

How one company is helping detect infections like norovirus

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No one wants to eat something and get sick. But foodborne illnesses, like the cases linked to Chipotle restaurants, can easily land you in the doctor's office.

Once you're there, the Verigene System, a molecular <u>diagnostic testing</u> platform developed by Chicago-area medical device company Nanosphere, helps clinicians quickly identify what ails you.

"Norovirus spreads quickly, like wildfire," said Scott Powell, marketing manager of Nanosphere. "The quicker you can identify a person with it, the quicker you can put them in isolation and away from other people so it doesn't spread."

Where laboratories would take days or weeks to get results, Verigene can identify infectious diseases in about two hours, Powell said. The system can be used to detect gastrointestinal infections like E. coli and norovirus, as well as bloodstream and respiratory infections.

"This whole syndromic approach to diagnostic testing in general is an advance for the laboratory," said Gary Procop, infectious disease pathologist and microbiologist at the Cleveland Clinic. "Rather than relying on the doctor to have to figure out what they want to test first, and if that's negative, trying something next, you basically are looking at all the most likely suspects right up front."

Although norovirus is one of the most common causes of gastrointestinal



infection, until a few years ago, there were no FDA-approved tests for norovirus detection, Powell said.

"For bacteria, you use a culture and let a sample grow," Powell said. "You put it on a selective media with nutrients to let that specific organism grow. With norovirus, it's much harder, and there's not really a culture-based technique that they could do at most hospitals."

Although norovirus often resolves itself after a few days for people who are generally healthy, Procop said detecting it can help prevent the spread of the virus to others whose immune systems may be compromised.

With Verigene, the technician loads a sample, and the system analyzes the DNA or RNA that is in the sample on the molecular level instead of waiting for a culture to grow.

"Molecular tests are inherently more specific and sensitive than culturebased tests," Powell said. "No test is ever perfect, but this is an improvement from what they were doing."

Nanosphere's norovirus-specific test came out in 2014, and there are only two other FDA-approved companies that produce similar systems, Powell said. Each Verigene component - the reader and the processor costs about \$20,000, and Procop said the systems are often more expensive than traditional testing.

Amanda Harrington, director of Clinical Microbiology Service at the University of Illinois at Chicago, said despite the price tag, the process has been more streamlined since they got the machines in December.

"I think this is where laboratory medicine is moving," Harrington said. "It's about getting people the information in a timely manner. The



demand for that is increasing as these tests become more available."

Earlier this month, Nanosphere reported preliminary fourth-quarter revenue of \$6.8 million, compared to \$4.6 million in the fourth quarter of 2014. Preliminary full-year revenue was \$21 million; in 2014 it was \$14.3 million. In 2014, the company lost \$39 million, or \$0.47 cents per share.

Nanosphere reported 35 new customers in the fourth quarter of 2015.

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