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QIAGEN gets SFDA's nod for careHPV Test

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Singapore:Ã?Â QIAGEN announced that 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. QIAGEN will introduce the careHPV Test and key data of its performance at the International Papillomavirus (IPV) conference, starting November 30 in Puerto Rico.

QIAGEN is the global market leader in HPV testing with its "gold standard" digene HC2 HPV Test, the most validated and sensitive diagnostic for detection of high-risk HPV - a primary cause of cervical cancer. It is the only assay that has demonstrated its effectiveness in close to one million women in clinical, randomized and independent studies. The digene HC2 test, compatible with modern laboratories and automated processing, is widely used in developed countries and large cities in emerging markets, including China. The digene HC2 test has protected more than 100 million women so far and remains QIAGEN's core product for cervical cancer prevention. The careHPV and digene HC2 tests are both based on clinically proven Hybrid Capture technology, and are highly complementary because they serve different laboratory needs.

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."

The careHPV Test is manufactured by QIAGEN in Shenzhen, China, making the "country of origin" approval a critical milestone. Many countries are able to use this approval by the SFDA for their own regulatory approval, instead of conducting lengthy and costly local regulatory submissions. The careHPV rollout will target areas in Asia, Latin America, Eastern Europe and Africa.

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.

The careHPV Test already plays a central role in QIAGENcares, the company's collaboration with NGOs and governments to expand access to high-quality cervical cancer screening in resource-poor regions. QIAGEN is committed to donating 1.5 million HPV tests to improve life in the world's poorest nations. For example, QIAGEN has partnered with vaccine manufacturer Merck & Co, to design and implement comprehensive public programs to fight cervical cancer in poor countries, starting in Rwanda. The programs have taken many forms: QIAGENcares has helped clinicians in Brazil install the careHPV device on mobile units to conduct cervical cancer screening in remote areas. El Salvador's government, working with the nonprofit group Basic Health International, is evaluating the integration of careHPV into a national screening program together with screening solutions based on the digene HC2 test which would be used in cities. Projects in South Africa and Burkina Faso have also used careHPV.