

WaferGen's alpha dog

Pitt Med School tapped as alpha test site for WaferGen's real-time PCR system

BY LLOYD DUNLAP

FREMONT, Calif.—As research on COPD and lung cancer moves forward at the University of Pittsburgh Medical School under Dr. Steven Shapiro, the university has entered into an agreement to test WaferGen's SmartChip real-time PCR system that, if successful, will process the entire genome in one pass.

According to Dr. David Gelfand, CSO at WaferGen and a pioneer in PCR technology, "The more RNAs you can measure, the better. Different genes express their RNAs at different levels—abundant, rare, not at all. Using techniques that rely on labeling and hybridization, detection sensitivity is a problem."

With six orders of magnitude involved, Gelfand adds, hybridization only detects the two most active orders. "PCR doesn't have this problem; it has an enormous dynamic range and can measure from a single RNA up to 10^6 or 10^7 . SmartChip will allow Dr. Shapiro's group at Pitt to look at 100,000 PCRs at once in order to measure and quantify all the copies of RNA across

the entire genome."

Asked to address the twin issues of time and cost saving, Alnoor Shivji, WaferGen's chairman and CEO, says that what can easily take 10 days using current technology to measure copies of from twenty to thirty percent of the genome's RNA, can be done in less than a day using the SmartChip system. He envisions up to 33,000 nano wells on a single chip, containing as little as 100 nL per well. "Months and months can be reduced to a single day without compromising dynamic range or accuracy," Dr. Gelfand adds.

The WaferGen system is fully configurable, Shivji explains, and can address any well in any array whether 1,000 or even 550,000. "I have spoken at many conferences over the years," he says, "and discussed drug discovery and development problems with pharma executives. From that experience, I became convinced that the convergence of high tech expertise, which is my background, with biochemistry and biology might provide useful answers." WaferGen Biosciences—Shivji's fourth company—was launched in 2003 based on expertise in semiconductors and materials science.

As seems to be the case frequently in science, Dr. Shapiro's introduction to WaferGen's tech-

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nology came about in an oblique way. A former trainee, Dr. Dean Hautamaki, heard about WaferGen from a venture capital source and suggested that the company's technology might be useful in his research. The research collaboration soon followed. Noting the apparent involvement of matrix degrading proteinases in COPD and lung cancer, Dr. Shapiro says that mice can smoke without ill effects when one such proteinase, MMP-12, is knocked out. "But," he adds, "a phase III study failed because the effect was reversed in humans." The WaferGen genome-wide assay should be useful, he adds, in unraveling such effects.

"Dr Shapiro quickly recognized the utility of our system," Shivji states. "By looking at all the genes, we believe he will discover other biomarkers." Shivji expects to be in beta testing soon with the SmartChip system and to release the product commercially in 2009. An early access program will be established for key customers, he adds. "Pharmas with millions of compounds in their libraries will be able to test them all for the first time," he says.

According to WaferGen, the genetic analysis market alone (comprised of gene expression and genotyping analysis) rang up approximately \$2.4 billion in worldwide sales in 2006 (\$1.74 billion for gene expression and \$650 million for genotyping) with revenues expected to reach \$5 billion by 2012.