

# VBC

As described in the FDA/CBER "Points to Consider" (PTC), each lot of product should be Quality-Control monitored and tested (21 CFR 600.3(x)) at specific intermediate production steps, as follows:

## Unprocessed Bulk Lots

The following tests should be performed on each crude material harvest:

- ❖ Sterility
- ❖ HPLC-SEC
- ❖ HPLC-Reversed Phase or Ion Exchange
- ❖ Peptide Mapping
- ❖ N-terminal Sequencing
- ❖ Isoelectric Focusing (recommended)

## Purified Product Lots

Routine testing of purified bulk lots of antibody should include the following:

- ❖ Purity (SDS-PAGE reduced and non-reduced) - HPLC-SEC
- ❖ Isoelectric Focusing (IEF)
- ❖ Sterility
- ❖ Amino Acid Analysis (recommended)
- ❖ pH and Appearance (recommended)

## Final-Filled Product Lots\*

The following tests should be performed on the contents of final containers from each filled lot (21 CFR 600.3(y)):

- ❖ Protein Concentration
- ❖ Purity (SDS-PAGE reduced and non-reduced)

## Lot-to-Lot Quality Control Monitoring of Recombinant Proteins

# VBC

- ❖ HPLC-SEC
- ❖ Isoelectric Focusing (IEF)
- ❖ Amino Acid Analysis (recommended)
- ❖ Potency
- ❖ Polyacrylamide Electrophoresis (Native and Reduced)
- ❖ HPLC-SEC (recommended)
- ❖ Western Blot (recommended)
- ❖ pH and Appearance (recommended)
- ❖ Isoenzyme

\* Complex formulations, freezing, and lyophilization may change the protein and may require additional testing.

For more information contact:

Robert Fleischaker, Ph.D.  
President, Vista Biologicals Corporation  
2120 Las Palmas Drive, Suite A  
Carlsbad, CA 92009 USA  
PHONE: (619)438-0230  
FAX: (619)438-0229

Lot-to-Lot Quality  
Control Monitoring  
of Recombinant  
Proteins

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Vista Biologicals Corporation  
Biotechnology Services

We can assist you with: