

New rapid 4th generation HIV test now available from Inverness Medical

Determine HIV 1/2 Ag/Ab Combo now CE marked



Bedford, UK, June 2009: Inverness Medical have announced that its new 4th generation rapid HIV diagnostic test – Determine[®] HIV 1/2 Ag/Ab Combo – has received CE marking and is now available for use in a range of healthcare settings.

By enabling simultaneous and separate detection of HIV p24 antigen (Ag) and antibodies (Ab) for HIV-1 and HIV-2 in human serum, plasma, or whole blood, Determine HIV 1/2 Ag/Ab Combo, based on the easy-to-use Determine format, increases the ability to detect and diagnose primary HIV infection. This unique test is able to detect HIV infection 2-20 days earlier than HIV antibody tests only (with an average mean of 5 days).

During HIV infection, the p24 antigen is produced during the first few weeks and is detectable 7-9 days earlier than the appearance of HIV antibodies. As a result, the p24 antigen is an ideal marker in aiding early HIV diagnosis. Fourth-generation HIV-screening assays represent the latest advancements in HIV serological tests. These assays are able to detect HIV antibody and HIV-1 p24 antigen simultaneously and were developed to detect acute, as well as latent infections using a time and cost-saving strategy. Most fourth-generation diagnostics are laboratory based tests (e.g. ELISAs) and are not appropriate for point-of-care application or for use in challenging environments, such as remote developing world settings.

The first test of its kind for acute HIV infection, Determine HIV 1/2 Ag/Ab Combo provides clear visual results during the patient visit in 20 minutes. The easy to use,

PRESS RELEASE



robust format of Determine does not require electricity, water, or the use of bulky laboratory equipment and can be performed in point-of-care settings and remote locations in developing countries where laboratory facilities are limited. This gives significant advantages over lab-based EIA and ELISA 4th generation HIV testing. With excellent sensitivity of 100% for patients at chronic stage of infection and a specificity of 99.23% and 99.66% for HIV antibodies and HIV-1 p24 antigen respectively, Determine HIV 1/2 Ag/Ab Combo provides clear and accurate results.

The Determine HIV 1/2 Ag/Ab Combo test is ideal to help diagnose and screen for early HIV infection. The ability of this test to enhance diagnosis of those with acute HIV infection will provide additional benefits in HIV prevention programs and ultimately contribute to a reduction in the spread of HIV.

- Ends -

Editors Notes:

About Inverness Medical

Inverness Medical Innovations is a major global developer, manufacturer and marketer of advanced, pioneering consumer and professional medical diagnostic products. A leading supplier rapid point-of-care diagnostics, Inverness Medical Innovations is committed to advancing health and creating shareholder value through a continuing flow of innovative new products brought about by our strong investment in R&D and intellectual property. Our expanding range of clinical diagnostic products focus principally on the fields of Cardiology, Oncology, DOA, Women's Health, Bloodborne Pathogens and Infectious Diseases.

www.invernessmedical.com