



## News Advisory

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### **Alere Pima™ CD4 Test receives prequalification from the World Health Organization**

***New prequalification establishes the Alere Pima™ Test as the first CD4 system to receive this distinction and will help improve access to testing***

Waltham, Massachusetts (December 14, 2011) – The World Health Organization (WHO) has prequalified the Alere Pima™ CD4 Test as part of an effort to increase access to rapid and accurate HIV/AIDS monitoring tools. The Alere Pima™ CD4 Test is the first and only point-of-care diagnostic designed for the measurement of absolute CD4 counts to receive such recognition from the WHO, which released its most recent list of prequalified products on November 25, 2011.

The WHO's evaluation consists of an in-depth product assessment, an inspection of the manufacturing facility, and independent multi-site performance studies to ensure the highest of standards of quality and reliability are met. The Alere Pima™ CD4 Test was accepted for the WHO's list of prequalified diagnostics on the basis of this evaluation and in advance of multi-site performance studies due to the significant public health impact this product, unique for its innovative point-of-care technology, could have.

"We believe that this is an important move on the part of the World Health Organization, which has conditionally prequalified the Alere Pima™ Test," said Avi Pelossof, Vice President of the Infectious Disease Business Unit at Alere Inc. "It is a testimony to the ability of this point-of-care system to provide rapid, accurate CD4 counts to those affected most by the HIV/AIDS epidemic."

In addition to the abundant, independent performance data that is currently available, Alere believes that its newly obtained WHO prequalification status provides further evidence that the Alere Pima™ CD4 Test meets the needs of those looking to deploy a point-of-care CD4 solution. Designed specifically to operate in the most challenging environments, this rapid point-of-care analyzer gives healthcare providers the ability to obtain absolute CD4 counts in under twenty minutes, enables more patients to access a CD4 result, and reduces both the number of patients lost to follow-up and the time to initiate antiretroviral therapy.

As part of the company's ongoing commitment to provide products that support the screening and monitoring of people living with HIV/AIDS, Alere manufactures the Alere Determine™ HIV 1/2 Test, which is designed for HIV screening at the point of care and also appears on the WHO's list of qualified diagnostics. To date, thirty seven HIV rapid tests have been submitted to the WHO for prequalification, and the Alere Determine™ Test has the notable distinction of being one of the first HIV rapid assays to complete the process.

"The WHO prequalification is a huge step forward in getting these products to the people and places that need them most," stated Pelossof. "Alere is dedicated to developing technologies like the Alere

Pima™ CD4 Test and Alere Determine™ HIV 1/2 Test to support the full continuum of HIV Chronic Disease Management.”

Alere product availability varies by region.

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### **About Alere**

By developing new capabilities in near-patient diagnosis, monitoring and health management, Alere (NYSE: ALR) enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on cardiology, women's health, infectious disease, oncology and toxicology. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere please visit [www.alere.com](http://www.alere.com).