# Clinical Immunoassays to Determine Concentration of Monoclonal Antibodies

Tech ID: 19801 / UC Case 2008-226-0

## BACKGROUND

Monoclonal antibodies are a powerful form of treatment for many cancers and other proliferative diseases. The development of treatment schedules is a difficult process since the desired in vivo levels must be extrapolated from in vitro studies, the route of administration can be very influential, and each monoclonal antibody may have its own biological interactions. Existing methods require the production of expensive custom and sometimes difficult to produce biological reagents.

There is a need, therefore, of simple, accurate, and sensitive assays to understand the pharmacokinetics of monoclonal antibodies treatments.

## TECHNOLOGY DESCRIPTION

This technology is a general method to develop assays to detect the circulating concentration of monoclonal antibodies in patients that have received them as treatment for cancer or other diseases. The method is applicable to any monoclonal antibody or other recombinant protein biologic therapy.

In addition, two specific assays, one for rituximab and one for alemtuzumab, have been developed. Synthetic biotinylated peptides have been produced based on the sequence derived from phage displayed peptide libraries. UCSD researchers have then developed an optimized ELISA protocol, and a complementary bead based immunoassay. The enhanced sensitivity of the bead based assay is ideal for detecting very low levels of the targeted antibody, while conventional ELISA is sufficient when the targeted antibody is expected to be higher.

## ADVANTAGES

- Generalizable to any monoclonal antibody or other recombinant protein biologic therapy
- Easier than current methods
- Developed two specific assays, one for rituximab and one for alemtuzumab
- Phage displayed peptide libraries used to select peptide sequences recognized by the specific monoclonal antibody
- Synthetic biotinylated peptides produced based on these sequences
- High sensitivity of bead based assay (less then 0.1 µg/ml) with extremely low background
- ELISA protocol on streptavidin - coated plates sufficient for higher antibody concentrations (>1.0 µg/ml)

## APPLICATIONS

There are over 100 monoclonal antibodies developed for current therapies. The peptide-based assays are ideal for the development of validated clinical assays and monoclonal antibodies pharmacokinetics analyses.

## STATE OF DEVELOPMENT

This technology is offered exclusively or nonexclusively in the US and/or worldwide territories. A commercial sponsor for potential future research is sought.

## OTHER INFORMATION

**UCSD Researcher:**

Dr. Thomas Kipps, M.D., Ph.D., is a professor of medicine, the chief of the Division of Hematology/ Oncology at the UCSD School of Medicine, and the Deputy Director of research at the Moores UCSD Cancer Center. He is also the director of the National CLL Research Consortium and associate director of the UCSD Gene Therapy Program.

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### OTHER INFORMATION

**KEYWORDS**

cancer, therapy, monoclonal, antibody, treatment, clinical, assay, immunoassay, pharmacokinetics.

**CATEGORIZED AS**

- **Medical**
  - Diagnostics
  - Disease: Cancer

**RELATED CASES**

2008-226-0

Dr. Bradley Messmer, Ph.D., is assistant project scientist at the UCSD Moores Cancer Center.

## RELATED MATERIALS

- Thomas J. Kipps, MD, PhD
- Bradley Messmer, PhD

## PATENT STATUS

| Country | Type | Number | Dated | Case |
|---|---|---|---|---|
| United States Of America | Issued Patent | 9,250,233 | 02/02/2016 | 2008-226 |
| United States Of America | Issued Patent | 10,359,432 | 07/23/2010 | 2008-226 |
| United States Of America | Published Application | 2019/032404 | 10/24/2019 | 2008-226 |

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