# *News Advisory*

For Immediate Release


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## Alere™ rapid flu test receives CLIA waiver from FDA

***The new Alere™ Influenza Test has gained waiver from the FDA, giving healthcare providers access to a new rapid, sensitive and easy-to-use test.***

Waltham, Massachusetts (January 23, 2012) – Alere Inc. (NYSE: ALR), a global leader in enabling individuals to take charge of their health at home through the merger of rapid diagnostics and health management, received confirmation that The U.S. Food and Drug Administration (FDA) has cleared the Alere™ Influenza A&B Test for the U.S. market, categorizing it as CLIA-waived. This highly sensitive rapid test is intended for use in the physician's office and will help healthcare practitioners manage patients with influenza-like illness more effectively.

The U.S. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 to set quality standards for all laboratory testing and ensure that tests, no matter where they are performed, deliver accurate, reliable and timely patient results. In 2008, the FDA, which determines what tests are eligible for waiver, established more stringent guidelines for *in-vitro* diagnostics to make certain that only accurate and easy-to-use tests reach the physician's office. In order for a device to be considered for waiver, manufacturers must demonstrate that it is accurate and simple to use in a CLIA-waived environment. Testing, moreover, must be performed by the intended user—for instance, a nurse, medical assistant, or doctor—as opposed to a specially trained laboratory technologist.

After multiple studies to validate the test and considerable collaboration with the FDA, the Alere™ Influenza Test has been granted waived status. "We are very pleased to receive the CLIA waiver for the new Alere™ Influenza Test," said Avi Pelossof, Vice President Infectious Disease at Alere Inc. "By getting this product into the waived segment of the marketplace, we are giving healthcare providers a new tool that will enable them to make better decisions about flu diagnosis and treatment while patients are still in the office."

The Alere™ Influenza A&B Test uses highly sensitive antibodies to detect influenza types A and B antigen. When compared to viral culture, the new Alere test showed performance with sensitivity / specificity of 93.8% / 95.8% for flu A and 77.4% / 98% for flu B. Sample collection for the Alere™ Influenza A&B Test, which makes use of a nasal swab, is minimally invasive. The test also provides

results in 10 minutes, making it possible for physicians to administer treatment while patients are still in their care.

The Alere™ Influenza A&B Test adds a dipstick format test to Alere's existing portfolio of influenza diagnostics, which includes the card format BinaxNOW® Influenza A&B Test, enabling Alere to provide primary care physicians with a full range of easy-to-use, effective tools for identifying influenza A & B at the point of care.

"Alere is dedicated to ensuring that only the highest quality products reach the hands of healthcare providers," stated Pelossof. "And the Alere™ Influenza A&B Test is one of them."

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 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