



Diagnostic Tool to Predict Occurrence of Cancerous Conditions in Hepatitis-C Patients

Description:

The Invention uses the detection of HCV integration for developing an efficient, reliable and simple test to identify Hepatitis-C patients at high risk for developing cancer.

Market Overview:

Hepatitis-C is a liver disease caused by the Hepatitis-C Virus (HCV). As the most common blood-borne virus, it is transmitted in many ways, and anyone who has ever had a tattoo, body piercing, blood transfusion (especially before 1992, when a screening test was developed), or even a manicure at a nail salon, could be at risk.

Hepatitis-C is called "The Silent Killer" because most individuals are not aware they have it until significant liver damage has occurred. Those who were infected in the 80s and early 90s are only now exhibiting symptoms. The World Health Organization predicts that Hepatitis-C will cause more deaths than AIDS by the end of the decade.

Hepatitis-C affects 200 million people worldwide, including 5.8 million in the United States. It is the leading cause of liver failure and transplantation. The worldwide treatment market was estimated at over \$2.72 billion in 2004 and is expected to reach more than \$3.97 billion by 2009. The sales of related pharma products are expected to spike from \$1.7 billion in 2001 to \$6.6 billion in 2011. More than 30 companies have Hepatitis-C therapies under development.

Chronic carriers of HCV also have a higher risk of developing hepatocellular carcinoma. (Primary liver cancer is the most common cancer in the world, and hepatocellular carcinoma is the most common type of primary liver cancer.) Between 10% to 20% of Hepatitis-C patients develop cancerous conditions, and HCV accounts for 50% of new liver cancer in the U.S. and 75% in Japan.

However, the average time to develop liver cancer after exposure to HCV is about 28 years. To date, there is no test for determining which HCV-infected individuals will develop an HCV-related neoplasm. A diagnostic tool to predict this occurrence will meet an urgent need in cancer prognosis and diagnosis.

The Invention:

HCV is an RNA virus which unlike retroviruses possesses no DNA

integration potential. Thus it would not be expected to integrate an oncogenic process into the host genome. Nevertheless, the Inventor has succeeded in detecting the integration of HCV into the genome of mononuclear cells (MNC) and hepatocytes of Hepatitis-C patients suffering from EMC (a variant of Non-Hodgkin lymphoma arising in 36% of chronic Hepatitis-C patients). A full 98% of EMC patients carry HCV antibodies and HCV RNA.

This discovery was the first of its kind in medical history. It suggests a new model whereby HCV sequences integrated into a host genome can act as an insertional activation (losing its function) or an inactivation mutagen. The primary goal would be to provide an efficient, reliable and technically simple test to identify the Hepatitis-C patients who are at high risk for developing cancerous or precancerous conditions. A further objective would be to provide early diagnosis of HCV-infected patients. The findings may also open the way to look at other non-retroviruses and their potential to affect host cells' genes.

The investigation will study HCV integrants by screening for additional cases and analyzing the integration sequences into the host genome, which can reveal the mechanism by which HCV induces tumors. In the first stage, the mechanism itself will not be investigated, but rather the incidence of integration and analysis of the integrants. The immediate goal is to develop a diagnostic kit to identify Hepatitis-C patients with a high risk of developing liver cancer.

IP Status:

A patent application entitled: "*Method and kit for diagnosing and predicting Hepatitis-C virus related neoplastic transformation*" was submitted on 13 February 2006.

The Inventor:

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