Alere q HIV-1/2 Detect Point-of-Care Molecular HIV Assay Receives WHO Prequalification

Developing countries can now add point-of-care molecular Early Infant Diagnosis to national health algorithms, facilitating immediate linkage to care for HIV-positive newborns

WALTHAM, Mass., June 16, 2016 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ q HIV-1/2 Detect assay has been awarded World Health Organization (WHO) prequalification, making it available for public sector procurement. The Alere q HIV-1/2 Detect is the first-ever molecular diagnostic that identifies HIV-1 and HIV-2 at the point of care (POC) in less than 60 minutes, and the first testing application on the Alere q platform.

The Alere q is a portable molecular diagnostic platform designed for use at the point of care. The WHO prequalification is for the Alere q instrument and its first application, the Alere q HIV-1/2 Detect cartridge. The Alere q HIV-1/2 Detect assay has the ability to detect and differentiate between HIV-1 and HIV-2 using just 25 µl of whole blood or plasma. An immediate and urgent application for this test is Early Infant Diagnosis (EID). Diagnosing HIV in infants via molecular, as opposed to antibody testing, is critical because babies born to HIV-positive mothers have the mother's protective antibodies in their blood, and current POC antibody tests are not able to discriminate between a mother's and an infant's antibodies to detect if a newborn is infected with HIV. With WHO prequalification, the Alere q HIV-1/2 Detect can be actively deployed by global health organizations in developing countries. The test will be used by health workers to identify infants born with HIV infection, and link them to antiretroviral therapy (ART).

"Children with HIV are significantly – and tragically – less likely to receive ART compared to adults[1], and traditional methods of EID do not address this gap because they don't allow for immediate linkage to care," said Avi Pelossof, Alere Global President of Infectious Disease. "Now, countries with the highest burden of HIV infection will have broader access to the Alere q HIV-1/2 Detect, which delivers lab-accurate results in 52 minutes. This will empower health workers to diagnose HIV while the mother and newborn are present, and immediately initiate ART if needed – giving these children a fighting chance to survive and thrive."

"Currently, most newborns in developing countries are screened for HIV infection via dry blood spot testing, but because health workers have to wait 3 to 6 weeks for results many potentially HIV-positive infants are lost to follow-up and remain untreated," said Landon Myer, M.D., Ph.D., Associate Professor, School of Public Health and Family Medicine, University of Cape Town. "Now that point-of-care molecular EID can be implemented as part

of national guidelines, health workers have a powerful tool to help meet WHO goals for timely viral HIV screening of newborns."

About the Alere q HIV-1/2 Detect Assay
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 assay 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 in 52 minutes. This ensures the broadest coverage of subgroups and recombinant circulating forms of any commercially available molecular diagnostic assay. The Alere q was designed and engineered to operate in diverse and challenging environments and can be battery-powered. The clinical evidence for Alere q HIV-1/2 Detect assay in EID was demonstrated in a 2014 study published in the *Journal of Acquired Immune Deficiency Syndromes (JAIDS)*. Results showed that five clinics in Mozambique used the assay, with high sensitivity and specificity, to diagnose HIV in infants, expediting the initiation of ART.[2]

Prior to WHO prequalification, the Alere q instrument was IVD CE marked (self-certified) on August 1, 2014 and the Alere q HIV-1/2 Detect assay received IVD CE certification on February 12, 2015.

For more information about Alere's complete continuum of HIV diagnostic solutions from initial screening and diagnosis to staging and ongoing monitoring, visit www.alerehiv.com.

About Early Infant Diagnosis
Among the world's 2.6 million HIV-infected children, 90% of whom live in sub-Saharan Africa, only 32% are receiving ART.[3] The 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 ART be initiated in infants diagnosed with HIV infection. According to the most recent UNAIDS Gap Report, however, only 42% of infants born to mothers living with HIV in low- and middle-income countries received this test within two months.[4] When children with HIV are not diagnosed and treated on a timely basis, as many as one-third will die before their first birthday and half will die before the age of two years.[5]

About Alere
Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters™**. 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.

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[1] UNAIDS. 2014 Gap Report.
[2] Jani IV, et al. Accurate early infant HIV diagnosis in primary health clinics using a point-of-care nucleic acid test. *JAIDS*. 2014.67(1):e1-e4.
[3] UNAIDS Children and HIV Fact Sheet. http://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf.
[4] UNAIDS. 2014 Gap Report.
[5] WHO/UNAIDS/UNICEF. Global HIV/AIDS Response: Epidemic update and health sector progress towards Universal Access 2011.