



Integrated Solutions for ASR Manufacturing at LakePharma

NR-7034.20200204

What are Analyte-Specific Reagents (ASR)?

“ASRs are defined as antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding and chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens”.

21 CFR 864.4020 (a)

Integrated Solutions for Analyte-Specific Reagent (ASR) Discovery and Manufacturing at LakePharma

- Identification and quantification of substances in biological specimens can be achieved with Analyte-Specific Reagents (ASR)
 - Examples include monoclonal antibodies against idiotypes, proteins, or haptens
 - Can be used in PK assays to measure free or total drug levels in preclinical and clinical studies, and as positive controls in ADA assays
- Discovery, engineering, development, and GMP manufacturing of ASRs performed in San Francisco Bay Area

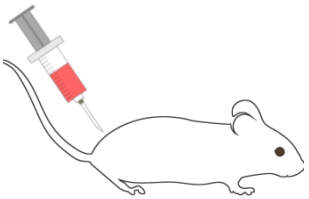
LakePharma Integrated Solutions



ASR Antibody Discovery

- Fast on-demand antibody discovery against any target
- Multiple formats available (IgG, Fab, scFv, VHH)

Multiple approaches available

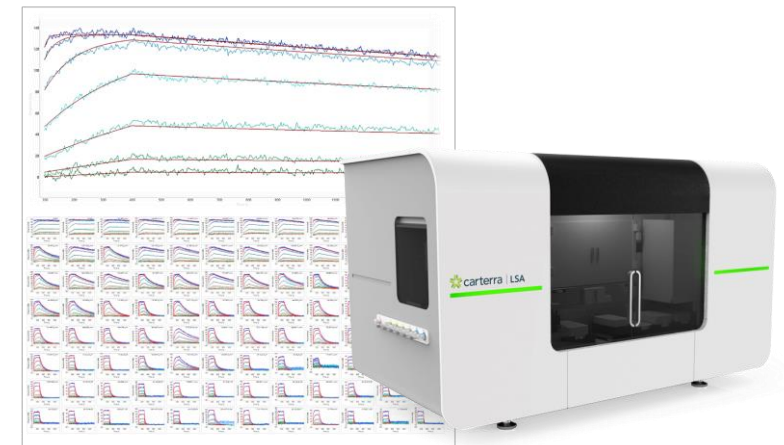


Immunization-based hybridoma and/or immune phage/yeast display



Naïve/synthetic phage display libraries

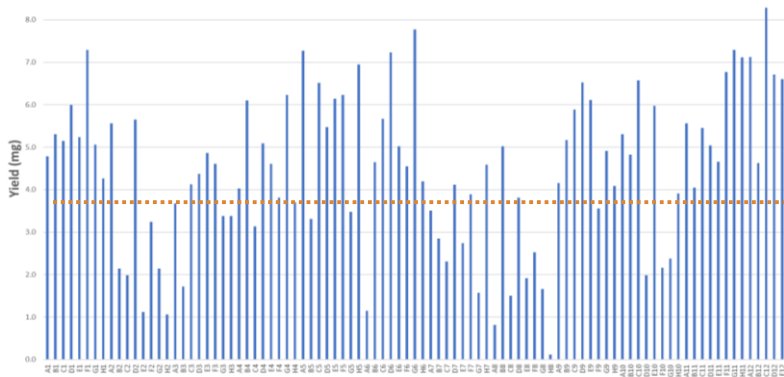
Powerful kinetic-based screening with Carterra™ LSA high-throughput SPR



Transient Protein Production with TunaCHO™

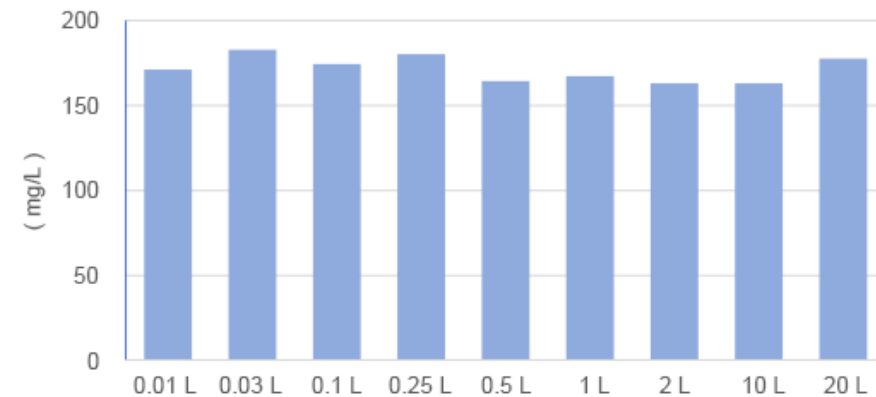
- Productivity can reach 2 g/L
- Consistent titer from 10 mL shake tubes to 20 L in WAVES
- Flexible scale and faster timeline

TunaCHO™ High Throughput Production



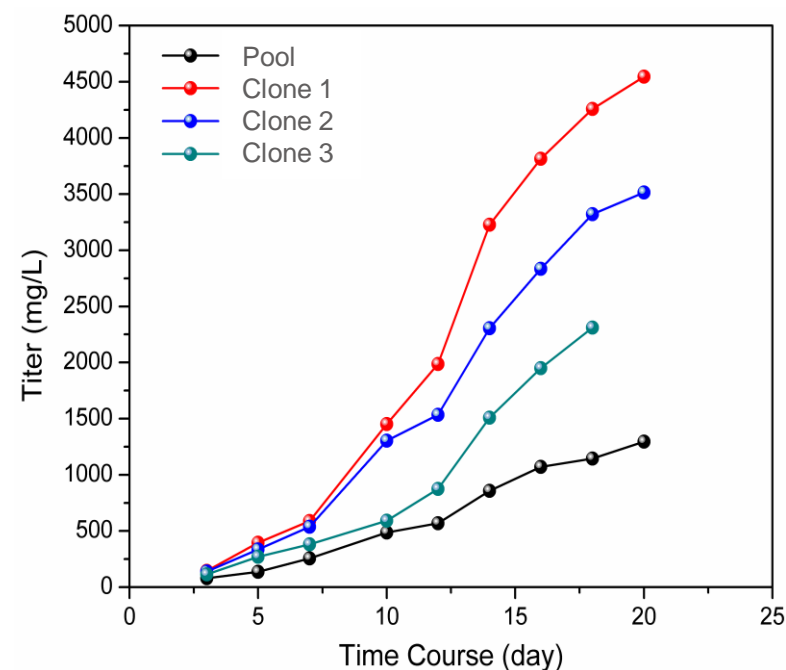
Average yield: 4.53 mg from 10 mL production
Best yield: >10 mg from 10 mL

Consistent Productivity at Different Scales



CHO-GSN™ Technology to Make Cell Lines for Manufacturing

- GS selection in CHO-K1 with GS knockout
 - High selection pressure
 - Enrichment of high yield clones
 - Good stability
- 3-7 grams per liter
- Multiple programs in clinic
- Have produced challenging molecules
- Royalty-free commercial license
- LakePharma Development Center in Hayward provides RCB, MCB, upstream, downstream, analytical and formulation packages



GMP Manufacturing for ASR Support

LakePharma can manufacture components of *in vitro* diagnostic kits for ASR or companion diagnostic applications under GMP conditions.

Key Highlights



ISO 9001:2015 certified



Two royalty-free CHO platforms are available to accommodate different timelines and needs:

TunaCHO™ Transient Platform

CHO-GSN™ Stable Platform



Various customization options available:

- Concentrations
- Release criteria
- Quantity

- Quick turnaround since RCB step is not needed
- 1 L – 100 L production tailored for specific needs

- Robust, high performance
- Flexible production scale from small to large quantities

GMP Manufacturing for ASR Support

Process Design & Development

- Proof of concept
- Small-scale models
- Seamless tech transfer
- Analytical Method Development

GMP Manufacturing

- Validated equipment and utilities
- Upstream and downstream processes
- Single use materials



Working with LakePharma

Various service packages are available tailored to the client's budget, timeline, and needs.

Key Benefits

- Comprehensive technology platform
- Technical consultation with experts in antibody discovery, protein production, and GMP manufacturing
- Online data system for 24-hour access to project information (timelines, data, team communications)
- Strong project management with regular project updates (email and teleconferences)



Contact your local Account Representative or email Inquiries@LakePharma.com.