR / Flow cytometry
- Viability / Flow cytometry and NC-200™
- Cell count – dose determination

### Characterization:

- Cell population / Flow cytometry

### Potency / Flow Cytometry:

- Cytokine release assays
- Killing assays
- T-cell activation assays

\* RCR/RCL tests are currently outsourced to trusted partners

