Item for Submission

Production of an Ad5 Wild-type Virus Bank in lysate form to support production of 10 lots of adenovirus reference material. The bidder will also provide a Certificate of Analysis summarizing characterization as called for below. The delivered virus bank will need to at a minimum be $5 \times 10^{13}$ total particles in at least 20 aliquots.

General Requirements for Bidding

The Virus Bank will need to be produced under well-documented conditions (not necessarily equivalent to CGMP). Virus stock and cells used for bank production will be supplied from other bid activities in this process. Indicate your minimum requirements / concerns for acceptance of these materials (cell bank vials and viral seed material). The bid should indicate the amount of time required from receipt of the cell bank vials and viral material for the production and release of the virus bank.

The institution will need to provide a brief statement describing the proposed method for production of this bank, including proposed vial configuration. The institution should include their proposed specifications, including information on the proposed test methods, and a proposed Certificate of Analysis addressing the following points:

- Identity
- Particle concentration
- Functional activity (such as infectivity)
- Sterility (USP or 21CFR610.12)
- Mycoplasma
- \textit{In vitro} adventitious viral agents, or equivalent
- \textit{In vivo} adventitious viral agents
- Human pathogens:
  - EBV
  - HIV 1& 2
  - HTLV 1& 2
  - HBV
  - HCV
  - 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)

The proposal should include details of the proposed method/container for shipping to ensure integrity of the viral bank vials upon arrival at the production facility for the purified reference material.

Documentation Requirements

A description of the method proposed for production of the virus bank.

A proposed Certificate of Analysis should be provided addressing the characterization described above along with the proposed specifications, and information on the proposed test methods,

Proposed details related to shipping of virus bank vials to production facility.

In addition to these specific documentation requirements, each institution bidding should include a brief statement describing their experience and capacity to perform such activity and a description of the facility in which the work will be performed. The facility description should address procedures to ensure segregation during viral bank production.

Please complete the following fields:

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<th>Contact Information – RFP 4.0</th>
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<tr>
<td>Contact Individual:</td>
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<td>Institution:</td>
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Please indicate if your institution is also submitting proposals for the other activities:

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

Please attach:
- Proposed Certificate of Analysis, specifications, and summary of test methods
- Description of production of viral bank including vial configuration
- Facility information
- Information on shipping

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 include an estimated cost and market value of all 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:** advector@wilbio.com