

**Bid Submission Form  
Participation in Assignment of Infectious Titer  
RFP 9.0**

Please complete the following fields:

*Contact Information – RFP 9.0*

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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 Particle Concentration
- 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 INFECTIOUS TITER METHOD

**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 infectious titer assay described in the RFP 9.0 document.

The UAB VVPF currently uses the CPE method, with modification 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 this assay as a part of quality control testing for characterization of Ad-vectors produced in the facility.

**Equipment to be used.** To perform the Infectious Titer procedure as proposed in the RFP, we suggest using all the appropriate equipment as listed in corresponding section of the SOP, included in RFP-9.0. The major equipment (such as Biosafety cabinet, CO<sub>2</sub> – incubator, centrifuge, inverted microscope, pipettors, etc) is certified and routinely calibrated, inspected or checked according to a written program designed to ensure proper performance. 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 Infectious Titer data could be available within 5-6 weeks once the sample of reference material is received.

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