Alere Receives IVD CE Mark for Alere™ q HIV-1/2 Detect Assay for Molecular Diagnosis of HIV at the Point of Care

The Alere q is a revolutionary new platform designed to enable point-of-care access to a suite of molecular assays

WALTHAM, Mass., March 2, 2015 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostic tests, today announced it has received IVD CE marking in Europe for the Alere q HIV-1/2 Detect assay, the first molecular diagnostic at the point of care (POC) that identifies HIV-1 and HIV-2 in less than 60 minutes. Molecular testing of HIV nucleic acids is required for acute detection as well as accurate Early Infant Diagnosis (EID). Current antibody POC tests cannot discriminate between a mother's and infant's antibodies to detect if a newborn has become infected with HIV.

"Accurate and timely diagnosis and access to anti-retroviral therapy is a matter of life or death for infants. In the absence of HIV testing and timely initiation of ART, one third of infants living with HIV die before their first birthday and half die before the age of two years,[i]" said Avi Pelossof, Alere Global President of Infectious Disease. "Before the development of the Alere q technology, early infant testing could only be performed in centralized labs with long lead times, delaying results and the initiation of critical treatment for children."

The clinical evidence for Alere q HIV-1/2 Detect assay in EID was demonstrated in a 2012 study that was published in the *Journal of Acquired Immune Deficiency Syndromes (JAIDS)*. Results showed that five clinics in Maputo, Mozambique used the Alere q HIV-1/2 Detect assay, with high sensitivity and specificity, to detect the presence of HIV in infants, expediting the initiation of anti-retroviral therapy. The sensitivity and specificity of POC EID with the Alere q HIV-1/2 Detect were 98.5% (95% confidence interval [CI]: 91.7-99.9) and 99.9% (95% CI: 99.3-99.9), respectively. Overall agreement between the two methods was high (Cohen Kappa = 0.981, 95% CI: 0.96 – 1.00).

"The Alere q will allow us to immediately initiate anti-retroviral therapy in HIV-positive infants, and reduce morbidity and mortality in this vulnerable population," said Landon Myer, M.D., Ph.D., Professor, School of Public Health and Family Medicine, University of Cape Town. "This robust platform can be easily transported to even the most remote primary care clinic, whether on the back of a motorcycle, car or truck, making this point of care technology uniquely well suited to applications in the field."

The Alere q was designed and engineered to operate in diverse and challenging environments and is battery-powered. The fully automated analyzer and uniquely designed

cartridge system completely eliminates the complexity of molecular diagnostics for the operator. Since sample manipulation between extraction, isolation, amplification and detection is not required, it eliminates processing errors and contamination concerns.

Alere q uses a multiplexed real-time polymerase chain reaction (PCR) methodology that allows amplification and detection of more than one target at the same time. In the case of the Alere q HIV-1/2 Detect, the test can identify and distinguish between HIV 1 subgroup (M/N), HIV 1 subgroup (O) and HIV 2 and incorporates a series of onboard controls with every sample run all in under 60 minutes. This ensures the broadest coverage of subgroups and recombinant circulating forms (CRF's) of any commercially available molecular diagnostic assay. The technology is also being investigated for potential applications for the diagnosis and monitoring of other infectious diseases, such as hepatitis C, tuberculosis and Ebola.

With the availability of Alere q HIV-1/2 Detect, Alere broadens its offering of diagnostic solutions for the complete continuum of HIV care from initial screening and diagnosis to staging and ongoing monitoring. For more information, visit www.alerehiv.com.

About Mother-to-Child Transmission of HIV and Early Infant Diagnosis
According to UNAIDS, almost 90% of HIV-infected children currently live in sub-Saharan Africa, and an estimated 90% of infections in children are acquired through mother-to-child transmission (MTCT) of HIV. The World Health Organization (WHO) recommends that all HIV-exposed infants have HIV viral load testing at 4 to 6 weeks of age or at the earliest opportunity thereafter, and that antiretroviral therapy be initiated in infants diagnosed with HIV infection.

The Alere q HIV-1/2 Detect assay is currently pending WHO pre-qualification.

About Alere

Because **Knowing now matters™**, Alere delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease, cardiometabolic disease and toxicology. For more information on Alere, please visit www.alere.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws, including statements regarding anticipated reductions in morbidity and mortality rates in infants. These statements reflect Alere's current views with respect to future events and are based on their current assumptions and information currently available. Actual results may differ materially due to numerous factors including, without limitation, the timing of regulatory decision making, as well as the other risks described in the "Risk Factors" section of Alere's Annual Report on Form 10-K filed with the SEC on March 3,

2014, as amended. The parties undertake no obligation to update any forward-looking statements contained herein.

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[i] UNICEF, Thematic Report 2013, HIV/AIDS and Children, p.8. Newell, Marie Louise, et al., 'Mortality of Infected and Uninfected Infants Born to HIV-Infected Mothers in Africa: A pooled analysis,' The Lancet, vol. 364, no. 9441, 2 October 2004, pp. 1236-1243.