Statement of experience and capacity to determine Adenovirus particle concentration by spectrophotometry

Qualification of Personnel

The assays will be carried out in the Assay Development laboratories of Cell Genesys by, or under the supervision of Dr. Heike Nesbit. Dr. Nesbit has 9 years of experience working with adenovirus and is responsible for the development of all analytical methods for the characterization of adenoviral vectors at Cell Genesys. Dr. Nesbit is familiar with the technique of spectrophotometry for the determination of particle concentration and this method is routinely performed at Cell Genesys. All data generated with the adenovirus type 5 wt reference material will be reviewed by Dr. Flavia Borellini, Senior Director of Assay Development and Quality Control of Cell Genesys, or by James Marich, M.S., Associate Director of Quality Control of Cell Genesys.

Equipment

The equipment that will be used for the spectrophotometric determination of adenovirus physical titer is routinely calibrated per Cell Genesys Standard Operation Procedures. The calibration status of each piece of equipment will be verified and documented prior to use. The following table specifies the calibration interval for each applicable instrument.

Equipment	Calibration interval
Orion 520A pH-meter	6 months
Hitachi U-2000 Spectrophotometer	12 months
Pipettes (1000, 200, 20, 10)	3 months
Biosafety cabinet	12 months

Turn around time

The procedure will be performed, reviewed and reported within two weeks upon receipt of the sample.

Readiness for the start of the testing

The participating laboratory will be ready to perform the proposed procedure in mid to late September 2001.