



Alere's SD BIOLINE HIV/Syphilis Duo is First Dual Test to Receive WHO Prequalification

Prequalification Expands Global Access and Facilitates Implementation of Screening Programs to Help Eliminate Mother-to-Child Transmission of HIV and Syphilis

WALTHAM, Mass., Nov. 9, 2015 – Alere (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere SD BIOLINE HIV/Syphilis Duo test has been awarded World Health Organization (WHO) prequalification, making it the first dual HIV/syphilis point-of-care test available for public sector procurement in resource-limited countries.

With WHO prequalification, global health organizations such as PEPFAR, UNAIDS and the Global Fund to Fight AIDS, Tuberculosis and Malaria can now deploy the HIV/Syphilis Duo test in national screening programs targeting those in greatest need. Utilization of the test will be focused on screening pregnant women for HIV and syphilis and linking those infected to care, in support of WHO's goal of eliminating mother-to-child transmission (EMTCT) of these serious diseases.

“Alere is committed to making our infectious disease diagnostics widely available to support prevention of mother-to-child transmission programs in resource-limited countries, and the WHO prequalification of HIV/Syphilis Duo test significantly advances this goal,” said Avi Pelossof, Alere Global President of Infectious Disease. “With this broadened access, the full potential of the HIV/Syphilis Duo test in helping meet EMTCT goals can now be unlocked.”

Her Excellency, Dr. Nana Lordina Dramani Mahama, First Lady of the Republic of Ghana and President of the Organisation of African First Ladies Against HIV/AIDS, said, “Alere has already provided test kits to help us screen 200,000 people for HIV and syphilis infections, and we are delighted that this productive relationship continues to grow and thrive.”

About Mother-to-Child Transmission of HIV and Syphilis

Globally, 1.4 million pregnant women have active syphilis and almost 1.5 million pregnant women are HIV infected. Both HIV and syphilis can be transmitted during pregnancy to the fetus. Additionally, syphilis infection during pregnancy increases the risk of mother-to-child HIV transmission by 180%.¹ In sub-Saharan Africa, 260,000 African children are infected with HIV each year. Mother-to-child transmission occurs through pregnancy, labor, delivery and breast feeding. In fact, breast-feeding alone increases the risk of MTCT by 12%-43%.² Maternal syphilis infection can cause stillbirth, neonatal death, prematurity, low birth weight or congenital syphilis. The impact of maternal syphilis can be prevented by testing early in pregnancy, treating seropositive pregnant women, and preventing re-infection.^{3,4}

Forty percent of pregnant women living with HIV have not received anti-retrovirals to reduce mother-to-child transmission during pregnancy.⁵ Without any intervention, up to 45% of infants born to mothers living with HIV will become infected.⁶

In 2014, WHO and key partners published guidance on and recommendations for the dual elimination of mother-to-child transmission of syphilis and HIV, and a framework for countries to monitor progress and validate success.⁷

About Alere SD BIOLINE HIV/Syphilis Duo

The Alere SD BIOLINE HIV/Syphilis Duo offers a simple, easy-to-use rapid diagnostic test for simultaneous detection of HIV and Syphilis. By enabling early detection of HIV, Syphilis or both in mothers, the Alere SD BIOLINE HIV/Syphilis Duo helps bridge the health equity gap and get patients onto treatment pathways faster. The test uses a solid-phase immunochromatographic assay for simultaneously qualitative detection of HIV-specific antigens (HIV-1 gp41, sub O, HIV-2 gp36) and recombinant *Treponema pallidum* antigen (17 kDa) in human serum, plasma, or whole blood.

Prior to WHO prequalification, the product received CE certification on July 1, 2015. For more product information, please visit

<http://www.standardia.com/en/home/product/rapid/HIVSyphilisDuo.html>.

About Alere

Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters.**[™] Alere delivers on this vision by providing reliable and actionable information through rapid diagnostic tests, enhancing clinical and economic health 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

<http://www.alere.com>.

###

Media Contacts:

Jackie Lustig
Senior Director, Corporate Communications
pr@alere.com
781 314 4009

Investor Relations Contact:

Juliet Cunningham
Vice President, Investor Relations
ir@alere.com
858 805 2232

¹ Mwapasa V, Rogerson SJ, Kwiek JJ, et al. Maternal syphilis infection is associated with increased risk of mother-to-child transmission of HIV in Malawi. *Aids* 2006; 20(14): 1869-77.

² Maputle MS, Jali MN. Pregnant women's knowledge about mother-to-child transmission (MTCT) of HIV infection through breast feeding. *Curationis*. 2008;31(1):45-51.

³ De Santis M, De Luca C, Mappa I, et al. Syphilis Infection during pregnancy: fetal risks and clinical management. *Infectious diseases in obstetrics and gynecology* 2012; 2012: 430585.

⁴ Gomez GB, Kamb ML, Newman LM, Mark J, Broutet N, Hawkes SJ. Untreated maternal syphilis and adverse outcomes of pregnancy: a systematic review and meta-analysis. *Bulletin of the World Health Organization* 2013; 91(3): 217-26.

⁵ 2013 Progress Report on the Global Plan. UNAIDS 2013.

⁶ UNICEF, Unite for Children, Unite Against AIDS. Towards an AIDS-Free Generation, report highlights. *Children and AIDS, Sixth Stocktaking Report* 2013.

⁷ World Health Organization (WHO). Global Guidance on Criteria and Processes for Validation: Elimination of Mother-to-Child Transmission of HIV and Syphilis. 2014. Available online at http://apps.who.int/iris/bitstream/10665/112858/1/9789241505888_eng.pdf?ua=1&ua=1.