**Statement of experience and capacity to determine infectious titer of Adenovirus 5 WT Reference Material in 293 cells in a 96-well format**

## 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 method using cytopathic effect as a read-out for the determination of infectious titer of adenovirus 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 to determine infectious titer of Adenovirus 5 WT Reference Material in 293 cells in a 96-well format 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** |
|---|---|
| Humidified incubator, 7+/-2%$C0_2$, 37°C+/-1°C | 12 months |
| Pipettes (1000, 200, 20, 10) | 3 months, traceable to NIST standard |
| Beckman Spinchrome R Centrifuge | 12 months |
| Fisher Scientific Isotemp Waterbath | 12 months |
| Biosafety cabinet | 12 months |

## Turn around time

The procedure will be performed, reviewed and reported within six 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.