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Dr Lubenow: QIAGEN HPV test is revolutionary

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Diagnostics seem to be the buzz word in the today's healthcare industry. Previously, undergoing a diagnostic test was very harsh for a patient and so instead of undergoing diagnostic, a patient preferred to go for directly for the treatment. However, this has changed over the period of time. Diagnostics have come a long way from being only a method to identify a patient's disease, to becoming a crucial segment that supports clinical development of drugs, helps in predicting diseases before symptoms appear, aids in predicting the progress of a disorder and identifying patients that are most likely to respond (or not respond) to specific treatments.

The seveal advantages of diagnostics has led to firms investing in diagnostics-based products. One such example is QIAGEN, the global leading provider of sample and assay technologies, which started its diagnostics operations in 2004. In the last one year, QIAGEN has been in the lime light for its diagnostics products. For instance in November 2012, the company's careHPV molecular diagnostic test, which is used to screen high-risk human papillomavirus (HPV), got the Chinese SFDA nod. The product, which is based out-of-China, is designed for low-resource clinical settings such as areas lacking electricity, water or modern laboratory infrastructure.

BioSpectrum connected with Dr Helge Lubenow, senior VP, molecular diagnostics business area, QIAGEN, to know about the details of its present products and the strategy adopted by the firm to capture APAC markets. Following are the excerpts:

Congratulations on receiving SFDA's nod for careHPV test. Please tell us more about the test?
The careHPV Test has been developed in a joint effort with PATH, an international nonprofit organization, and is the first HPV test designed for areas with limited healthcare infrastructure, complementing QIAGEN's market-leading digene HC2 HPV Test.

How is careHPV different from digeneHC2 HPV test?
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. 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.

The careHPV Test detects 14 high-risk types of HPV DNA (16/ 18/ 31/ 33/ 35/ 39/ 45/ 51/ 52/ 56/ 58/ 59/ 66/ 68). It is designed to be used in low-resource facilities with a running time that is less than three hours. It is a manual assay, specially designed for low-throughput, low-resource settings, and it is designed to be performed by any healthcare worker. It is approved by the regulatory authorities in China (SFDA).

The digene HC2 HPV DNA Test remains the gold standard for HPV DNA testing. It detects 13 high-risk types HPV DNA (16/18/31/33/35/39/45/51/52/56/58/59/68), is fully automated, and has the capability to accommodate any volume of HPV testing, from lowest to highest throughput settings. The digene HC2 HPV DNA Test requires a skilled laboratory technician to perform the test. The sensitivity of the digene HC2 HPV DNA Test is higher than the careHPV Test. It is approved by the regulatory authorities for the US FDA and the European Union (CE mark) and China (SFDA).

When do you plan to launch the test in China and are you planning to launch the product in other geographies in Asia Pacific?
The product will be available by January 2013 in China. This 'country-of-origin' approval is key for dissemination. We can use it as a basis for registration in other countries. In India the marketing launch for the careHPV Test is planned for Q2 2013. QIAGEN is also evaluating product registration in other regions such as Latin America, Asia Pacific and Eastern Europe to assess making the careHPV Test commercially available in these regions as well.

What is the cost of the test?
QIAGEN will offer the careHPV Test following a differential or tiered-pricing model. Low-income countries are charged a reduced price as compared to the open market rate. This is often managed through bulk procurement systems, including IPPF, UNFPA, IARC, JHPIEGO, UNICEF and PAHO.

The pricing for public health systems will be a function of: economic power of the respective countries, requested volume of tests, duration of commitment and the value addition expectations, including education and training. The pricing for private health systems will be market driven and a function of committed test volumes.

What are some of the benefits of this test?
The throughput is 180 patient samples per-day per-careHPV instrument system. Two plates can be run easily and comfortably every day. 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.

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 within 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.

What are the marketing strategies in place to expand the reach of the kit in China and in other countries?
Following the recent SFDA approval, the careHPV product will be commercially available in China, starting January 2013. The careHPV Test will also be sold in India in 2013, when the national registration has been granted. Once local registration is obtained, the product will also be sold in Latin America and Eastern Europe in the near future.

QIAGEN has been focusing on diagnostics related products. What according to you is the importance of this segment? What are the strategies in place to tap the market in the diagnostics segment?
QIAGEN's expansion from a provider of life science tools into new areas, such as molecular diagnostics and applied testing, actually started from as early as 2004. We saw both as significant growth opportunities. Before that, what we were missing were assets such as truly global presence, content breadth, including a block-buster franchise such as HPV screening, and integrated platforms, as well as access to physicians and companion diagnostics. Between 2003-11, our net sales increased from $351 million-to-$1,170 million, which is a good proof of why we entered to the new areas.

Besides acquisitions, QIAGEN's organic growth comes from newly introduced products as we are committed to expanding content. In addition, one of our focuses has been on automated platforms, namely to integrate solutions that allow customers to process complete workflows, from sample extraction to sample processing, assay setup and detection. For all throughput needs, we offer corresponding instrumentation platforms.

How important is the Asia Pacific market for the company?
It is easy to see that APAC holds great potential as a huge market with broad untapped areas. So we have great

opportunities to bring our exceptional technologies to more people. We are a technology leader, a solutions leader and a thought leader in this field. As a multinational company, we face competition from both foreign and local companies; yet our combination of international gold standard technologies and local products for local needs give us an edge that neither can match.

QIAGEN started expanding in APAC region from 2005, since when the company executed on two milestone strategies. One is expanding to the molecular diagnostics business from our traditional sample and assay areas, primarily serving the research segment, and moving to the clinical segment. The other milestone decision that the company took was to expand to emerging markets, where APAC was a prior target. This is how we get started. First we set up the regional office in Shanghai, and then we looked at what should be our strategies to fast expand into the dynamic market here.

With these strategies, we expanded our own presence as well as through acquisitions in both research and clinical segments. Through the acquisitions and the regional expansion, we have had faster market penetration, having the access to channels of the acquired companies and also the customers.

What percentage of your revenue comes from the Asia Pacific?
In the fiscal year of 2011, Asia Pacific (Japan excluded) contributed 12 percent of QIAGEN's net sales throughout the world. Since 2005, basically APAC region, in particular China, has built from the ground and has become the fastest growing region for QIAGEN as a whole. In APAC, China has been the fastest growing market. Since 2005, the revenue of China has grown by more than 30 times and China has become QIAGEN's third largest country in the world after the US and Germany.

What are the other segments that QIAGEN is hopeful about, apart from diagnostics?
Now we have a deep MDx pipeline across all indication areas, personalized healthcare, virology and microbiology. Besides that, in June 2012 QIAGEN announced initiative to create next-generation sequencing (NGS) workflow with a benchtop sequencer, a full range of sample and assay kits and bioinformatics tools that can be expected in 2013 for research use. We've already launched a series of consumable products to improve NGS workflows in research. QIAGEN is also continuously expanding menu-of-pathway and biomarker products for life sciences, and applied testing content in food, forensics and veterinary.