A comparative analysis of viral clearance by Affinity and AEX chromatography

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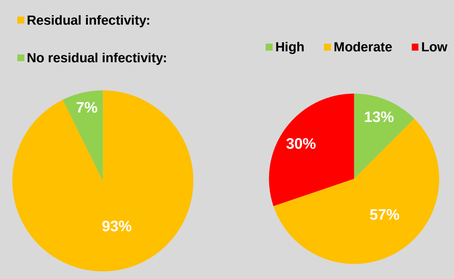
Selection/evaluation criteria

- Products: Recombinant proteins and Monoclonal Antibodies
- Resin/membranes: different vendors / different specifications
- Mostly applied model viruses: MuLV, PRV, Reo-3, MVM
- Virus removal capacity discriminated between: No residual infectivity / Residual infectivity
- Residual infectivity discriminated between: > 4 log_{10}: high reduction
  2-4 log_{10}: moderate reduction
  < 2 log_{10}: low reduction

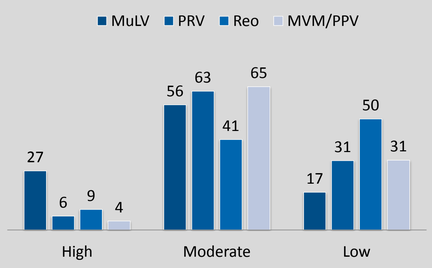
Affinity Chromatography - General

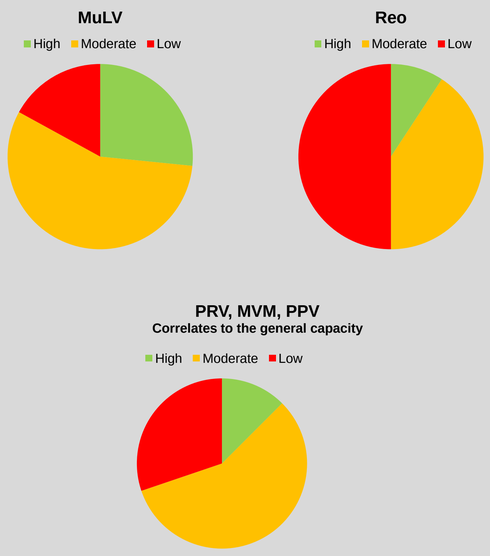
- 288 duplicate runs evaluated
- After AEX chromatography the mostly applied chromatography in VC studies
- All runs in binding mode
- MuLV and PRV are mostly analyzed by qPCR and only those chromatography runs are considered

Affinity Chromatography - General Capacity



Capacity per Model Virus

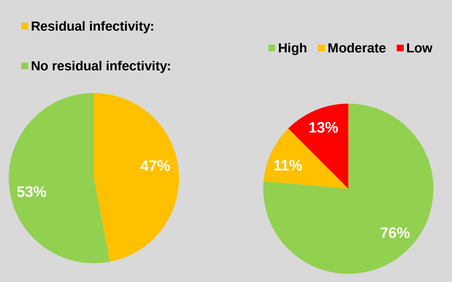




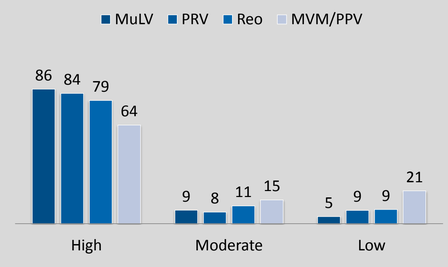
AEX Chromatography - General

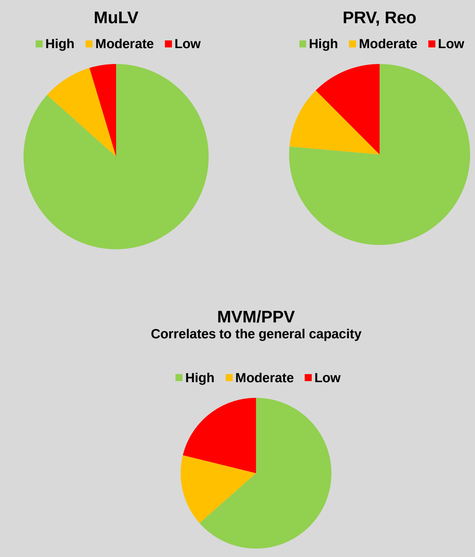
- 585 duplicate runs evaluated
- Majority in flow through mode; some in binding mode
- AEX chromatography is the mostly applied chromatography in VC studies
- Mostly investigated with respect to virus removal capacity and robustness

AEX Chromatography - General Capacity



Capacity per Model Virus

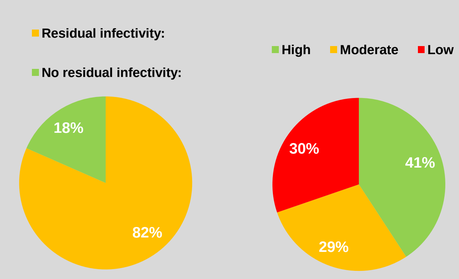




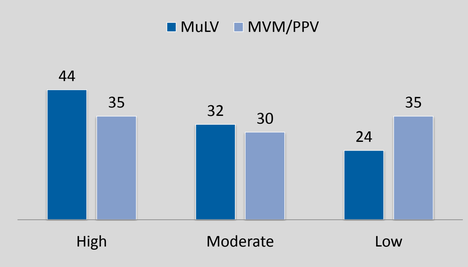
AEX Adsorber Chromatography - General

- 76 duplicate runs evaluated
- Always run in flow through mode
- Are more and more integrated into the DSP; only few BLA/MAA/IND with Membrane Adsorbers
- Fractionated collection of product flow through

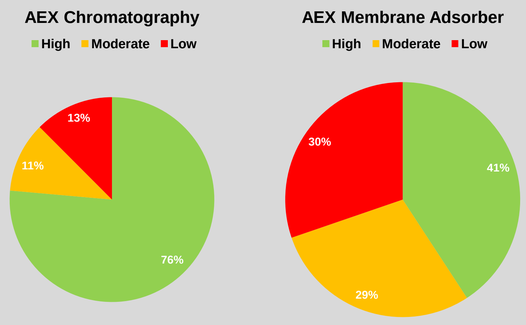
AEX Ads. Chromatography - General Capacity



Capacity per Model Virus



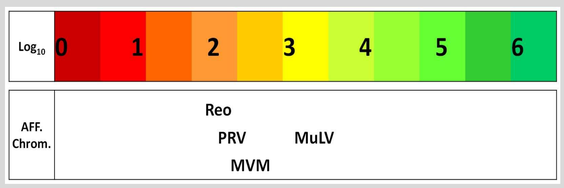
Comparative Analysis

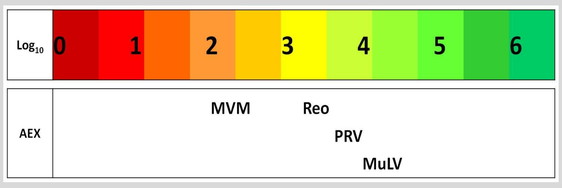


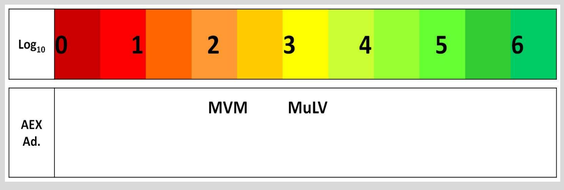
Capacity Phase III studies – same conditions for all viruses

1: low capacity

6: high capacity







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