

All At Once

Seegene Inc, Rockville, Md, seeks to ease the testing demands on laboratorians with multipathogen diagnostics. "Our approach is the multiple pathogen test with a low cost," says Jong-Yoon Chun, PhD, CEO of Seegene and the founder and inventor of the company's new multiplexing PCR technology, Seplex.

Seplex employs a Dual Priming Oligo (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. 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.

The company has two STD tests in commercial development: the HPV4 ACE Screening and the HPV/STD4 ACE Screening. The tests have been CE marked, and Chun expects to submit the technology to the FDA for approval within the coming year.

Both offer multiple pathogen results for the cost of a single test. The HPV4 ACE Screening detects 11 high-risk and five low-risk types of HPV as well as performs genotyping on HPV 16 and HPV 18 strains—all at once. The HPV/STD4 ACE Screening detects the 13 high-risk and five low-risk types of HPV as well as *Chlamydia trachomatis* (chlamydia) and *Neisseria gonorrhoeae* (gonorrhea), also all at once.

Chun points out that by combining multiple tests into one, a patient can be screened for conditions for which they might not necessarily have been tested, which can be especially true for pregnant women. "These types of infection can have no symptoms. So if the pathogen is not included in a routine screening, there is no chance of identifying and successfully treating the disease," Chun says.