

Beckman Coulter Diagnostics Obtains CE Marks for New HCV RNA & HIV-1 Assays on DxN VERIS MDS

—Beckman Coulter Diagnostics has obtained CE Marking for its DxN VERIS HCV Assay*, a real-time PCR assay for the rapid and reliable quantitative determination of Hepatitis C Virus (HCV) RNA in human plasma, and DxN VERIS HIV-1 Assay*, a real-time PCR assay for the rapid and reliable quantitative measurement of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma. The two assays are the latest additions to the growing menu of CE-marked assays for use on the DxN VERIS Molecular Diagnostics System.*

"Beckman Coulter is committed to the ongoing development of assays for DxN VERIS and aims to rapidly expand the DxN VERIS infectious disease portfolio, delivering assays that are both cost- and time-effective," said Arnd Kaldowski, president, Beckman Coulter Diagnostics. Like all DxN VERIS assays, the HCV and HIV assays are supplied in the unique DxN VERIS single cartridge system, which reduces wastage and consumable costs compared to traditional batch-plate systems.

"Tests can be up and running in 10 minutes and, with true single sample random access and the shortest turnaround time available, results can be delivered to physicians faster than ever before," said Richard Creager, senior vice president, Molecular Diagnostics Business Unit, and chief scientific officer at Beckman Coulter Diagnostics.

With proven sensitivity, specificity and precision^{1,2}, the CE-marked DxN VERIS HCV Assay reliably detects HCV genotypes one to six², and is calibrated to the 4th WHO International Standard for HCV (NIBSC 06/102) using the DxN VERIS technology.

The prevalence of HCV infection in Europe ranges from 0.4% to 3.5% by country³, however the full burden of HCV is unknown due to differences in surveillance systems across Europe.⁴ HCV RNA quantification is invaluable for the assessment and monitoring of patients undergoing antiviral treatment, helping to assess patient compliance, to inform response-guided therapy and to determine sustained viral response (SVR)^{5,6}, which corresponds to a definitive cure of HCV infection in more than 99% of cases.⁷ With rapid, automated sample processing, amplification and detection on DxN VERIS and an assay run-time of less than 102 minutes, the DxN VERIS HCV Assay delivers results in the shortest time possible, allowing faster clinical decision making and improved HCV patient management.

In 2011, it was estimated that 2.3 million people were living with HIV throughout Europe and Central Asia, with approximately 170,000 newly diagnosed cases that year.^{8,9} Quantitative measurement of HIV-1 RNA viral load in plasma plays a vital role in the prognosis and management of patients infected with HIV-1, helping to decide when antiretroviral therapy should be initiated, to monitor response to treatment and to predict clinical progression.¹⁰ With rapid, automated sample processing, amplification and detection on DxN VERIS and an assay run-time of less than 87 minutes, the DxN VERIS HIV-1 Assay delivers results in the shortest time possible, allowing faster clinical decision making and improved HIV patient management.

With proven sensitivity and precision¹¹, the CE-marked DxN VERIS HIV-1 Assay is available for 1000 µL and 175 µL sample volumes. The DxN VERIS HIV-1 Assay reliably detects HIV-1 subtypes: Group M (A, C, D, F, G, H); Group N; Group O; CRF AE and CRF AG¹¹, and is traceable to the WHO International Standard for HIV-1 using the DxN VERIS technology.

In addition to the DxN VERIS HCV and DxN VERIS HIV Assays, the range of CE-marked assays for use on the DxN VERIS also includes DxN VERIS CMV Assay (for the quantitative determination of human Cytomegalovirus (CMV) in plasma) and DxN VERIS HBV Assay (for quantitative measurement of Hepatitis B Virus (HBV) in plasma and serum), with many other assays under development.

1. Gilfillan, R, Wang, Z, Xu, Y et al (2014) Quantitative Detection of Hepatitis C Virus (HCV) on the VERIS MDx System. Poster presentation, ECCMID. 2. Xu, Y, Gilfillan, R, Wang, Z et al (2014) Quantitative Detection of Hepatitis C Virus (HCV) on the VERIS Molecular Diagnostics System. Poster presentation, ESCV, Prague 3. European Centre for Disease Prevention and Control (ECDC): TECHNICAL REPORT: Hepatitis B and C in the EU neighbourhood: prevalence, burden of disease and screening policies, September 2010, available at www.ecdc.europa.eu 4. ECDC Fact Sheet: Hepatitis C. Available at http://www.ecdc.europa.eu/en/healthtopics/hepatitis_C/Pages/index.aspx 5. EASL (European Association for the Study of the Liver) Clinical Practice Guidelines: Management of hepatitis C virus infection, Journal of Hepatology 2014 vol. 60, 392-420 6. AASLD, IDSA, IAS-USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed April 24, 2014. 7. Swain MG, Lai MY, Shiffman ML, Cooksley WG, Zeuzem S, Dieterich DT, et al. A sustained virologic response is durable in patients with chronic hepatitis C treated with peginterferon alfa-2a and ribavirin. Gastroenterology 2010;139:1593-1601 8. UNAIDS Regional Fact Sheet 2012. North America, Western and Central Europe. Available at http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/2012_FS_regional_nawce_en.pdf 9. UNAIDS Regional Fact Sheet 2012. Eastern Europe and Central Asia. Available at http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/2012_FS_regional_ecca_en.pdf 10. Centers for Disease Control and Prevention (CDC). Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR 2006 / 55(RR14):1-17. 11. VERIS HIV-1 Instructions for Use

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