

Nanosphere submits 510(k) for rapid, POC influenza test

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If FDA cleared, **Nanosphere's** (Northbrook, Illinois) new respiratory test to run on the Verigene SP may offer the kind of point-of-care diagnostic needed for a potential H1N1 pandemic.

The company this week submitted a 510(k) application to the FDA for its influenza and respiratory syncytial virus (RSV) test to run on the Verigene SP, with complete sample-to-result automation in one device, avoiding the need for complex PCR testing and reference labs.

"The technology is based on gold nanoparticles that are turned into probes by functionalizing the surface of them with oligonucleotides," William Moffitt, Nanosphere's president/CEO told *Medical Device Daily*. "As it turns out these gold nanoparticles exhibit an extraordinary degree of specificity. It's cost effective and easy to use. All of this can be packaged into a single-use disposable test cartridge. The only thing the user needs to do is to put the sample in, which is a nasal swab or nasal wash."

Verigene is a random-access, molecular diagnostic workstation for nucleic acid and protein diagnostics, and is FDA-cleared for *in vitro* diagnostic (IVD) use with specific Verigene tests. Verigene SP is a newer version of the bench-top workstation that provides automated sample-to-result molecular diagnostics capabilities in a multiplexed, random-access, modular system using the same imaging technology as the first generation Verigene.

"The most important thing is the sample-to-result feature in one instrument," Moffitt said. "And it's random access, so there's no batch processing. Most other assays on the market are batch-processed with a significant number of steps. It's just not cost effective to go to that effort for one assay. But with Verigene SP you can run one assay as inexpensively as you can run 100."

"Think about taking a PCR-based reaction and multiplexing it," he said. "That's what the industry has been doing. You've got to go to some post-PCR device to multiplex. But those probes lack a degree of specificity inherent in gold nanoparticles."

The test takes about three hours to produce results, but Moffitt said the company is continuing to shorten that time frame.

The respiratory assay just submitted for FDA review is designed to test for all sub strains of flu, including detection of H1N1, "But we can't make that claim until FDA clears it," he said.

When asked if Nanosphere requested an expedited review of the new assay given the looming H1N1 pandemic, Moffitt said, "You can request an expedited review, but my experience is that they are treating all of them (tests for flu) as expedited reviews because of the potential for a flu pandemic."

With its commercialization of Verigene SP and the new respiratory assay, Nanosphere is doing more than introducing just another quick test – it's attempting to alter the molecular testing landscape and offer a test that rivals PCR accuracy, but at point of care.

"If you think about a central hospital-based lab today and the kinds of tests they run and the rest of services in that hospital, the systems are highly centralized. In general molecular testing has been highly centralized and it needs to be decentralized into the average community hospital," Moffitt said. "These molecular diagnostic labs are highly complex, but the market would benefit from a technology that's simple and can be decentralized."

As it stands now, a regional medical center may include a half a dozen clinics or more. Given a flu pandemic, the samples would have to be taken at clinics and then transported to the hospital labs to be run later or the next day.

"A diagnosis would have to be made in absence of that information," he said. "The Verigene system has simplicity of operation and you could put these systems in those clinics. It would move molecular diagnostics closer to patients and move infectious disease assays to point of care for more timely diagnoses."

If the FDA grants clearance, Moffitt said the company will turn to the task of gearing up production for instruments and test cartridges. He declined to provide production estimates or turnaround if the world faced an H1N1 crisis.

"It would be a reasonably short time frame, adding staff and shifts of labor for production processes," he said.

Verigene SP is priced at \$20,000 and sample processing modules can be purchased individually. After being on the market for just two years in the U.S., Moffitt said no units have required replacement and he estimated the machines would last for "years."

Individual flu tests would cost between \$30 and \$70. ■