

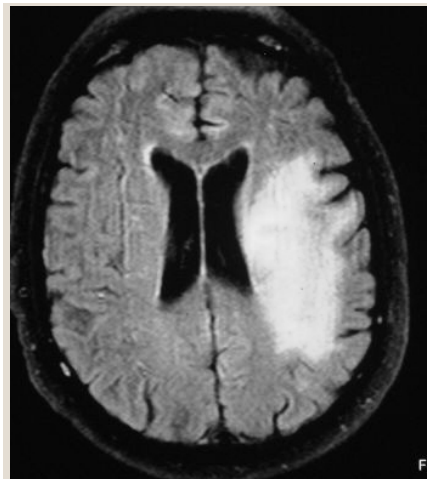
Assessing the Risk for PML

VLP/VP1 based assay for detection of anti JCV antibodies

Reference Number: TO 07-00022

Challenge

Progressive multifocal leukoencephalopathy (PML) is a rare but often fatal brain disease caused by the polyomavirus JC (JCV). Recent data suggest that approximately half of the population is silently infected with JCV. Caused by reactivation of the latent JCV, PML can occur in immunosuppressed or immunocompromised patients, e.g. approx. 5% of AIDS patients developed the disease during the HIV epidemic. Several classes of medications that suppress the host cellular immune response have been associated with this severe brain disease and PML is currently increasingly recognised due to its occurrence in multiple sclerosis patients treated with natalizumab/Tysabri® as well as to other monoclonal therapeutic antibodies that have been recently associated with PML (e.g. efalizumab or rituximab). To date PML is diagnosed by testing for JCV DNA in cerebrospinal fluid, via brain biopsy or by CT or MRI, but all available diagnostic approaches suffer from various disadvantages (e.g. insufficient sensitivity,



Typical PML-lesion shown through MRI
Source: www.emedicine.com

risk of contamination or late time of detection) and to date there is no cure for PML. The increasingly diverse populations at risk for PML emphasises the need for an easy to use and cost effective diagnostic tool to check for JCV infections.

Technology

Virus Protein 1 (VP) of the JC Virus is an excellent agent for immunological detection of JCV. VP1 can be produced in large amounts in the form of virus-like particles (VLP). VLP have an icosahedral structure (diameter of 50 nm). Due to this specific structure VLP reacts particularly well with anti-JCV antisera and therefore is highly suitable for developing a diagnostic tool. Further advantages over the natural virus are increased work safety and the fact that VLP has a higher immunogenicity than the purified total virus.

Commercial Opportunity

The technology was developed at the DPZ (German Primate Research Center). It is available for licensing for development of a diagnostic kit for JCV-detection or other diagnostic applications related to JCV.

Patent Situation

US6238859 and EP0862633 are granted, Japanese and Canadian applications are pending.

Further Reading (Additional information on request)

Khanna N et al. JCV-specific immune responses in HIV-1 patients with progressive multifocal leukoencephalopathy *J. Virol.* 2009 May 83 (9): 4404-11

Goldmann C et al. Molecular cloning and expression of major structural protein VP1 of the human polyomavirus JC virus: formation of virus-like particles useful for immunological and therapeutic studies. *J Virol.* 1999 May; 73(5):4465-9

Sindic CJ et al. Detection of CSF-specific oligoclonal antibodies to recombinant JC virus VP1 in patients with progressive multifocal leukoencephalopathy. *J Neuroimmunol.* 1997 Jun; 76(1-2):100-4.

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