

clean cells

SOLUTION FOR BIOLOGICS

OUR SERVICES

QUALITY CONTROL TESTING



BIOSAFETY TESTING

- Sterility/Bioburden and mycoplasma test
- Specific contaminant via qPCR and RT-qPCR
- Transmission Electron Microscopy (TEM)
- Retrovirus detection via infectivity and/or QPERT assay
- RCL, RcAAV
- *in vitro* and *in vivo* testing

POTENCY

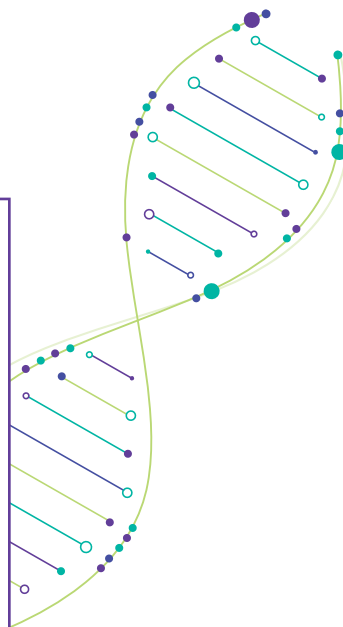
- Monoclonal antibodies: Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) assay
- Telomerase testing, interferon testing, etc.

PURITY

- Residual Host Cell Protein (HCP) quantification
- Residual DNA testing
- Endotoxin testing
- Residual reagents quantification (BSA, benzonase)

IDENTITY

- Karyotype and FISH analysis
- RAPD-PCR based characterization
- Q-PCR-based species identification
- Genetic characterization of recombinant cell lines (gene copy number, vector copy number)
- Gene sequencing



Clean Cells is a GMP-licensed company dedicated to support the biopharmaceutical industry.

BIOASSAY

CYTOTOXICITY ASSAYS

- Innovative cytotoxicity potency assay, compliant with the Regulatory Authorities requirements
- *In vitro* assay for characterization of ADCC, CDC and/or apoptosis activities of the classical cytolytic antibodies
- Effector function: innovative standardized effector cell line or PBMCs
- Read-out: High-performance luminescence-based method or Chromium
- CAR-T: potency assays using the high-performance luminescence-based method

AN INNOVATIVE NON-RADIOACTIVE LUMINESCENT CYTOTOXICITY MEASUREMENT METHOD

- Specific of the target cell lysis triggered by cytotoxic antibodies
- Improved standardization potential via a reporter molecule
- Easy to implement via the use of widely available equipments (luminometers)



SPECIFICALLY DEVELOPED STANDARDIZED ADCC EFFECTOR CELLS

- Human cytotoxic T cells expressing Human CD16
- Absence of non-specific background lysis
- No inter-individual variability in ADCC response
- Intra-batch homogeneity
- Thaw-and-use format and long-term stability

STORAGE



STORAGE FOR R&D AND GMP PRODUCTS

- Qualified refrigerators (+5°C ± 3°C)
- Qualified freezers (-25°C ± 10°C / -80°C ± 20°C)
- Qualified cryocontainers (liquid or vapor nitrogen)
- Shared or dedicated storage
- Manual or semi-automatic filling
- Continuous temperature and nitrogen levels monitoring
- 24/7 externalized alarm system
- Restricted area

R&D SERVICES



ANALYTICS

- Customized molecular biology and cell-based assays can be developed and/or validated (ICH Q2R1)

PROCESS DEVELOPMENT

- Manufacturing upstream and downstream process development for Biologics

MANUFACTURING

EUKARYOTIC CELL BANK

- Adherent cell cultures or suspension cell cultures
- Manual or automated filling/Controlled-rate freezing available
- Strict environmental monitoring and validated cleaning procedures

VIRAL SEED STOCK

- Production of MVSS and WVSS
- A wide expertise with a variety of viruses such as Vaccinia virus, Enterovirus, Coxsackievirus, Dengue, Rubella, Measles, Influenza virus, Adenovirus, Zika Virus, Epstein Barr Virus
- BSL-2 or BSL-3 environment
- QC testing available

LIVE ATTENUATED AND INACTIVATED VIRAL VACCINE, VIRAL VECTORS FOR IMMUNOTHERAPY AND ONCOLYTIC VIRUSES

- Performed at Naobios
www.naobios.com

PROKARYOTIC CELL BANK

- Substrate for recombinant products/plasmid generation/bacteriophage generation

BACTERIOPHAGES

- Microbial cell banks
- Phage stocks
- Drug substance (single phage)
- Drug product (phages cocktail)