Bid Submission Form
Participation in Assignment of Particle Concentration
RFP 8.0

Please complete the following fields:

Contact Information – RFP 8.0

*Contact Individual:	Dr. Erno Pungor
Institution:	Berlex Biosciences
Address:	15049 San Pablo Avenue P.O. Box 4099 Richmond, CA 94804
Phone Number:	510.669.4264
Fax Number:	510.669.4920
Email Address:	erno_pungor@berlex.com

***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 Infectious Titer

☒ Donation of Supplies/Other Services for Characterization Phase

Capability statement with regard to performing the spectrophotometric procedure

Berlex Biosciences, a division of Berlex Laboratories, Inc, is a company involved in adenoviral synthesis and characterization. Berlex Biosciences is capable of performing the spectrophotometric procedure described in the RFP 8.0 document. Berlex Biosciences currently uses this method, with modification for specific laboratory equipment, in the characterization of its adenoviral materials currently being used in active clinical trials in the United States.

Proposal to perform other quantitative methods on adenoviral standards

Berlex Biosciences has developed other methods for the determination of adenoviral particle count including reverse phase HPLC (measuring viral proteins) and has also further developed dye based spectrophotometric methods for particle determination (Pico Green, measuring viral DNA). Attached please find standard operating procedures for the rp-HPLC and Pico Green procedures that we propose including in this study. We also propose inclusion of our infectious titer determination by endpoint dilution (SOP also attached)

Staff capabilities

All staff to be included in this study routinely perform these assays as quality control assays for drug product release of our clinical drug product.

Equipment to be used

Equipment to be used in these studies are detailed in our SOPs which are attached. To perform the Maizel procedure as proposed in the RFP, we propose using a Shimidzu 1600 dual beam spectrophotometer.

Timing

Including the infectious titer determination, all data should be reviewed and available within 6 weeks of receipt of the materials. The particle count methods could be available within 4 weeks of receipt of the materials if a split submission of results is requested.

Quantities of materials needed

For the RP-HPLC method, we would need 10^{10} particles for each assay. For the Pico Green assay, we would need 10^{10} particles for each assay. For the infectivity assay, we would need 10^{5} particles per assay.