

Cell Line Release Authorisation for Vaccine Production

Please read Appendix 2 – Instruction to the Customer for Ordering Vero (WHO) Cell Line

Depositor's Note: The WHO Vero reference cell bank 10-87 cells are not "approved" in any way for vaccine manufacture by WHO. These repository cells are provided for the purpose of establishing master cell banks (MCB). Regardless of any previous testing, any cells transferred to and cultured in a new environment will require re-qualification. Therefore, it is the responsibility of each manufacturer to ensure appropriate handling, expansion, and maintenance of the cells and to perform the qualification tests necessary to establish a cell bank for vaccine manufacture.

Section 1- Customer	
PO/Order Number: <i>(Please enter your customer purchase order number, website reference or Culture Collections order number)</i>	
Cell Line Name:	Catalogue Number:
Name of requesting scientist:	Position:
Organisation:	
Address:	
Phone:	Email:
Intended use of cell line:	
Signed: <i>(requesting scientist)</i>	Date:

Culture Collections (contact details for the return of this form)	
Email:	culturecollections@ukhsa.gov.uk
Post:	Culture Collections, UK Health Security Agency (UKHSA), Porton Down, Salisbury, Wiltshire, SP4 0JG, UK

Internal use only- Depositor/Technology Transfer Office			
Norms and Standards for Biologicals Team, Technical Standards and Specifications (TSS) Unit Health Product Policy and Standards (HPS) Department, Access to Medicines and Health Products (MHP) Division, World Health Organization Avenue Appia 20, 1211 Geneva 27, Switzerland Team Lead: Dr Ivana Knezevic; Responsible Officer: Dr Tiequn Zhou			
Email:	knezevici@who.int	Email:	zhout@who.int

Section 2- Authorisation for sale (Depositor/ Technology Transfer Office)		
I agree to release this cell line to the customer named in section one for the intended use	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Name:		
Signed:	Date:	

Once signed please return this form to the Culture Collections using the contact details in section one

Section 3: Authorisation for Sale (Culture Collections)	
Name:	
Signed:	Date:

Appendix 1

List of cell lines that require this form to authorise release for research use in commercial organisations

Cell Line Name	Catalogue Number
VERO (WHO)	88020401

Appendix 2 - Instruction to the Customer for Ordering Vero (WHO) Cell Line

Release of this cell line requires permission from the World Health Organization. **Section one** of this Cell Line Release Authorisation form **must be completed** and **returned to the Culture Collections** who will forward it to the WHO to obtain permission to release the cell line before the order can be processed.

Please fill the form with **clear eligibility**, or it will be returned to the requestor for re-submission. If the intended use meets the criteria below, the depositor will require additional information about details related to the intended use and the requestor's experience, capacity and plan in establishing and characterising cell banks.

If the application is considered appropriate, WHO will approve the application and notify ECACC by forwarding the Cell Line Release Authorisation. A copy will be provided to the requestor.

WHO Vero cell will be released by the WHO if customers satisfy the criteria below:

- Production of a vaccine or biological defined in WHO recommendations/guidelines
- Development of new candidate vaccines or biologicals of global health importance as determined by WHO

Unacceptable criteria to the WHO include: Use for testing or cell therapy applications

Due to limited stock of WHO Vero cell available, only one (1) ampule is released to each requester.

If the seed material is referred to any publication, correct reference will be made to the World Health Organization. WHO does not accept any liability whatever in connection with the handling, further manipulation, modification, and use of the seed material.

It is understood that neither ECACC nor its depositors accept any liability whatsoever in connection with the handling or use of the cell line. The Culture Collections Terms & Conditions of Supply do not apply to this cell line.

See <http://www.culturecollections.org.uk/orderinginfo/terms.aspx>

If the cell line is referred to in any publication, then correct reference will be made to the work of the original depositor and no alteration will be made to its ECACC title or acronym.