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ASIA EDITION

China SFDA approves first-ever test to screen HPV

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QIAGEN gets SFDA approval for "Made In China" diagnostic kit

Singapore: China's State Food and Drug Administration (SFDA) has approved QIAGEN's careHPV Test and instrument platform. The careHPV Test is the first molecular diagnostic to screen for high risk human papillomavirus (HPV) designed for low-resource clinical settings, such as areas lacking electricity, water or modern laboratory infrastructure. QIAGEN expects to announce the product availability of careHPV in China in January 2013, followed by India later in 2013 and other emerging markets as approvals are received.

The careHPV Test is manufactured by QIAGEN in Shenzhen, China, making the country-of-origin approval a critical milestone. QIAGEN developed the careHPV Test in collaboration with PATH, an international nonprofit organization, to expand access to HPV screening in low-resource settings. The robust, portable, and easy-to-use careHPV assay, instrument and collection devices are designed for areas with limited infrastructure and can provide results during the patient visit. Many regions with the highest burdens of cervical cancer lack electricity, water or modern laboratory infrastructure.

To address the needs in such regions, QIAGEN's careHPV Test includes many innovative design and technology features. For example, the system has color coded, easy to understand menus, contained reagents, and tolerates temperature variations that occur in rural clinics lacking refrigeration for sample storage due to limited electricity or water. Non-medical staff can be trained in hours to use the careHPV system, and the test also has been shown to avoid cross-contamination of samples even in the most stringent settings.

"As the only test of its kind, careHPV offers the life-saving benefits of sensitive molecular diagnostics to resource-poor regions. About 275,000 women a year die from cervical cancer, more than 85 percent in less-developed countries. We have teamed with PATH to create careHPV as part of a preventive strategy that will save many women's lives," said Dr Helge Lubenow, senior vice president, Molecular Diagnostics Business Area.

"We are expanding QIAGEN's Prevention portfolio by launching the careHPV system in emerging markets, both through a commercial offering to healthcare providers and through donations to governments and NGOs that are in the process of

implementing large scale cervical cancer prevention plans. This new product complements our well-established global leadership with the digene HC2 HPV test and can also be used very synergistically for example to allow national or regional screening programs to cover the infrastructure profiles of all segments within the targeted region," Dr Lubenow added.

Clinical studies with the careHPV Test have been conducted in China, Nigeria, Rwanda and Thailand in parallel with PATH demonstration trials in China, India, Uganda and Nicaragua. The data demonstrate the high sensitivity and reliability of the careHPV Test in low-resource settings.