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Qiagen receives CDSCO approval for blood-borne virus testing assays

01 November 2023 | News

The assays make use of Qiagen's fully automated NeuMoDx molecular PCR platform

Qiagen N.V. has announced that its NeuMoDx human immunodeficiency virus type 1 (HIV-1), hepatitis B virus (HBV) and hepatitis C virus (HCV) quantitative assays for blood-borne virus (BBV) testing has received Central Drugs Standard Control Organization (CDSCO) approval in India. These blood-borne virus assays are the first to be registered in India with additional NeuMoDx infectious disease assays to follow.

The NeuMoDx HIV-1 Quant Assay is designed for the quantitation and detection of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma. It can be used as an aid in the clinical management of HIV-1 infected patients and monitoring the effects of anti-retroviral treatment, as measured by changes in plasma HIV-1 RNA levels, and as an aid in the diagnosis of HIV-1 infection, including acute or primary infection.

The NeuMoDx HBV Quant Assay is designed for the quantitation of hepatitis B virus (HBV) DNA in human plasma and serum specimens for HBV genotypes A through H of HBV-infected individuals. It is intended to be used as an aid for determining proper course of treatment for patients with HBV infection

On the other hand, the NeuMoDx HCV Quant Assay is designed for the quantitation of hepatitis C virus (HCV) RNA genotypes 1 through 6 in human plasma and serum specimens from HCV antibody positive individuals. It is intended to be used as an aid in the management of patients with HCV infections.