



# *In Vitro* Diagnostic Solutions

## Our Role in Your IVD Research

Leinco Technologies offers antibodies for OEM *In vitro* diagnostic assays and custom large scale, low cost monoclonal antibody production. With over 25 years experience, Leinco provides excellent services:

### Cell Banking & Cell Line Optimization

Leinco offers the preparation of highly optimized master cell banks (MCB's) and working cell banks (WCB's) with offsite storage capabilities. Cell line optimization and banking is an important component for lot to lot consistency and long term production requirements. Testing is performed on each cell bank to assure cells are mycoplasma negative and free of other adventitious agents.

#### Cell Banking Benefits

- Automated cryogenic refrigeration equipment
- All units contain local and remote alarm systems
- Cell lines are maintained at -150°C or less
- Restricted access to freezers
- Electronic inventory system
- Dual site backup available

#### Cell Line Optimization Benefits

- Optimization of cells for cGMP manufacturing
- Quality Control Checks – viability, clonality, sequencing, sterility, IEF gel, pathogen (-), mycoplasma (-)
- Certification free of adventitious agents including MCB, Pathogen (-) reporting, Mycoplasma (-) reporting
- Freeze 30+ vials or more

### Protein & Antibody Production

Each product starts off in cell culture where the seed culture is prepared for transfer to bioreactors. Separate downstream suites are used to clarify and concentrate bioreactor harvest and prepare it for purification using appropriate chromatography. This ensures the highest standards on every lot we deliver.

### cGMP Facility & ISO 9001:2015

Leinco Technologies is ISO certified adhering to the ISO Quality Standard 9001:2015 and is cGMP compliant subject to numerous annual quality audits. Manufacturing of proteins and antibodies at Leinco is confined to dedicated class 10,000 cleanroom suites. Leinco has developed and validated efficient procedures, uses custom built equipment and manufactures its own cell culture media; we are able to pass on this added value to our partners.

### Rigorous QC Testing

Leinco has an extensive bioanalytics department to assure that each active diagnostic component manufactured meets the required purity and functional specifications established for the product.

# Antibodies for IVD

## Infectious Disease

### Marker

|                            |                             |
|----------------------------|-----------------------------|
| Adenovirus                 | Parainfluenza Virus Type 2  |
| CT 1                       | Respiratory Syncytial Virus |
| Influenza A Virus          | CHLM                        |
| Influenza B Virus          | CMV                         |
| HSV 1, 2, Bi               | Gonorrhea                   |
| Parainfluenza Virus Type 1 |                             |

## Hormones

### Marker

|          |
|----------|
| FSH      |
| HCG Beta |
| LH Beta  |
| TSH      |
| Total T4 |

## Tumors

### Marker

|          |
|----------|
| PSA      |
| Free PSA |
| AFP      |
| Hepsin   |

## Coagulation

### Marker

|         |
|---------|
| D-Dimer |
|---------|

## Secondary Antibodies/Controls

### Marker

|                             |
|-----------------------------|
| Human Ig Kappa Light Chain  |
| Human Ig Lambda Light Chain |
| Human IgE                   |
| Human IgG Fc Specific       |
| Human IgM                   |
| Murine IgG2b                |

Contact Leinco for additional information!



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