

PCR Pipeline

Seegene Inc, Rockville, Md, is also working toward FDA approval for its multiplex real-time PCR tests, which are currently CE marked. The Seeplex 18-Plex Respiratory Test detects 11 RNA respiratory viruses, two DNA, and five bacterial infections; the Seeplex RV12 ACE Detection simultaneously detects 12 respiratory viruses; and the Seeplex RV5 ACE Screening enables rapid screening for the most prevalent respiratory viruses.

Multiplex screening is more efficient, labor-wise, time-wise, and cost-wise. "[With the Seeplex RV12 ACE Detection], laboratories get 12 different results for the price of one or two tests," says Jong-Yoon Chun, PhD, Seegene's CEO and inventor of the Seeplex platform. He estimates that a hospital laboratory with a patient volume of 1,000 patients per month would save \$1 to \$2 million annually.

The technology is based on a dual priming oligo, or DPO, platform that works in conjunction with automatic detection systems, such as capillary electrophoresis or sequencing instruments. The DPO-based primers are comprised of two priming parts that serve to amplify only the target gene, generating consistently high PCR specificity. Amplicons are separated and analyzed automatically. "Our goal is to provide a very accurate diagnostic for the proper treatment of the patient," Chun says.

Very accurate and very fast—because more than one disease marker can be detected at a time, results are produced rapidly. The average turnaround is about 5 hours, according to Chun.

Seegene is not the only company with multiplex real-time PCR tests in development. Nanogen Inc, San Diego, has been awarded a \$10.4 million, 2-year contract from the CDC to develop a multi-analyte molecular diagnostic that will detect and differentiate influenza A, influenza B, seasonal flu (H1N1 and H3N2) strains, and RSV. The test will be developed in partnership with the Medical College of Wisconsin and HandyLab Inc.

The project is based on the company's proprietary MGB probe technology, and is expected to produce an assay that can be completed in half the time it takes to run molecular diagnostics today while increasing sensitivity. Competition exists with not only similar technology but with tests that incorporate more complex technologies, such as microarrays and microspheres.