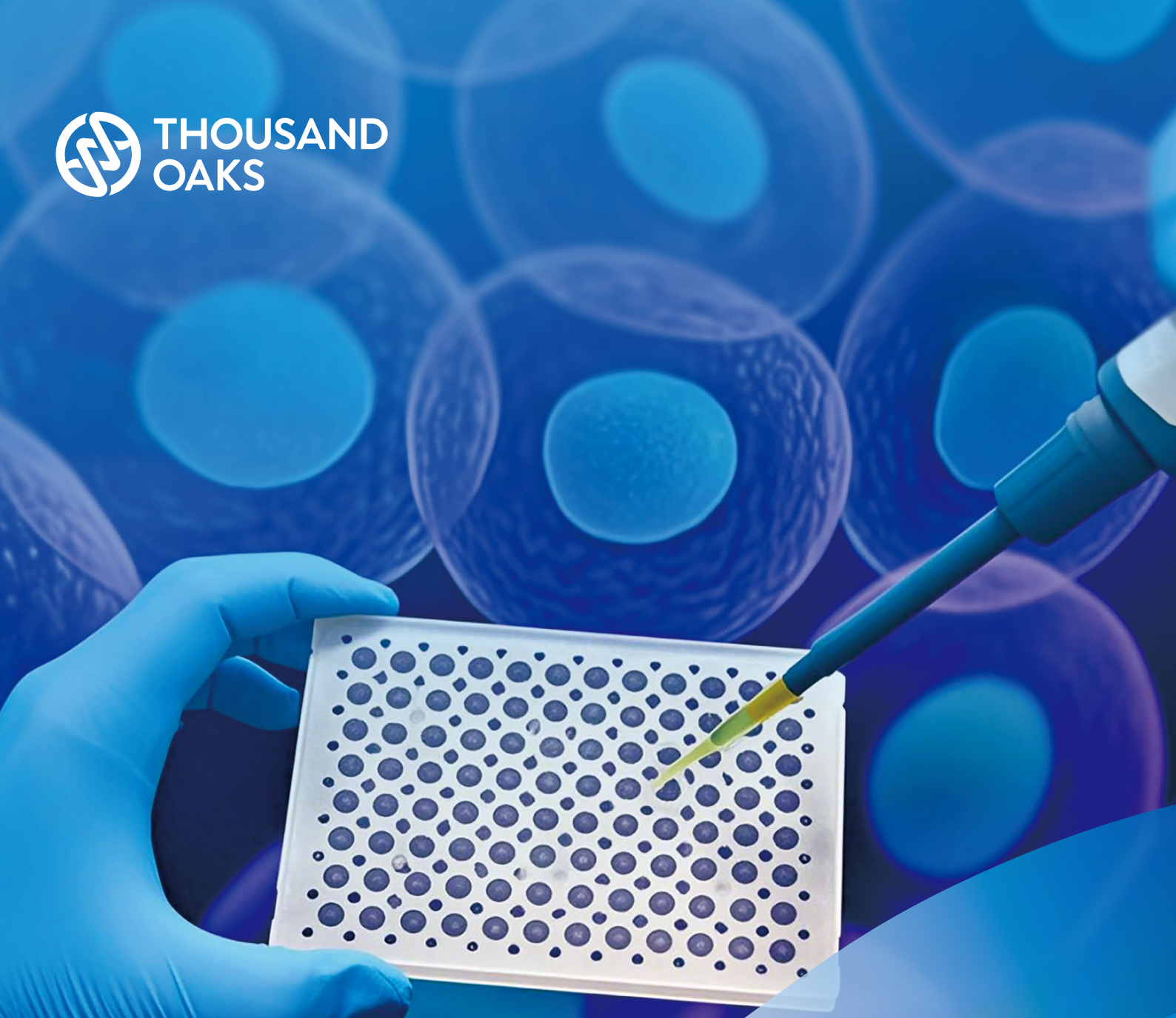
THOUSAND OAKS



MeCHOta® CHO-K1 Cell Line Development Platform

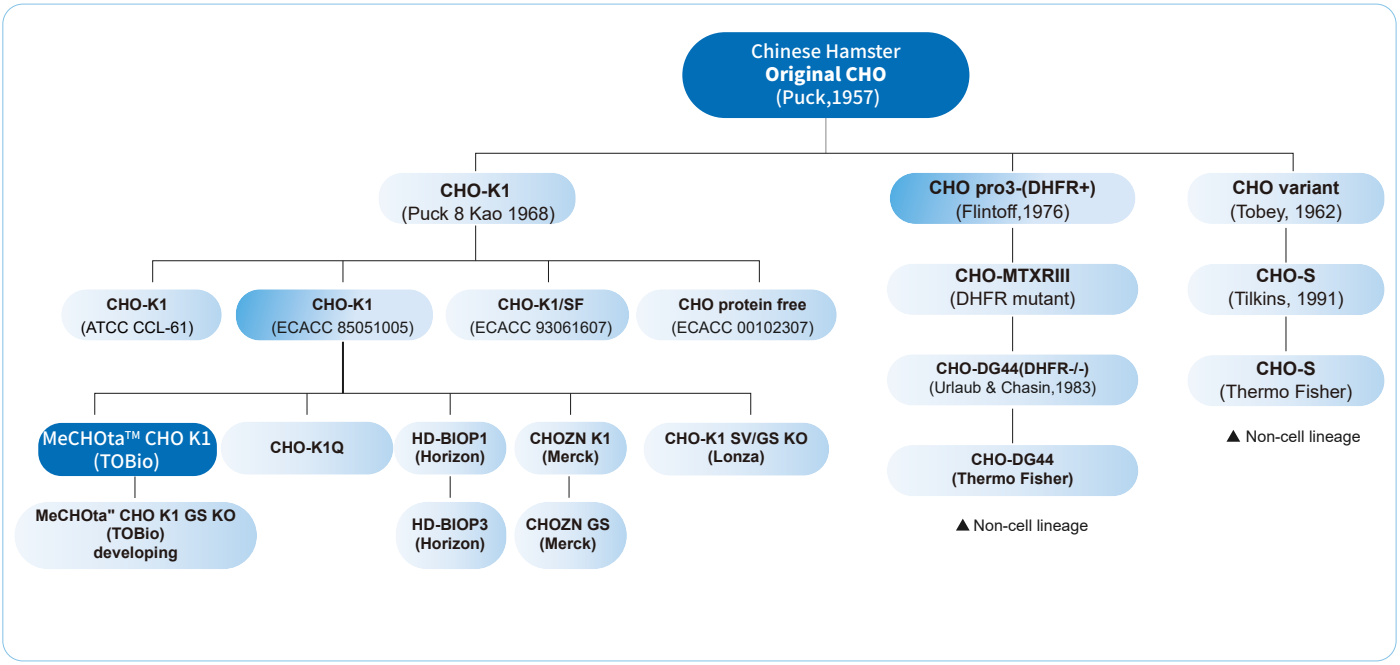
An Integrated CMC Organization

MeCHOta® Introduction

MeCHOta® CHO-K1 cell line is derived from ECACC CHO-K1, adapted to suspension culture in serum-free medium and selected by monoclonal screening, It has global authorization and proven supporting service kit(expression vector, medium), ensuring stable production capacity from laboratory to commercial scale.

MeCHOta® CHO-K1 Pedigree

MeCHOta® CHO-K1 is derived from CHO-K1 (ECACC 85051005), with clear background and clear lineage, meeting the compliance requirements of excellent commercial engineering cell lines.



Superity of MeCHOta®

Stability, compliance (traceability) and scalability (excellent metabolism) are the most important indicators for evaluating commercial engineering cell lines. MeCHOta® CHO-K1 has a clear background, complete traceability and compliance, has passed comprehensive cell testing, has reliable stability, excellent metabolic level and environmental tolerance, meets all standards of engineering cell lines, and is an excellent commercial project cell line.

01

Perfect Background and Traceability

Originated from ECACC CHO K1, complete purchase records, customs declaration list, temperature control records and cell COA

02

Perfect Package Kit

Expression vectors with independent intellectual property rights and customized matching culture media

03

Reliable Stability

Genetic stability across passages, consistent productivity and product quality, stable transgene integration and copy number.

04

Serum-Free Adaptation Process

Performed in CD CHO 031 basal medium using serum-free, chemically defined medium throughout the process.

05

Comprehensive Cell Testing

Sterility, mycoplasma, endogenous viral factors, retrovirus, cell identification, etc.

06

Excellent Metabolism and Tolerance

Maintains low lactate levels and tolerates high ammonium and hyperosmotic conditions.

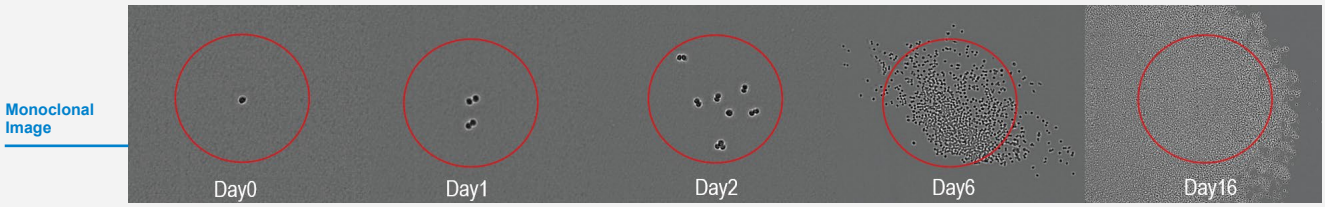
MeCHOta® Host Cell Background Traceability

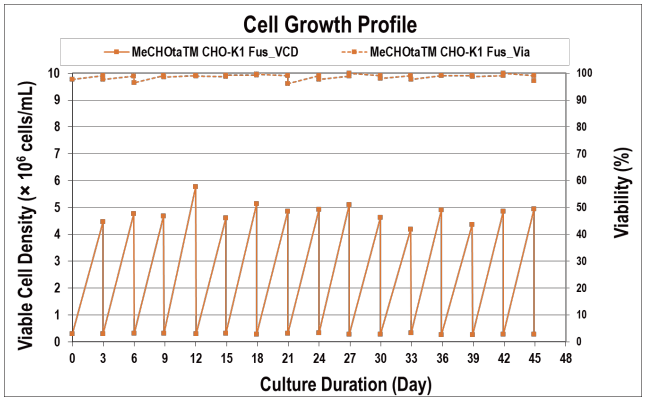
- Protocell Purchase Order
- Protocell Purchase Invoice
- Logistics and transportation certificate
- cGMP Cell Bank
- Customs declaration/clearance
- COA of Cell Line
- Adaptation Process Raw Material COA
- Raw material TSE/BSE statement for adaptation process
- Complete cell differentiation and detection of endogenous virus
- Material transportation temperature record
- Complete adaptation and monoclonal screening records

MeCHOta® CHO-K1 has a complete traceability of the whole process from original purchase to cGMP banking and testing, ensuring the compliance of cell line for IND and BLA.

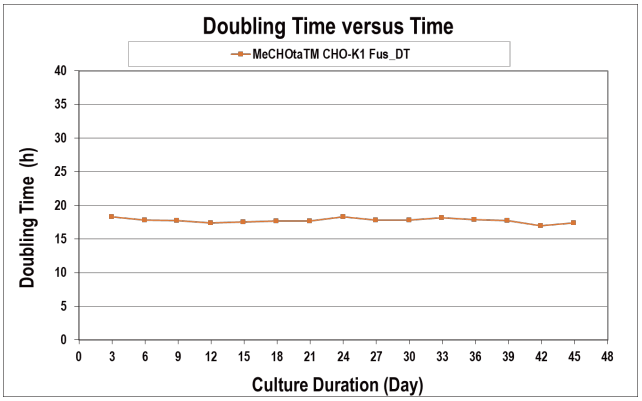
Excellent Growth Characteristics of MeCHOta® Host Cells

MeCHOta® CHO-K1 has uniform cell shape and size (~15 μm), stable growth, short doubling time (~18h), and excellent growth characteristics. It is an ideal cell line for commercial large-scale production.





MeCHOta® Cell Growth Profile



MeCHOta® Cell Doubling Time

Complete Detection Report of MeCHOta® Host Cells

The MCB and WCB established by MeCHOta® CHO-K1 under cGMP conditions have been tested for cell identification, sterility, mycoplasma,endogenous and adventitious viruses, and retroviruses, ensuring production compliance and safety under the GMP system.

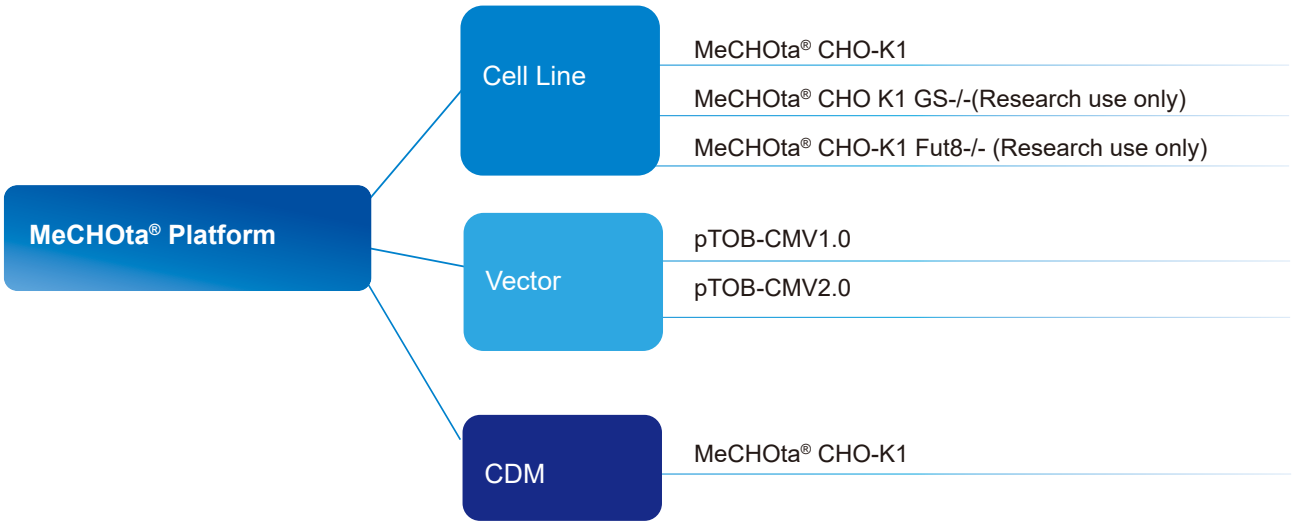
Sponsor	Thousand Oaks Biologics Inc.
Sample name	MeCHOta® CHO-K1 Fus-MCB
Lot No.	******
Start and end date	2023-10-17~2023-12-15
Test rationale	ChP/USP/ICHQ5A(R1)/ICHQ5D/US FDA PTC (1997) /US FDA PTC (1993)/9CFR

Test item	Test method	Test code	Reference standard	Test result[1]
Cell identification	Cytochrome oxidase I (CO1) detection	006002	Source from China Hamster cells	Source from China Hamster cells
Test for bacterial and fungi	Membrane filtration (Method suitability study)	007004	Report	Method suitable
	Membrane filtration	007004	Negative	Negative
Mycobacterium test (Declare for China)	Pouring method (Methodsuitability study)	008001	Report	Method suitable
	Pouring method	008001	Negative	Negative

Test item	Test method	Test code	Reference standard	Test result[1]
Detection of murineminute virus	Cytopathic observationmethod (NB324K)*	016002	Negative	Negative
	Quantitative real-time PCR*	016003	Negative	Negative
Detcction of bovine virus	Cytopathic effect(BT, MDBK, Vro, MRC-5)	017002	Negative	Negative
	Hemadsorption(BT. MDBK, Vero, MRC-5)	017002	Negative	Negative
	Fluorescent antibody detection: Bovine viral diarrhea virus Bovine parvovirus Bovine adenovirus type 3 Reovirus type 3 Bovine parainfluenza virus type 3 Bluetongue virus Bovine respiratory syncytia virus Rabies virus	017002	Negative	Negative

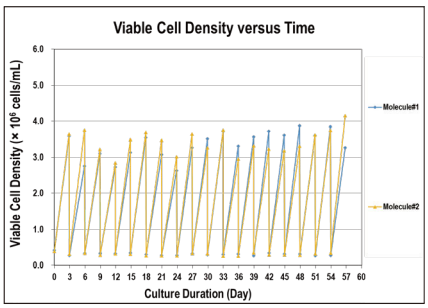
MeCHOta® Perfect matching of host cells

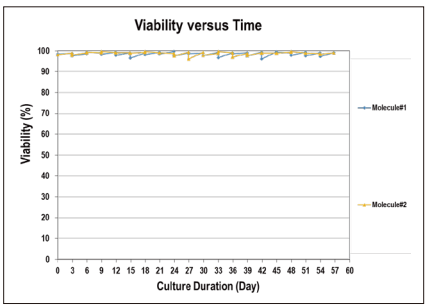
MeCHOta® CHO-K1 has a proven supporting services kit, including the expression vector system (pTOB series) with independent intellectual property rights, and the corresponding high-expression medium, to help customers quickly advance projects from DNA sequences to shelf products.



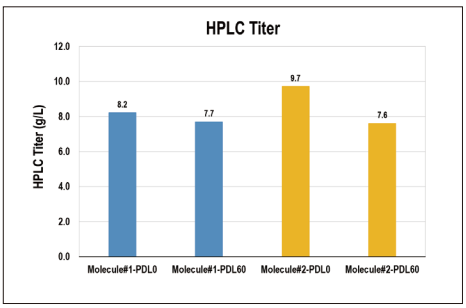
Reliable Stability of MeCHOta® Host Cell

MeCHOta® CHO-K1 exhibits excellent stability in multiple dimensions such as copy number of exogenous genes, cDNA sequence, passaging, expression level, and expression quality, and no sequence variants are produced, meeting the requirements of commercial continuous production.





Cell Growth of Cell Stability Study



Titer of Cell Stability Study

High expression of MeCHOta® CHO-K1 host cells

Gene synthesis Vector construction > Transfection > Minipool screening and evaluation > Single cell selection > Single cell evaluation > PCB establishment

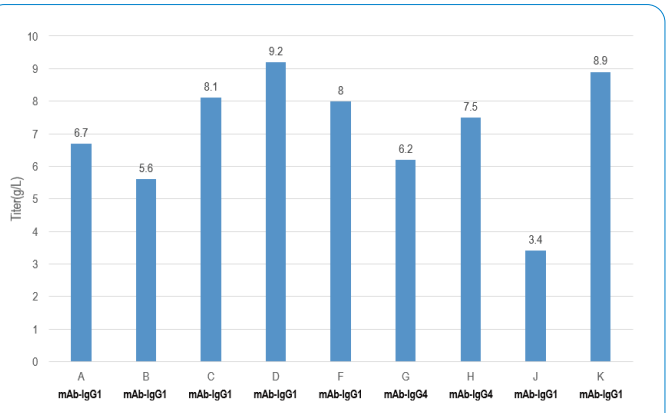
1 day > 8.5 Weeks > 5 Weeks > 2 Weeks > 1.2 Weeks

Cell lines and types of culture medium

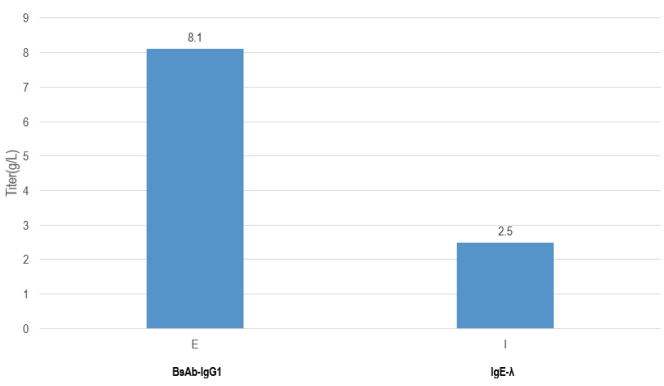
Molecule Code (based on amino acid sequence)	Molecule Type	Cell Line
A	mAb-IgG1	MeCHOta® CHO-K1
B	mAb-IgG1	MeCHOta® CHO-K1
C	mAb-IgG1	MeCHOta® CHO-K1
D	mAb-IgG1	MeCHOta® CHO-K1
E	BsAb-IgG1	MeCHOta® CHO-K1
F	mAb-IgG1	MeCHOta® CHO-K1
G	mAb-IgG4	MeCHOta® CHO-K1
H	mAb-IgG4	MeCHOta® CHO-K1
I	IgE-λ	MeCHOta® CHO-K1
J	mAb-IgG1	MeCHOta® CHO-K1
K	mAb-IgG1	MeCHOta® CHO-K1

Note: MeCHOta® CHO-K1 is derived from ECACC CHO-K1.

Titer and analysis of molecules



Titer of 9 mAb molecules



Titer of BsAb molecule and IgE-λ molecule

Our MeCHOta® CHO-K1 host cells demonstrate high-yield production, achieving high titers ranging across 11 molecules - including 9 monoclonal antibodies, 1 bispecific antibody (8.1 g/L), and 1 IgE-λ molecule.

Notably, molecules D (9.2 g/L) and K (8.9 g/L) showcase exceptional yield performance.

Molecule	Molecule type	Qp (pg/cell/d)	SEC			nrCE-SDS			rCE-SDS
			HMW (%)	Main (%)	LMW (%)	LMW (%)	Main (%)	HMW (%)	LC+HC (%)
C	mAb-IgG1	52	1.8	98.1	0.0	5.7	94.3	/	98.9
D	mAb-IgG1	56	0.0	99.3	0.7	4.0	96.0	/	99.0
G	mAb-IgG4	44	3.7	96.1	0.2	4.3	95.7	/	98.1
H	mAb-IgG4	68	3.9	93.5	2.5	3.9	96.1	/	/
E	mAb-IgG1	32	1.3	98.5	0.2	6.1	93.9	/	98.1

Molecule	Molecule type	N-Glycan (%)										
		G0-GN	G0F-GN	G0	G0F	Man5	G1Fa	G1Fb	G2F	G2S1F	G2S2F	Others
C	mAb-IgG1	1.5	3.5	6.4	54.5	4.8	16.5	6.1	2.0	/	/	4.7
D	mAb-IgG1	1.9	2.9	6.9	40.8	6.0	23.7	6.8	4.1	/	/	6.9
G	mAb-IgG4	0.5	1.1	3.9	71.6	1.3	8.0	7.9	2.1	/	/	3.6
H	mAb-IgG4	1.7	3.5	6.4	48.3	5.1	11.5	11.2	3.9	/	/	8.4
E	mAb-IgG1	0.3	0.6	3.5	51.9	0.8	19.9	8.7	6.5	1.8	1.5	4.5

CHO-K1 Sub-Licensing Process in 4 Steps

Transparent, Efficient, and Risk-Free

Step1

Initiate CDMO Collaboration

Confirm partnership with TOBio, with plans to utilize the CHO-K1 cell line.

Step2

Report to ECACC

TOBio files the cell usage record with ECACC.

Step3

Sign Sub-License Agreement

You sign an agreement with TOBio to define the scope of rights.

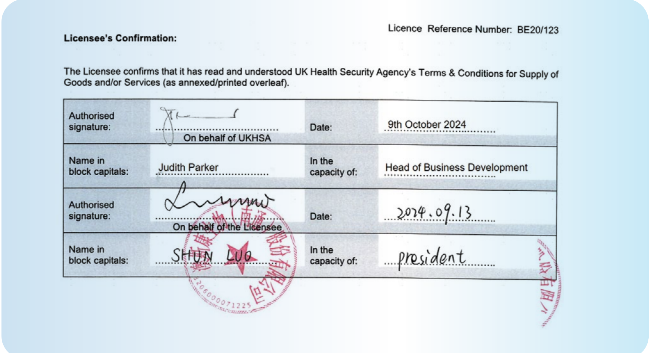
Step4

Obtain Cell Line and Sub-License

You obtain the cell line and sub-license to proceed with commercialization legally.

(Note: ECACC = European Collection of Authenticated Cell Cultures, a recognized world-leading cell bank)

License from ECACC



Licensee's Confirmation:

Licence Reference Number: BE20/123

The Licensee confirms that it has read and understood UK Health Security Agency's Terms & Conditions for Supply of Goods and/or Services (as annexed/printed overleaf).

Authorised signature:	On behalf of UKHSA	Date:	9th October 2024
Name in block capitals:	Judith Parker	In the capacity of:	Head of Business Development
Authorised signature:	On behalf of the Licensee	Date:	2024.09.13
Name in block capitals:	SHUN CUO	In the capacity of:	president

Three Key Guarantees

Global Authorization:
Worldwide commercialization rights.

One-Time Fee:
No annual fees, royalties, or hidden costs.

Termination Protection:
Existing sub-licenses are unaffected by future agreement changes.

Thousand Oaks Biologics Inc.

contact us

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