

Protein-based method for HLA Tissue Typing

Business opportunity

New South Innovations, the commercialisation office of the University of New South Wales (UNSW), is offering a licensing opportunity for a new protein-based HLA typing technology.

Current typing technologies

Currently for transplant procedures, HLA is typed using PCR techniques to amplify polymorphic regions of the HLA encoding genes. These methods often require the use of multiple (up to 100) specific primers and reactions. HLA typing is complex, expensive, resource intensive, and can take days to complete. Timing is a critical issue when dealing with donor tissue sourced from accident victims.

Protein-based typing

An ideal method for HLA typing would sequence and compare an individual's HLA protein.

The technology for accurately sequencing proteins is well developed with the advent of the Mass Spectrometer (MS). However, this approach requires the protein sample to be of high purity. The cost effective purification and concentration of HLA from the myriad proteins present in a biological sample has until now been considered technically too difficult.

UNSW solution

UNSW researchers, Dr Wallace Bridge and Matthew Clemson have developed a relatively simple method for extracting, purifying and concentrating a patient's HLA from a small (less than 1 ml) blood sample. The resulting protein is of sufficient quantity and purity to allow accurate MS-based amino acid sequencing. This technology is covered by a provisional patent lodged with IP Australia in March 2008.

Tissue typing market

All six major manufacturers/distributors of HLA typing kits license-in PCR-based technologies. They compete and differentiate on the basis of distribution networks and supporting technologies.

Our technology is expected to displace the current Sequence Specific Primer (SSP), Sequence Specific Oligohybridization (SSO), and Sequence Based Typing (SBT) methods over the next 5-10 years.

Effect on market

Licensing companies can expect to benefit from increased penetration into the HLA tissue typing market. Many large organisations use in-house typing methods due to the high costs of the current commercially available kits. The reduction in cost

barriers will encourage their uptake of HLA typing kits, and inherently increase market demand for kits.

Our method's high resolution and low cost could potentially lead to States (or HMOs) sponsoring HLA typing of nominating tissue donors. This would allow the elimination of problematic delays arising from the need to determine donor HLA types after death.

Some companies currently offer well over 200 different versions of HLA typing kits based on SSP, SSO, and SBT technologies. Licensee companies will ultimately be able to streamline the number of products on offer, whilst still meeting their customers' requirements.

Competitive advantages of protein-based method:

- High resolution (complete analysis of HLA protein)
- Eliminates need for PCR
- Sequences HLA protein. Negates the need to test for null alleles
- Resolves heterozygous HLA in a single assay
- High throughput (reduced technical complexity)
- Higher reliability (reduced risk of mismatching due to DNA contamination)
- Relatively rapid analysis
- **Readily adaptable to kit product format**
- Lower production costs per unit assay, which offers potential higher margins and/or competitive pricing
- Addresses needs for both solid organ and bone marrow HLA typing.

New market opportunities

The high resolution capacity of protein-based HLA analysis will allow market expansion beyond typing for transplant procedures. Many medical disorders and diseases are HLA mediated. Individuals with particular HLA types are at higher risk of developing certain autoimmune disorders and types of cancer.

Software opportunity

Opportunities would be available to our licensees for the development and sale of software for protein-based HLA analyses. Currently, companies operating in the tissue typing market offer software for interpreting PCR-based HLA analyses.

Further Information:

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