

VBC

As described in the FDA/CBER “Points to Consider in the testing of Monoclonal Antibody Products for Human Use (1994)” and “Points to Consider in the Characterization of Cell Lines used to Produce Biologicals (1993)”, each cell line for the product of biological therapeutics, as follows:

Master Cell Bank Characterization (MCB)

The following tests should be performed on a representative inoculum from the MCB:

- ❖ Sterility
- ❖ Reverse Transcriptase
- ❖ Cultivable and Non-cultivable Mycoplasma
- ❖ Adventitious Virus Contamination (with three indicator cell lines)
- ❖ Mouse Antibody Production (MAP)
- ❖ HIV 1 and 2 Co-Cultivation (for human derived cell lines only)
- ❖ Epstein-Barr virus Southern Blot (for human cell lines only)
- ❖ Cytomegalovirus (for human derived cell lines only)
- ❖ Hepatitis ~B and C (for human derived cell lines only)
- ❖ Human Herpes virus 6 PCR (for human derived cell lines only)
- ❖ Retroviral Contamination (Transmission Electron Microscopy)
- ❖ Isoenzyme

Master Working Cell Bank (MWCB)

The following tests should be performed on a representative inoculum from the MWCB:

Characterization of
Cell Lines (P TC)

VBC

- ❖ Sterility
- ❖ Cultivable and Non-cultivable Mycoplasma
- ❖ Adventitious Virus Contamination (with three indicator cell lines)
- ❖ Isoenzyme

End of Process Cell Harvest (EPC)

The following tests should be performed on a representative sample from the EPC:

- ❖ Sterility
- ❖ Reverse Transcriptase
- ❖ Cultivable and Non-cultivable Mycoplasma
- ❖ Adventitious Virus Contamination (with three indicator cell lines)
- ❖ Mouse Antibody Production (MAP)
- ❖ HIV Co-cultivation (for human derived cell lines only)
- ❖ Cytomegalovirus PCR (for human derived cell lines only)
- ❖ Retroviral Contamination (Transmission Electron Microscopy)
- ❖ Isoenzyme

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Characterization of
Cell Lines (P TC)