Statement of experience and capacity to determine particle concentration of Adenovirus 5 WT Reference Material by TaqMan PCR analysis

Amount of Ad5 WT Reference Material required for TaqMan PCR analysis
The minimal amount of Ad5 wt reference material required for the TaqMan PCR analysis is 20µl. Approximately 10µl of the material will be required for one assay. The titer of Ad5 wt reference material will be derived as the mean of two separate assays.

Description of the proposed method
See attached protocol: Quantitation of adenovirus particles by TaqMan analysis.

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 TaqMan method and the assay is routinely performed at Cell Genesys. The %CV values for intra- and inter-assay precision for the assay are below 5%. 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 for each applicable instrument.

Equipment
The equipment that will be used for the quantitation of adenovirus particles by TaqMan analysis 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
ABI Prism 7700 Sequence Detection System unit	12 months
Pipettes (1000, 200, 20, 10)	3 months
Beckman Spinchrom R Centrifuge	12 months
Biosafety cabinet	12 months

Turn around time
The procedure will be performed, reviewed and reported within four 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.