

Press Release

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

Reliable viral load monitoring

Hamburg, April 1st, 2021 altona Diagnostics GmbH, today announced the launch of the **AltoStar[®] HIV RT-PCR Kit 1.5**, an *in vitro* diagnostic test, based on real-time RT-PCR technology, for the detection and quantification of human immunodeficiency virus type 1 (HIV-1) specific RNA (groups M, N and O) in human EDTA plasma.

Designed as a dual target assay, the **AltoStar[®] HIV RT-PCR Kit 1.5** allows amplification of separate regions of the HIV-1 genome to monitor HIV infected patients. The ready-to-use kit consists of master reagents, a No Template Control and Quantification Standards calibrated against the 4th WHO International Standard for HIV-1 RNA.

“With this CE-IVD RT-PCR test for the monitoring of HIV-1 for use with the AltoStar[®] Workflow we complete our AltoStar[®] blood borne virus product portfolio. The broad AltoStar[®] assay menu now includes test systems for reliable viral load monitoring of blood borne viruses like HIV, Hepatitis B and Hepatitis C Virus”, says Dr. Markus Hess, General Manager of altona Diagnostics.

About the AltoStar[®] Molecular Diagnostic Workflow

The **AltoStar[®]** product line is the automated real-time PCR testing solution. The flexible and efficient AltoStar[®] Molecular Diagnostic Workflow automates your real-time PCR analyses from sample extraction, PCR set-up, to real-time PCR enabling full traceability. The AltoStar[®] Automation System AM16, a pipetting workstation, in combination with the AltoStar[®] Connect software, is the centerpiece of the AltoStar[®] Workflow.

All AltoStar[®] RT-PCR kits are configured for use with the AltoStar[®] Automation System AM16 and the AltoStar[®] Purification Kit 1.5. As a one-for-all purification chemistry the AltoStar[®] Purification Kit 1.5 is designed for both DNA and RNA extraction and validated for use with several sample types.

About HIV

The human immunodeficiency virus (HIV) belongs to the genus Lentivirus, which is a subgroup within the family of *Retroviridae*. Of the two species of HIV described, HIV type 1 (HIV-1) and HIV type 2 (HIV-2), HIV-1 is the most common [1].

HIV has caused 1.7 million (1.4 million – 2.3 million) new infections (all ages) globally in 2018. Although HIV infections are diagnosed worldwide, the highest prevalence is located in sub-Saharan Africa [2]. Transmission of HIV occurs primarily sexually, however, HIV infections are also caused by contaminated blood transfusion, the reuse of injection needles, perinatal transmission at pregnancy, and breastfeeding [3].

Patients suffering from an HIV infection may experience a short acute phase with flu-like symptoms. Non-treated infections lead to an acquired immunodeficiency syndrome (AIDS), which is characterized by the progressive failure of the immune system [4].

To date, there is no vaccination available. Since there is no cure for HIV infections, the medical treatment of HIV relies on the containment of the infection by an antiretroviral therapy (ART). The reduction of the viral load, which is monitored by HIV testing, leads to a chronic condition preventing the progression towards AIDS [5].

About altona

altona Diagnostics is a medical diagnostic company that develops and manufactures *in vitro* diagnostic tests for the DNA based detection of pathogens such as viruses, bacteria or parasites. Headquartered in Hamburg-Altona, Germany, altona Diagnostics is privately owned and employs more than 300 people worldwide. The company has been in the molecular diagnostics business for over 20 years and is ISO 13485 certified. altona Diagnostics sells its registered products to private and clinical laboratories globally through subsidiaries and more than 40 distribution partners.

Molecular diagnostic tests from altona Diagnostics are based on real-time PCR technology and are packaged as ready-to-use kits. The company's product catalog contains over 50 CE marked kits that are compatible with open real-time PCR platforms. In addition, altona Diagnostics offers an automated workflow solution that is complete with instrumentation, nucleic acid extraction chemistry and a dedicated software.

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