

Basel, 3 March 1999

Roche receives FDA approval for most sensitive HIV test

Roche today received marketing approval from the US Food and Drug Administration (FDA) for its Amplicor HIV-1 Monitor UltraSensitive Method. This test is the most sensitive means of measuring the amount of HIV circulating in an infected person's blood (viral load). It can measure levels previously considered undetectable - to as few as 50 copies per millilitre of plasma.

This approval represents a significant advance in the battle against HIV. Published studies indicate that lowering plasma HIV RNA (ribonucleic acid) to below 50 copies per millilitre is associated with more complete and durable viral suppression. Physicians will now have a clearer picture of the effectiveness of anti-HIV therapy.

In Europe the test is sold commercially in manual test format. The automated version, Cobas Amplicor HIV-1 Monitor Test (Version 1.5), is currently provided for research use only. Roche expects to launch it commercially in the first half of 1999. In Japan, Roche is seeking registration of both test formats.

Since the Amplicor HIV-1 Monitor UltraSensitive Method was made available for research use in studies of new drugs in early 1997, it has become the test of choice in pharmaceutical trials designed to demonstrate the efficacy of antiretroviral therapy. This reflects current thinking about HIV-1 infection - that no virus is tolerable, and that the goal of optimal antiretroviral therapy is to reduce virus levels to as low as possible for as long as possible.

Following FDA approval of the Amplicor HIV-1 Monitor UltraSensitive Method, Roche plans to incorporate this high sensitivity into all future HIV-1 Monitor tests, including the Cobas Amplicor™. Cobas Amplicor™ is an automated bench-top analyser that allows clinical laboratories to test PCR-ready specimens for the presence of infectious disease. It performs both amplification and detection and is the first automated system with this capability.

The Amplicor HIV-1 Monitor UltraSensitive Method is based on the Nobel Prize-winning polymerase chain reaction (PCR) technology. PCR enables amplification and identification of specific DNA (deoxyribonucleic acid) or RNA sequences in blood samples. Because PCR can directly detect the presence of viral material in a person's blood, it has become the diagnostic "gold standard" in the management of infectious diseases such as HIV/AIDS and hepatitis. Roche Diagnostics received FDA approval for the first PCR-based HIV test - Amplicor HIV-1 Monitor™ test - in June 1996. This test measures the amount of active HIV in a person's bloodstream across a dynamic range of 400 to 750,000 copies of HIV-1 RNA per millilitre of plasma.

The Amplicor HIV-1 Monitor UltraSensitive Method was also used to monitor HIV in many investigations applying Roche's antiretrovirals Invirase®, Fortovase®, Viracept® and Hivid®, as part of state-of-the-art-therapy. The results of a number of these studies were presented at international conferences and demonstrate that the integration of the most sensitive test system and very effective modern treatments with good tolerability provides the best service to people with HIV infection and their health care providers. With this test system any change in efficacy of a given therapy may be identified well before there is a clinical manifestation and the treatment regimen can be adjusted. Consequently, therapy of HIV infection can now be individualised to be as effective as possible.

The Roche Group is a world leader in research-based healthcare, with principal businesses in pharmaceuticals, diagnostics, vitamins, fragrances and flavours. Through its Diagnostics Division Roche provides innovative testing products and services for physicians, patients, hospitals and laboratories worldwide. Roche Molecular Systems, a business unit of Roche Diagnostics, is responsible for the research, development, manufacture and marketing of PCR-based products under the Amplicor® trademark.