



New Alere™ q Point-of-Care Early Infant Diagnosis Test Prototype Accurately Detects HIV in Infants with High Sensitivity and Specificity in Primary Health Clinics in Mozambique

Results Published Ahead of Print in the *Journal of Acquired Immune Deficiency Syndromes (JAIDS)*

WALTHAM, Mass., July 14, 2014 – Alere Inc. (NYSE: ALR) today announced the publication of a study demonstrating the viability of accurate and rapid HIV screening among infants at the point of care (POC). The study was conducted in five clinics in Maputo, Mozambique, with the prototype of Alere's new POC nucleic acid test, the Alere™ q HIV-1/2 Detect assay. Results of the study have been published ahead of print in the *Journal of Acquired Immune Deficiency Syndromes (JAIDS)*.

In the study, conducted under the auspices of the National Institute of Health together with the Clinton Health Access Initiative and the University Eduardo Mondlane (all Maputo, Mozambique), nurses in five clinics in Maputo tested infants with the Alere q HIV-1/2 Detect assay, which provides results in less than 60 minutes. Samples were also reference tested as per standard of care (SOC) with a laboratory-based nucleic acid test. Results showed that the new Alere q HIV-1/2 Detect assay administered at the POC had rates of sensitivity and specificity comparable with the reference method with high overall test agreement between the two platforms of 98.5% for positive results and 99.9% for negative results.

Commenting on the study results, Landon Myer, M.D., Ph.D., Associate Professor School of Public Health, University of Cape Town in South Africa, said, "The ability to provide a definitive HIV test result in less than 60 minutes changes how we relate to our patients and how patients experience the healthcare system. If approved, this test will allow us to immediately initiate ART in HIV-positive infants, and reduce morbidity and mortality in this vulnerable population."

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. It is estimated that more than half of HIV-positive infants who are not diagnosed and who do not receive anti-retroviral treatment (ART) within the first three months of life will die before their second birthday. The World Health Organization (WHO) recommends that all HIV-exposed infants have a molecular HIV test at 4 to 6 weeks of age or at the earliest opportunity thereafter, and that antiretroviral therapy be initiated as early as possible in infants diagnosed with HIV.

"In Mozambique and other resource-limited settings, far too few infants are screened for HIV infection, and clinicians often cannot initiate therapy in those who test positive because they are lost to follow-up before results can be obtained," said Willem Pretorius, Global Product Manager - HIV Care, Alere. "Results of this study suggest that point-of-care early infant diagnosis is clinically feasible when administered by non-laboratory personnel, can improve access to screening and treatment, and can help keep people who initiate therapy retained in care."

About the Study

In the blinded, cross-sectional study, 827 HIV-exposed infants between one and 18 months of age were enrolled in four public primary health clinics in and around Maputo and Maputo Central Hospital, between February and September 2012. The majority of infants were between the ages of 1-2 months (60%) and 2-3 months (14.9%), with a median age at testing of 1.4 months.

HIV-exposed infants routinely referred for early infant diagnosis (EID) testing were recruited for the study. Trained nurses conducted Alere q HIV-1/2 Detect testing at the POC using blood samples collected through heel pricks, and also collected samples through the same heel pricks for SOC testing with a laboratory-based nucleic acid test (Roche COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV Quantitative Test) from dried blood spots. Of the 827 samples tested on both the Alere q and the laboratory platform, 825 concordant results were reported, with 761 negative and 64 positive results detected with both assays. 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 HIV-1/2 Detect assay is currently pending WHO pre-qualification, and application for CE IVD marking will be made in July 2014.

About Alere

By developing new capabilities in near-patient diagnosis, monitoring and health information technology, 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 infectious disease, toxicology, cardiology and diabetes. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

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