

**Adenoviral Reference Material Working Group  
Bid Submission Form  
Cell Bank Donation  
RFP 1.0**

Item for Submission

A minimum of 20 one-mL vials of a commonly used cell line for production of Adenovirus.

General Requirements for Bidding

Cell vials should be part of a Master or Working Cell Bank that has been tested according to the current FDA recommendations. This list includes:

- ?? Viability
- ?? Isoenzyme – human origin (identity)
- ?? Sterility (USP or 21CFR610.12)
- ?? Mycoplasma
- ?? *In vitro* adventitious viral agents
- ?? *In vivo* adventitious viral agents
- ?? Electron Microscopy for viral particles
- ?? Human pathogens:
  - EBV
  - HIV 1& 2
  - HTLV 1& 2
  - Hepatitis B Virus
  - Hepatitis C Virus
  - CMV
  - Parvo B19
  - AAV
- ?? Bovine virus – Certificate of Analysis where applicable (raw material or final vial test) (per 9CFR113.47)
- ?? Porcine parvovirus – Certificate of Analysis where applicable (raw material trypsin or final vial test)

Each vial should contain adequate cell numbers to support the production of a batch of reference material ( $1 \times 10^6$  cells/mL typically). If possible, the cell line should be appropriate for production of both wild-type and replication deficient adenovirus. Materials should be available for transfer approximately 1-2 weeks after the bid is awarded. The proposal should include details of proposed method/container for shipping to ensure integrity of the cell bank vials upon arrival at the virus bank production facility.

Documentation Requirements

Characterization information is required. This would include the Certificate(s) of Analysis and copies of final reports for assays performed. A short description of the cell line source and how the cell bank was produced should be included. If vials are to be donated from a Working Cell Bank, then a copy of the Certificate of Analysis from the Master Cell Bank used for the Working Cell Bank production should also be included. The information should include the relationship between the MCB and WCB, such as passage numbers, for donation of WCB vials. Information on the propagation of the cell line should also be included for use in viral production.

**Please complete the following fields:**

***Contact Information RFP 1.0***

Contact Individual:	Alexander Kotov, M.D., Ph.D.
Institution:	University of Alabama at Birmingham (UAB) Vector & Vaccine Production Facility (UAB VVPF) at Comprehensive Cancer Center
Address:	Alexander Kotov UAB Vector & Vaccine Production Facility 550 South 11 <sup>th</sup> Street Birmingham AL 35294-4558
Phone Number:	(205)-934-0250 Fax: (205)-934-0253
Email Address:	<u>Alexander.Kotov@ccc.uab.edu</u>

***Cell Bank Donation Information – RFP 1.0***

Cell Line/Type (e.g., 293 HEK):

293 HEK

Check one:  MCB  WCB

Number of vials to donate:

100 x 1mL (please note, not 99!)

Cell Concentration/Volume:

10<sup>7</sup> cells/mL (ten million) in 1 mL/vial

Passage Number:

45

Indicate Propagation Method:

Suspension  Adherent

Please indicate if your institution is also submitting proposals for other activities:

- Donation of Ad5 Wild-type Virus
- Ad5 Wild-type Virus Bank Production
- Ad5 Wild-type Purified, Formulated Bulk Production
- Vialing of Ad5 Wild-type Reference Material
- Donation of Repository Services
- Donation of Supplies or Other Services

*Please attach:* Characterization Information  
Certificate(s) of Analysis  
Description of production of cell bank  
Suggested Procedures for Propagation

Submit this completed form and all attached information for receipt **by February 28, 2001** to the address below. Electronic submissions are encouraged. Final decisions will be communicated by or about March 31, 2001. Please note that all information submitted will be publicly available. Please do not mark any information confidential, as we cannot honor that request. Please provide an estimated cost and market value for the goods and services donated.

**Williamsburg BioProcessing Foundation**  
**Attn: Adenovirus Reference Material Working Group**  
**4015 Killam Avenue**  
**Norfolk, VA 23508**

**PH: 757-423-8823**  
**FAX: 757-423-2065**

**EMAIL: [advect@wilbio.com](mailto:advect@wilbio.com)**

**Please see attachment below for details**

**293 HEK Working Cell Bank (WCB) Generation at University of Alabama at Birmingham (UAB) Vector & Vaccine Production Facility (UAB VVPF)**

Schema:	Description:
Source: 293 Master Cell Bank (MCB), Magenta Corp.	293 cells (validated MCB) originally received from Magenta Corp. (Passage 40) Product Information Sheet as well as MCB Certificates of Analyses available
?	
Expansion of 293 HEK cells from MCB	Expansion of 293 according to subculture/maintenance procedure in five consecutive passages without antibiotics resulting in obtaining of cell amount sufficient for production of WCB. Standard Operating Procedure and Production Batch Record (SOP/PBR) for WCB generation is available.
?	
Cryo-preservation	Cells aliquoted by 1 mL/cryo-vial, labeled (see below), and frozen in Liquid Nitrogen. Freeze medium: 45% FBS, 45% Ham's DMEM:F12 50:50 cell culture medium, 10% DMSO (sterile, pyrogene-free) Passage 45
?	
WCB Generation	293 cells (WCB) Lot # A5I201, 9-13-00 10 <sup>7</sup> cells/vial, 1 mL UAB VVPF
?	
WCB Characterization	Performed by Bioreliance, Certificates of Analyses are available (copies of Final Reports)

**Note:** Since each assay is concluded at Bioreliance in a separate final report while WCB validation/characterization and there is no brief summarized report, the UAB VVPF would like to submit all the documentation required (copies of Product Information Sheets and Certificates of Analyses) by fax.

Information on shipping: WCB of 293cells from UAB VVPF is available any time by shipment in DRY ICE in compliance with IATA Dangerous Goods regulations "Packing and Shipping Infectious Material".