

**Example of Testing schedule for CHO cell banks
according to EU/FDA/ICH/WHO (for r-protein or Mab)
(Genetic Stability tests provided separately)**

Methods	Study Protocol Number	Lead Time (days)	Testing time (days)	Time to result (days)	Total to Report (days)
Cell Cultivation for assay inoculation: TAT added to below assays - cost and time could be shortened if client provides directly fresh cells	SP-V.0004	3	14	17	27
<u>Identity</u>					
Isoenzyme Analyses with 4 isoenzymes	SP-M.8400	18	28	48	58
<u>Purity</u>					
Sterility test and qualification of sterility test by direct inoculation (Eu Pharm current edition 2.6.1. sterility,US Pharmacopeia)	SP-GSM.6981	7	21	30	44
Sterility test by direct inoculation (EU Parm current 2.6.1. sterility)	SP-GSM.6958	7	21	30	44
Myco Test and Mycoplasmastasis Assay for Mycoplasma (European Pharmacopoeia Current edition, 2.6.7 mycoplasmas)	SP-GSM.6980	7	28	37	51
Test for mycoplasma (Eu Pharm, current edition 2.6.7. mycoplasmas)	SP-GSM.6956	7	28	37	51
<u>Adventitious Viruses</u>					
28 days In-vitro assay with 3 detector cell lines, MRC5, Vero and CHO	SP-V.1301	18	28	48	58
In-vivo assays performed on suckling mice, adult mice and Embryonated chicken eggs	SP-GSM.6971	18	49	69	83
<u>Retroviruses</u>					
TEM on cells, (Q5A, 200 cells)	SP-V.3502	18	35	55	70
Co cultivation on Mus dunni cells with S+L- PG4 end point for detection of infectious retroviruses	SP-V.2009	18	50	70	80
OR Co cultivation on Mus dunni cells with IF end point for detection of infectious retroviruses	SP-GSC.6965	18	50	70	80
Detection of Infectious Retrovirus by Direct and Extended MiC11 S+L- Assay	SP-GSC.6967	18	59	79	89
<u>Species-specific viruses testing</u>					
Detection of MVM by Q-PCR	SP-V.8129	18	10	30	40
HAP assay	SP-GSM.6983	18	37	57	71
LCMV Challenge	SP-GSM.LCMV	18	37	57	71
MAP assay	SP-GSM.6982	18	37	57	71
TOTAL (week)		2 w.	7 w.	10 w.	12 w.
Max Prelim result per cell bank (weeks)					

**This list doesn't correspond to a contractual document
Please ask for a quotation for specific project**