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

Summary: For the 96 well TCID50 assay, AppTec Laboratory Services, LLC (formerly ViroMed) is willing to perform this assay exactly as detailed in the RFP. We have experience with performing viral detection assays with TCID50 procedures and with adenoviral detection. The assays will be performed with experienced research staff, as outlined below. The company can be ready to initiate cell growth for the critical cells for the assay at the end of September, or earlier, if they are provided in advance of the virus standard. When the cells are ready, the assays and reporting phase will take 4 weeks.

AppTec Laboratory Services, LLC Origins: ViroMed Biosafety Labs was a privately owned contract service company founded in 1982, that had been performing testing in the clinical virology, biopharmaceutical and medical device testing industries. The company sold its clinical and pharmaceutical testing to LabCorp Inc. in May 2001. To concentrate on biotech and medical device testing, AppTec was formed from three sections of ViroMed that were not sold. AppTec has three sites, and over 120 employees, and will concentrate on expanding its present services in biopharmaceutical, safety and analytical testing, medical device testing and validations, and germicidal validations. The testing for this RFP would be performed by the Biotech Division, located in Camden, New Jersey. This division has considerable relevant virology experience. The New Jersey division has been testing biopharmaceutical products for over 12 years, and has been testing adenoviral products for over eight years. As part of our testing we have performed TCID50 assays for several years with HIV, HAV, EMC, and most recently, with adenoviruses. We have performed studies using the exact protocol provided in this RFP, and we are comparing this method with an assay that measures plaque formation in 6 well plates. We have also initiated the documentation for the protocol to ensure this test can be run under GLP regulations, if needed. Most of the assays at AppTec are run under GLP and / or GMP. To add a second level of verification of the data from this testing, the data for the two runs will audited by our Quality Assurance department.

1. **Qualifications of the Personnel involved in performing the procedure and reviewing the data**

Individuals who will perform the assay include Amanda Newman, Michael Burnham and Wayne Boclair**.**

a**. Amanda (Mandee) Newman, Research Scientist II**, has a BA in Biology from Eastern College in St. David's, PA (1992) and is completing an MS in Microbiology from the Thomas Jefferson University in Philadelphia. She started with the company in 1994, has prior experience working in the Cell Biology and mycoplasma testing laboratories. She is currently a Research Scientist II in the Virology laboratory and her responsibilities including supervising and serving as Study Director on all in vitro viral testing including plaque assays and replication competent adenovirus tests.

b. **Michael S. Burnham, Senior Lab Manager**, has a BS in Biological Sciences from the University of Delaware in Newark, DE in 1992 and received an MS in Biological Sciences from Rutgers University in Camden, NJ in 1999. He has prior experience serving as Lab Manager at the Institute for Human Gene Therapy at the University of Pennsylvania where he developed, optimized and validated a novel strategy to purify rAAV vectors. As Senior Lab Manager at AppTec, he oversees the Viral Clearance laboratory, serves as Study Director and assist clients with studies performed in-house. These custom process validations all involve detection of infectious titers for viruses using TCID50 or plaque formation assays.

c. **Wayne Boclair, Senior Scientist I**, received his MS in Virology from Villanova University in Villanova, PA in 1969. As Senior Scientist I for AppTec, he was responsible for establishing a bacterial clearance lab and oversees viral and bacterial custom studies. His extensive career includes 28 years with Vineland Laboratories, an affiliate of IGI Inc., where he worked in vaccine Research &

Development. He developed and implemented vaccine stability monitoring programs for 12 USDA-licensed vaccines and consulted with Vaccine Production staff in a program designed to improve vaccine production efficacy and yields.

Cell Development/Growth:

Virginia M. Timoteo, Senior Lab Manager, received her BS in Biology from Cabrini College in Radnor, PA in 1976. She previously served as a Supervisory Research Technician at Hahnemann University in Philadelphia, PA. She has worked at out testing labs since 1989. Presently, as Senior Lab Manager, she oversees the Cell Biology and Mycoplasma laboratories and serves as study director for numerous related assays. Her areas of technical expertise include hematology, molecular biology and cell biology and she specializes in the maintenance of cell cultures and cell banking.

(We assume that the assay will be performed on the 293 Master Cell Bank that was used in the generation of this standard and that we will have to obtain that and grow up a small master or working bank to perform these assays. This work will be performed in our Cell Biology department, supervised by Virginia (Ginny) Timoteo.)

Individuals who will review the data include Joseph Hughes and Myrna Thomas.

a. Joseph V. Hughes, Ph.D., President and General Manager, Biotech Division of AppTec. Dr. Hughes received his Ph.D. in Microbiology from Northwestern University Medical School in 1977. His career spans over twenty years in the pharmaceutical (Merck and Sterling Winthrop) and biotech (Quality Biotech, U. Pennsylvania and ViroMed) fields where he has gained senior scientific management experience, as well as specific experience in vaccine and antiviral research and development, vector production and development, toxicity testing, and biosafety and analytical GLP/GMP testing. He recently completed several business management courses at the Wharton Business School. Since 2000 he has overseen the entire operation at the ViroMed Laboratories in New Jersey facility as Vice President and General Manager. As President of AppTec Biotech Division, which was formed in early June, 2001 from ViroMed divisions, he will implement a large expansion of the biotech services for AppTec.

b. Myrna F. Thomas, MS, Director of Quality Assurance, received her BS in Biochemistry/Biophysics from Plattsburgh State University in Plattsburgh, NY in 1982 and her MS in Analytical Chemistry from the Illinois Institute of Technology in 2000. As Director of QA for AppTec Laboratories, she is responsible for regulatory and compliance guidance and corporate QA auditing for all ViroMed sites. At the Camden site, she manages the QA department and hosts client, FDA, foreign regulatory agency and internal audits. Ms. Thomas's extensive background includes QA management positions with Aventis Behring (formerly Centeon L.L.C.) and ESI Lederle**.** One of her jobs at Wyeth-Lederle Vaccines and Pediatrics was to initiate a stability program and to start a Pilot Plant performing bacterial fermentations. In this capacity she was involved with the entire process from media prep to fermentor inoculations to harvest and was responsible for technical transfer of processes to manufacturing, including training of personnel. She is familiar with all aspects of sterile fill and aseptic technique, from room cleaning and environmental monitoring, to compounding of material, to glassware, stopper and crimp cap cleaning and depyrogenation, to actual filling. Her expertise in QC testing and data auditing and monitoring has been invaluable for overseeing QA's role in GLP and GMP compliant testing for AppTec's contract services.

2. **The Equipment that will be used and its calibration status**

AppTec is a contract testing company and the vast majority of our assays are performed under and GLP and GMP regulations. Our equipment is calibrated on a routine basis. The schedule for this is listed below for the pieces of equipment expected to be involved in the assay. The assays would be performed using a Batch Record that will document all equipment used and the next date for calibration. All equipment in the virology and cell biology labs that will be used to perform these assays are calibrated according to their recalibration schedule.

The following table indicates the frequency used for calibration

Calibrations / Certifications	**Frequency**
Pipetters	6 months
Centrifuges – Speed and Temperature	1 year
Fyrites	6 months
Thermometers (Digital & Mercury)	1 year
Autoclaves	1 year
Refrigerators	1 year
Freezers	1 year
Incubators	1 year
Biological Hoods	6 months
Microscopes	6 months

3. Timing for the laboratory to perform the procedure, and review and report results back to the Working Group once the sample is received.

   A. If the Reference Committee supplies the 293 bank to be used, then the cells will have to be amplified and a new mini cell bank will have to be made before the assays could be performed. This will add approximately 3 to 4 weeks to the start date. We normally would do some initial characterization to include sterility, mycoplasma testing and detection of bovine and porcine viruses before using a master or working bank. We could forgo this testing or perform it simultaneously with the assay.

      1. Preparation of Cell Bank from Committee's 293 cell line: 3 to 4 weeks
      2. Assay performance in duplicate: 2 weeks
      3. Data Analysis and auditing/checking by management and QA: 2 weeks

Total turn around would then be 8 weeks after we receive cells and the virus.

   B. If we should use our own 293 cells, this eliminates the preparation of the cell bank.

      1. Preparation of Cells for assay: 1 week
      2. Assay performance in duplicate: 2 weeks
      3. Data Analysis and auditing/checking by management and QA: 2 weeks

Total time : 5 weeks after we receive the reference virus.

4. Laboratory's readiness to begin testing in mid to late September 2001.

We would be ready to perform these assays at that time, and do a better if given more advance notice when samples are coming.