

## 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) and master working cell banks (MWCB). 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	
<b>PO/Order Number:</b> <i>(Please enter your customer purchase order number, website reference or Culture Collections order number)</i>	
<b>Cell Line Name:</b>	<b>Catalogue Number:</b>
<b>Name of requesting scientist:</b>	<b>Position:</b>
<b>Organisation:</b>	
<b>Address:</b>	
<b>Phone:</b>	<b>Email:</b>
<b>Intended use of cell line:</b>	
<b>Signed:</b> <i>(requesting scientist)</i>	<b>Date:</b>

Culture Collections (contact details for the return of this form)	
<b>Email:</b>	<a href="mailto:culturecollections@phe.gov.uk">culturecollections@phe.gov.uk</a>
<b>Post:</b>	Culture Collections, UK Health Security Agency (UKHSA), Porton Down, Salisbury, Wiltshire, SP4 0JG, UK

Internal use only - Depositor / Technology Transfer Office			
World Health Organization, Technologies, Standards and Norms (TSN) Essential Medicines and Health Products (EMP) CH-1211 Geneva 27, Switzerland Group lead: Dr Ivana Knezevic, Responsible Officer: Dr Hye-Na Kang, Administrator: Mrs Joanna McMahon			
<b>Email:</b>	<a href="mailto:knezevici@who.int">knezevici@who.int</a>	<b>Email:</b>	<a href="mailto:kangh@who.int">kangh@who.int</a>
<b>Fax:</b>	+41 22 791 4971	<b>Email:</b>	<a href="mailto:mcmahonj@who.int">mcmahonj@who.int</a>

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
<b>Name:</b>		
<b>Signed:</b>		<b>Date:</b>

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

Section 3: Authorisation for Sale (Culture Collections)	
<b>Name:</b>	
<b>Signed:</b>	<b>Date:</b>

## 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.

### **Vero (WHO) 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

Exceptionally samples may be released for reverse genetics or similar vector production intended for manufacture or development of vaccines or biologicals.

### **Unacceptable criteria to the WHO include:**

Transferring the released cells and their progenies to third parties without permission of WHO

Use for testing or cell therapy applications

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.phe-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.