Adenoviral Reference Material Working Group  
Bid Submission Form  
Participation in Characterization of Reference Material –  
Other Characterization  
RFP 10.0

Item for Submission

An Ad5 Wild-type Virus is being produced as a reference material for use in defining particle number and infectious units of adenovirus gene therapy vectors. This RFP invites laboratories to participate in the characterization phase, specifically to perform analyses not already described under RFPs 8, 9, 11, and 12 (determination of particle concentration, determination of infectious titer, short- and long-term stability studies). The Working Group will select laboratories to perform other types of characterization so that the reference material is as fully characterized as possible. The Working Group encourages submissions from individual laboratories or groups of laboratories planning to work together. Testing is anticipated to begin in mid-September 2001. **All proposals are due to the Williamsburg BioProcessing Foundation by Monday, July 30.** Electronic submissions are preferred.

General Requirements for Bidding

An Adenovirus 5 WT reference material is being produced under the guidance of a Working Group. The producing institution will provide a provisional particle concentration as part of a Certificate of Analysis along with confirmation of identity, functionality, purity, and freedom from adventitious agents. Particle concentration and infectious titer will be assigned to the reference material through measurements made by different laboratories, all performing methods provided by the Working Group. Short-term and long-term stability studies will also be performed under the guidance of the Working Group. However many other types of characterization would be desirable, including further characterization as to the purity and identity of the Reference Material. The following list contains suggestions, all of which would be welcomed:

**Purity**
- assays for residual host cell DNA
- assays for residual proteins including host cell, Benzonase/nuclease, or serum proteins
- particle sizing using laser light scattering, electron microscopy, or other methods
- purity by RP-HPLC
- purity by SDS-PAGE
- purity by Western blot analyses
Identity

- sequencing of the entire vector, both strands
- extensive restriction enzyme mapping analysis
- identity by RP-HPLC
- identity by SDS-PAGE
- identity by Western blot analyses

Each laboratory submitting a proposal should provide a statement describing their experience and capacity to perform the proposed characterization method. The proposal should specifically address:

- the amount of Ad5 WT Reference Material that will be required to perform the proposed analysis,
- a complete description of the method, preferably in the form of an operating procedure,
- any available supporting historical data, qualification data, or publications regarding the proposed method regarding its suitability for its stated purpose,
- the laboratory’s experience in performing the proposed procedure,
- the qualifications of the personnel involved in performing the procedure and reviewing the data,
- the equipment that will be used and its calibration status,
- how long it will take the laboratory to perform the procedure, and review and report results back once the sample is received, and
- the laboratory’s readiness to begin testing in mid to late September 2001.

Documentation Requirements

Capability statement with regard to performing the proposed procedure addressing the points listed above
A detailed description of the method proposed
Amount of reference material required for the proposed analysis
Submission and Deadline

Submit the completed form and all requested information for receipt by Monday, July 30, 2001 to the address below. Electronic submissions are encouraged. Final decisions will be communicated by or about August 31, 2001 at the latest. Testing is anticipated to begin in mid to late September. 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. Participants will be responsible for the cost of shipping the Reference Material to their location (express courier, dry ice). The estimated cost for US domestic locations is US$65-$100, but is dependent on the amount of reference material to be shipped.

Williamsburg BioProcessing Foundation
Attn: Adenovirus Reference Material Working Group
P.O. Box 1229
Virginia Beach, VA  23451
PH:  757-423-8823
FAX:  757-423-2065

EMAIL:  advector@wilbio.com
Bid Submission Form  
Participation in Characterization of Reference Material – Other Characterization  
RFP 10.0

Please complete the following fields:

*Cf. Information – RFP 10.0

<table>
<thead>
<tr>
<th>*Contact Individual:</th>
<th>Institution:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fax Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Email Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

*If laboratories are submitting a proposal as a group, a main contact should be provided along with contact information for each participating laboratory (attach additional copies of this form).

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

- [ ] Determination of Particle Concentration
- [ ] Determination of Infectious Titer
- [ ] Short-term/Field Stability Studies
- [ ] Long-term Stability Study
- [ ] Donation of Supplies/Other Services for Characterization Phase