

Press Release

altona Diagnostics receives CE-IVD mark for HCV RT-PCR test

Hamburg, February 07, 2019 altona Diagnostics GmbH, today announced the launch of the **AltoStar[®] HCV RT-PCR Kit 1.5**, an *in vitro* diagnostic test, based on real-time RT-PCR technology, for the detection and quantification of hepatitis C virus (HCV) specific RNA (genotypes 1 to 6).

The AltoStar[®] HCV RT-PCT Kit 1.5 represents altona Diagnostics first List A test, in compliance with the *in vitro* Diagnostic Directive (IVDD) 98/79/EC.

“We are very proud to announce the launch of our first List A product with HCV, and this is the first in a series of List A tests soon to follow” said Dr. Ulrich Spengler, altona Diagnostic’s Managing Director.

The assay is designed for use with the AltoStar[®] Automation System AM16, the AltoStar[®] Purification Kit 1.5, the AltoStar[®] Internal Control 1.5 and the Bio-Rad CFX96™ Deep Well Real-Time PCR Detection System.

About the AltoStar[®] Molecular Diagnostic Workflow

The automated AltoStar[®] workflow offers enhanced versatility sample-to-PCR management. High sensitivity, specificity, flexibility of operation and handling, as well as maximum process reliability are important characteristics of the AltoStar[®] workflow, launched in 2018.

The AltoStar[®] Automation System AM16, a pipetting workstation used in combination with the AltoStar[®] Connect software, is the centerpiece of the AltoStar[®] workflow. It enables versatile and reliable infectious disease testing comprising nucleic acid purification and PCR setup for subsequent PCR analysis on the Bio-Rad CFX96™ Deep Well Real-Time PCR Detection System. The instruments, the purification chemistry and the universal internal control, as well as the real-time PCR assays are **CE-IVD marked** products.

Broad AltoStar[®] Assay Menu

altona Diagnostics offers a **broad portfolio of quantitative CE-IVD marked AltoStar[®] PCR kits**. They are validated for use in combination with the **AltoStar[®] workflow** and allow the detection and quantification of: adenovirus, CMV, EBV, HHV-6, HSV, VZV, BKV, JCV, parvovirus B19. New AltoStar[®] products to become **available soon are tests for HEV, HBV and alpha herpesviruses**.

About HCV

Hepatitis C virus (HCV) is a member of the Flaviviridae family, which comprises 7 genotypes. Being a blood-borne virus the most common modes of infection are through unsafe injection practices, inadequate sterilization of medical equipment in health-care settings, and unscreened blood and blood products. The global prevalence of viraemic HCV is estimated to be 1.0 % in 2015, corresponding to 71.1 million (62.5 - 79.4) viraemic infections [1]. However, geographical distribution of the genotypes varies by region; the most common being genotype 1.

Clinical manifestations vary between acute and chronic disease. Most acutely infected people are asymptomatic and unaware of their infection. The risk of acquiring chronic disease after acute infection is very high (55 % - 85 %) [2]. Therefore, reliable diagnostics is needed to provide for the best possible therapy in each and every case.

About altona Diagnostics GmbH

altona Diagnostics GmbH is a diagnostic company developing, manufacturing and distributing **molecular diagnostic test solutions** for fast and specific detection of pathogens. A particular focus of the company is on the field of **emerging diseases and tropical pathogens**. **As a consequence altona Diagnostics was one of the first companies to make reliable molecular diagnostic kits commercially available during outbreak situations for SARS, Swine Flu (H1N1nv), MERS, Ebolavirus and Zika virus.**

altona[®] is ISO 13485 certified and manufactures under cGMP guidelines. The company is currently marketing more than 50 CE-IVD labelled **RealStar[®]** PCR kits that can be used on several PCR-Thermocyclers. With the **AltoStar[®]** product line altona[®] is offering a complete IVD workflow consisting of instrumentation and kits for nucleic acid extraction and PCR amplification.

altona[®] Diagnostics is headquartered in Hamburg, Germany and has subsidiaries in France, the UK, Canada, USA, Brazil, Argentina and India. The company is selling its products through direct sales and through distribution partners into **more than 70 countries worldwide.**

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[1] The Polaris Observatory HCV Collaborators. Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. *Lancet Gastroenterol Hepatol* 2017; 2: 161-76.

[2] WHO guidelines for the screening, care and treatment of persons with HCV infection (ISBN 978 92 4 154961 5, April 2016).

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