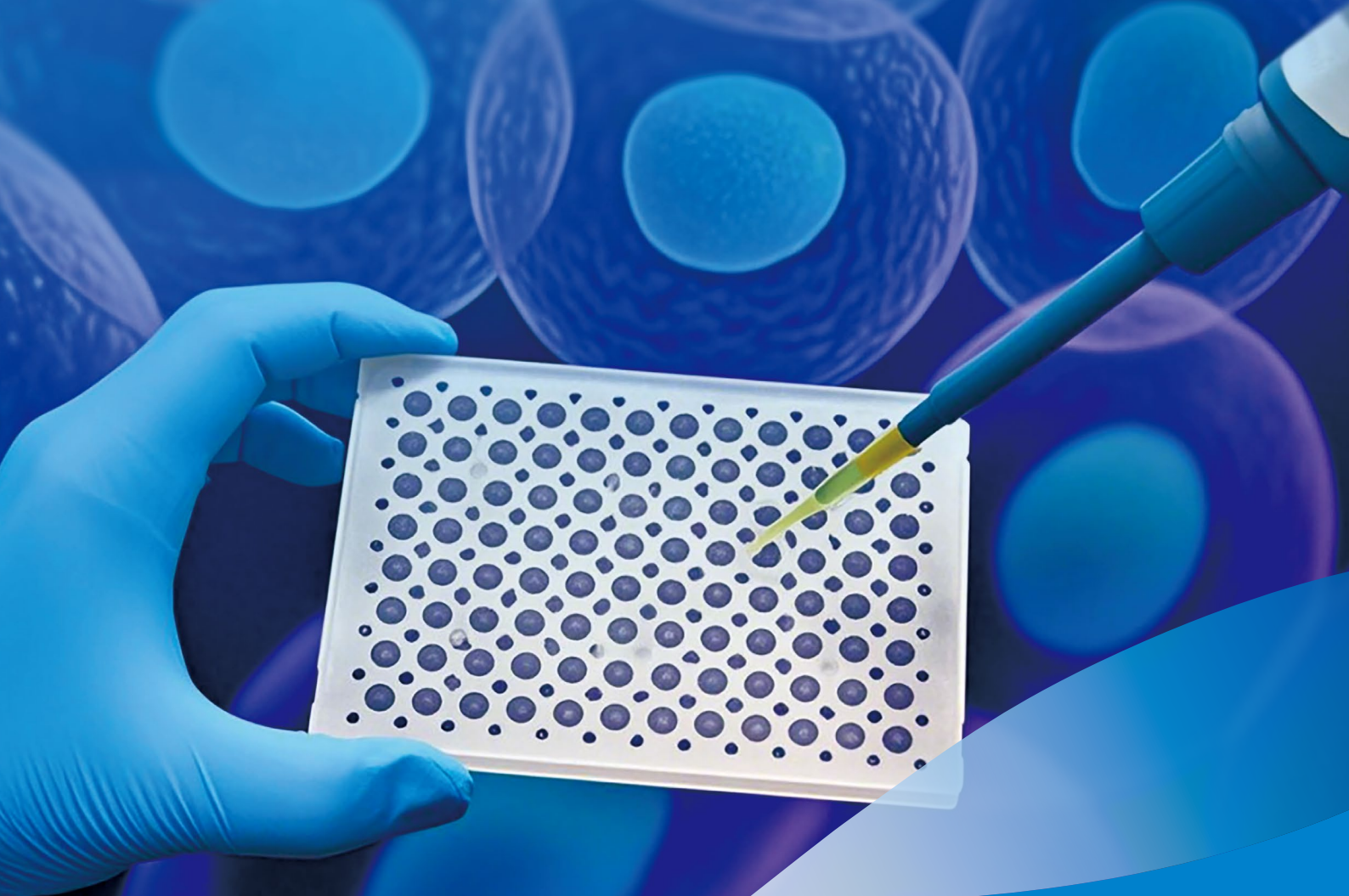




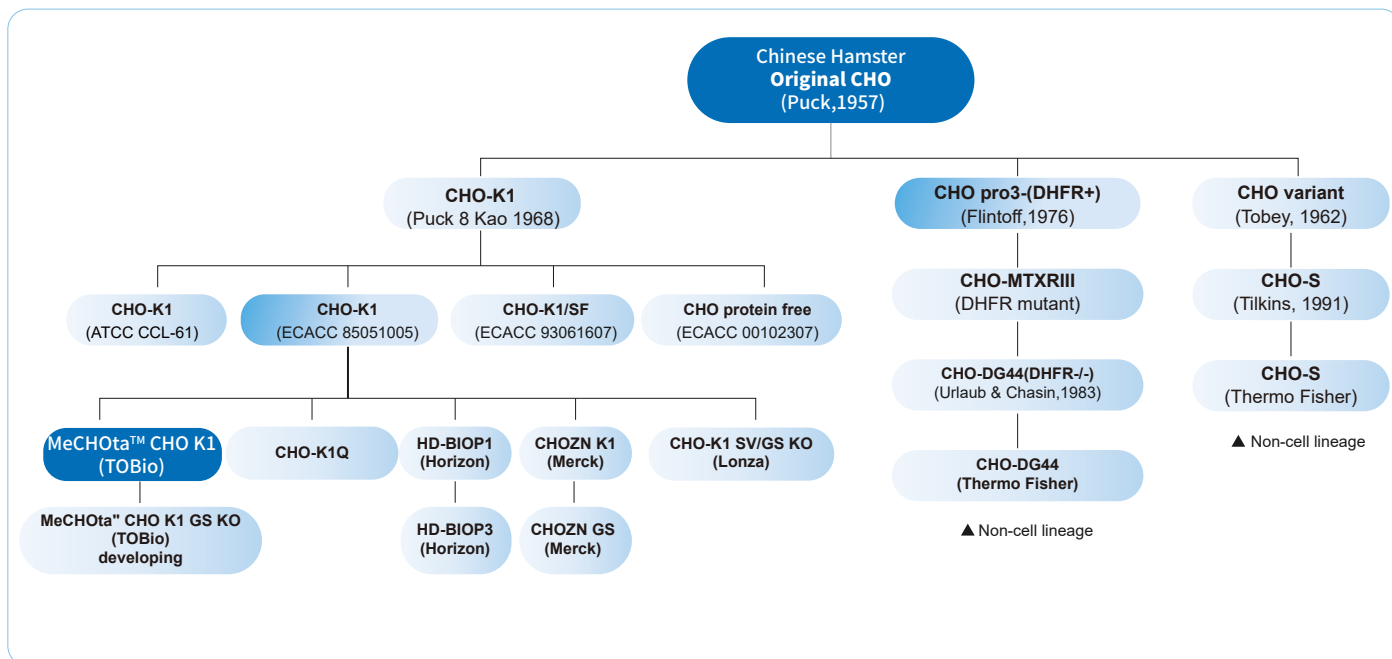
MeCHOt[®]a CHO-K1 Cell Line Development Platform

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.



MeCHOTA® Host Cell Background Traceability

Protecell Purchase Order

Protecell 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

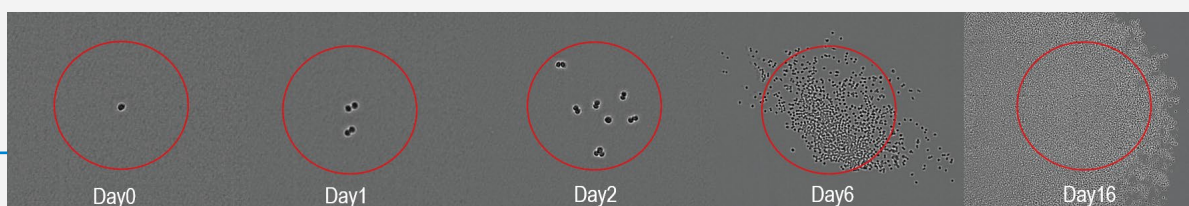
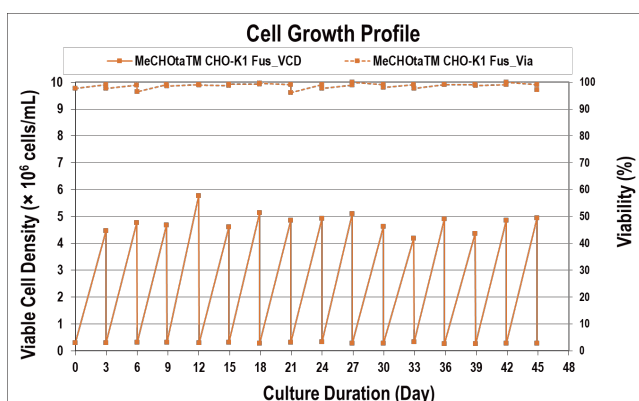
Complete adaptation and monoclonal
screening records

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.

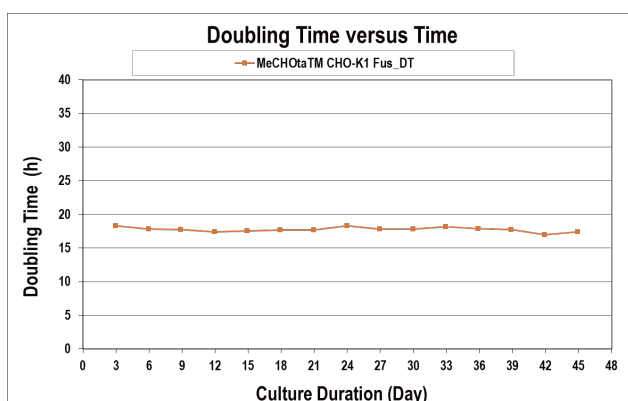
Excellent Growth Characteristics of MeCHOTA® Host Cells

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.

Monoclonal
Image



MeCHOTA® Cell Growth Profile



MeCHOTA® Cell Doubling Time

Complete Detection Report of MeCHOTA® Host Cells

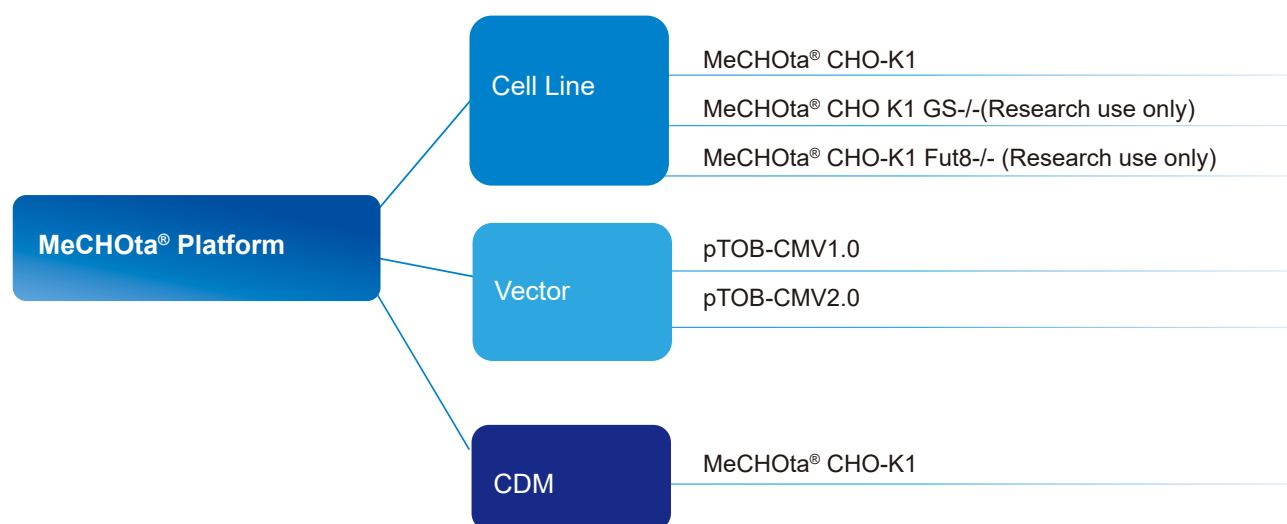
The MCB and WCB established by MeCHOTA® CHO-K1 under cGMP conditions have been tested for cell identification, sterility, mycoplasma, endogenous and adventitious viruses, and retroviruses, ensuring production compliance and safety under the GMP system.

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/CHQ5A(R1)/CHQ5D/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 (Method suitability study)	008001	Report	Method suitable
	Pouring method	008001	Negative	Negative

Test item	Test method	Test code	Reference standard	Test result ¹
Detection of murine minute virus	Cytopathic observation method (NB324K)*	016002	Negative	Negative
	Quantitative real-time PCR*	016003	Negative	Negative
	Cytopathic effect (BT, MDBK, Vro, MRC-5)	017002	Negative	Negative
	Hemadsorption (BT, MDBK, Vero, MRC-5)	017002	Negative	Negative
Detection of bovine virus	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

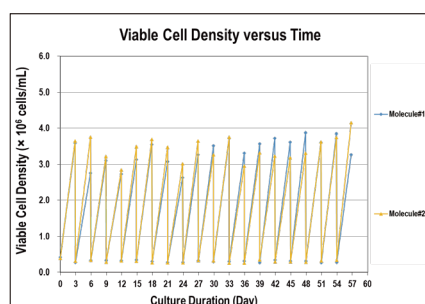
MeCHOTa® Perfect matching of host cells

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.

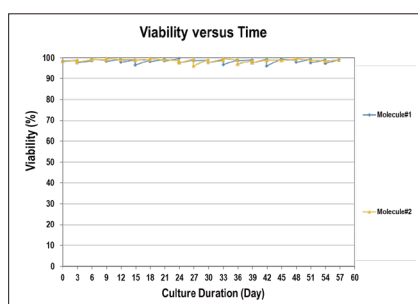
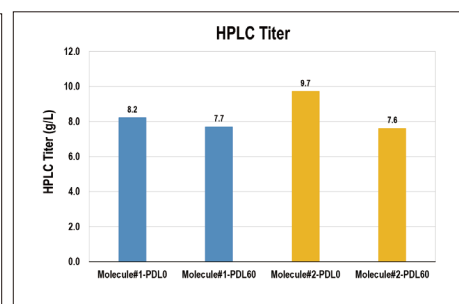


Reliable Stability of MeCHOTa® Host Cell

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.

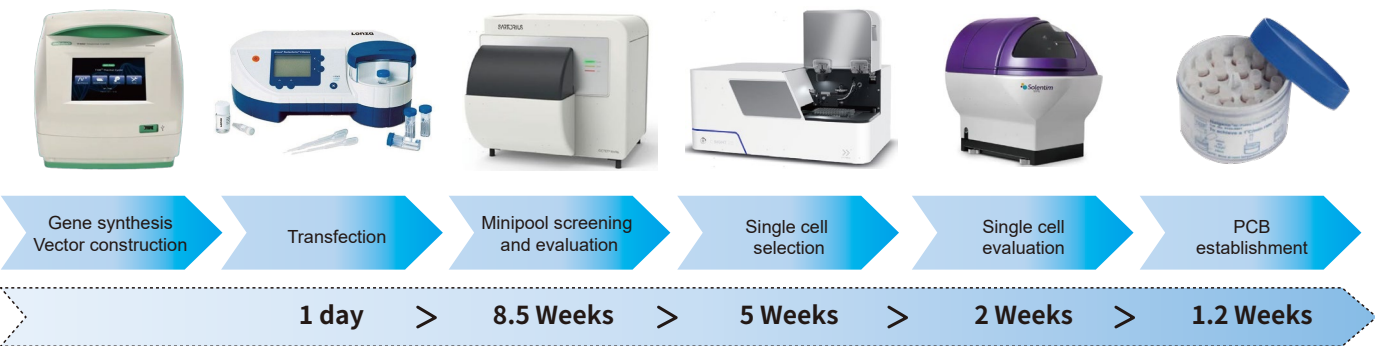


Cell Growth of Cell Stability Study



Titer of Cell Stability Study

High expression of MeCHOt^a® CHO-K1 host cells

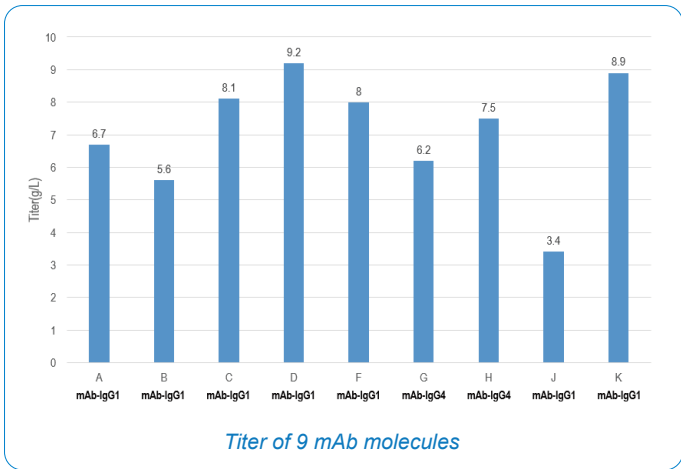
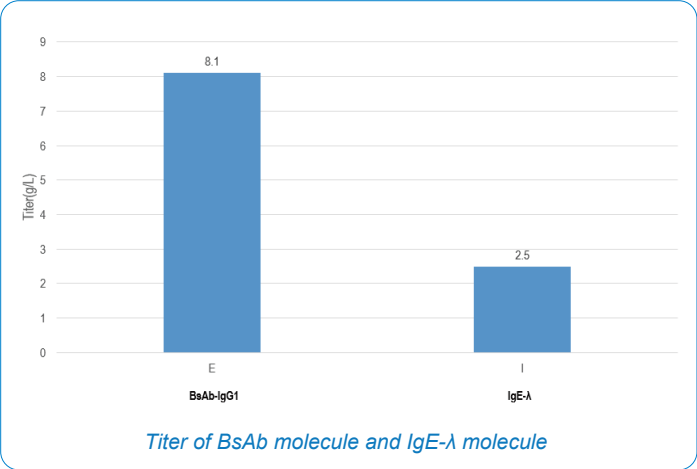


Cell lines and types of culture medium

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

Note: MeCHOt^a® CHO-K1 is derived from ECACC CHO-K1.

Titer and analysis of molecules



Our MeCHOt^a® 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.

Thousand Oaks Biologics Inc.



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