



***Entamoeba histolytica* Rapid Test Receives CE Mark**

First rapid test to distinguish between pathogenic and non-pathogenic species

WALTHAM, Mass., Oct. 2, 2014 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, announced today that the new *E. HISTOLYTICA QUIK CHEK*[™] test, which identifies the *Entamoeba histolytica* parasite, has received CE Mark for sale in international markets outside of the United States. The test is developed and manufactured by TECHLAB[®] Inc.

Entamoeba histolytica is an intestinal parasite that infects an estimated 50 million people worldwide. Infected individuals can develop bloody diarrhea, colitis and liver abscesses, and up to 100,000 deaths from amebiasis are estimated annually.¹ *E. histolytica* disease has also been diagnosed in 12% of travellers returning from the developing world with acute diarrhea.²

“Accurate diagnosis of *E. histolytica* is very difficult because it is identical in appearance to a non-pathogenic species, *Entamoeba dispar*,” said Dr. James Cottam, Alere Global Product Manager for Gastro-Intestinal Disease. “Currently available tests and microscopy cannot differentiate between the two species, often resulting in inaccurate diagnosis and inappropriate treatment.”

Invasive *E. histolytica* infections can be treated effectively with antibiotics, whereas *E. dispar* colonization does not require treatment.³ The current global antibiotic resistance crisis highlights the need for prudent antibiotic use. Inappropriate use of antibiotics can also result in adverse complications for patients, including *C. difficile*-associated disease.

The *E. HISTOLYTICA QUIK CHEK* test targets an adhesin unique to *E. histolytica* and is therefore the first rapid test available that can distinguish between pathogenic *E. histolytica* and non-pathogenic *E. dispar*. The test can be used for quick and reliable diagnosis of amebiasis.

“Achieving CE Mark for the new *E. histolytica* test enhances Alere and TECHLAB’s position as market leaders for gastro-intestinal disease diagnostics and is a testament to our strong partnership with TECHLAB,” said Dr. Cottam. “By improving the accuracy of diagnostics for

¹ Buss, S. et al. (2008) Comparison of Two Immunoassays for Detection of *Entamoeba histolytica*. J. Clin. Micro. Vol 46, No. 8, pp.2778-2779.

² Freedman, D.O. et al. (2006) Spectrum of Disease and Relation to Place of Exposure among Ill Returned Travellers. N. Engl. J. Med. 354;2.

³ Guerrant. G.L. et al (2011) Tropical Infectious Diseases: Principles, Pathogens and Practice. Vol 1. Enteric Amebiasis. Chapter 67:pp.685-702.

this important parasite, the *E. HISTOLYTICA QUIK CHEK* promises to be a significant help to clinicians, improving diagnosis and treatment decisions.”

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About Alere

Alere's global leading rapid diagnostic products and services, as well as its new product development efforts, focus on infectious disease, cardiometabolic disease and toxicology. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

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