

Bid Submission Form
Participation in Assignment of Particle Concentration
RFP 8.0

Please complete the following fields:

Contact Information – RFP 8.0

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***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
- Short-term/Field Stability Studies
- Long-term Stability Study
- Other Characterization
- Donation of Supplies/Other Services for Characterization Phase

CAPABILITY STATEMENT WITH REGARD TO PERFORMING THE SPECTROPHOTOMETRIC PROCEDURE

General information. The University of Alabama at Birmingham (UAB) Vector & Vaccine Production Facility (UAB VVPF) is an academic institution involved in adenoviral vector synthesis, production and characterization. The UAB VVPF is capable of performing the spectrophotometric procedure described in the RFP 8.0 document.

The UAB VVPF currently uses this method, with modification for specific laboratory equipment, in the characterization of its adenoviral materials currently being produced in P-3 level containment laboratory under GLP conditions. More detailed information about the UAB VVPF operational capacity is posted on the WBF web-site.

Qualification of the personnel. All members of the UAB VVPF that will be involved in performing the procedure and reviewing the data have appropriate qualifications. All individuals keep either M.D. or Ph.D. degree and some of them have experience working under P-4 Biohazardous material level. All staff to be included in this study routinely performs these tests as quality control assays for characterization of Ad-vectors produced in the facility.

Equipment to be used. To perform the Particle Concentration procedure as proposed in the RFP-8, we suggest using Beckman DU-640B single beam spectrophotometer in blanking method mode. The equipment is calibrated and before each operation its performance is verified. Tests, which are performed, include: wavelength accuracy and repeatability, resolution, baseline flatness, noise and signal stability. We are normally using quartz micro-cuvette with a 1-cm path length and 100 μ L working volume. The Ad5 WT Reference Material after receiving will be stored in ultra-low freezer at -80°C until performing the tests. Units of critical storage equipment, freezers and refrigerators are connected to the emergency outlets and an emergency generator that activates automatically in a power outage. The generator is tested weekly and checked for fuel and oil by UAB maintenance personnel.

Timeline. The particle count data could be available within 2 weeks of receipt of the reference materials.

Laboratory readiness. The UAB VVPF will be ready to begin testing in mid to late September.