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## In Pilot Project, FDA Places MiSeqs in State and Federal Labs to Track Food-Borne Pathogens

by Monica Heger

**THE US FOOD AND DRUG ADMINISTRATION** is beginning a pilot project that will bring the Illumina MiSeq system into state and federal regional microbiology laboratories to test whether the technology makes sense for tracking food-borne pathogens and outbreaks.

As part of the project, the FDA has awarded Illumina a five-year contract to supply the agency with instruments and reagents, as well as to provide training and support.

As a first step, the FDA plans to install around four MiSeq instruments in different state laboratories across the country, and between four and 10 in its own regional field labs.

“What we’re doing is evaluating the technology and how it might work in a microbiology lab,” Steve Musser, the director of the office of regulatory science at the FDA’s Center for Food Safety and Applied Nutrition, told *In Sequence*.

Musser declined to disclose the details of the contract bidding process and whether other companies applied. He said the FDA is currently evaluating all the major platforms, including those from Illumina, Pacific Biosciences, Life Technologies’ Ion Torrent, and Roche’s 454.

“We have all the platforms and we’re testing them and actively working with them,” he said. “But Illumina won

this particular contract.”

The contract essentially sets a price for instruments, reagents, and technical support over the next five years, Musser said, with a ceiling of \$17 million. Only a “small amount” of that will be spent on the initial two-year pilot.

After about two years, the FDA will evaluate the pilot to determine how effective and usable the next-gen systems are in a regulatory microbiology lab, at which point additional machines, reagents, and services could be purchased if funding allows, Musser said.

The primary use of the MiSeq systems will be for tracking the origin of food-borne pathogens and sequencing the whole genomes of pathogen isolates that the labs have been collecting over the years to help build up a database of reference pathogen genomes. Additionally, labs can use the systems alongside traditional technology for any other application, such as investigating outbreaks.

The systems will be installed in both state laboratories and federal regional field laboratories in order to test the technology in labs that are not currently using next-gen sequencers, to see how the machines work in a “typical microbiology lab, as opposed to a lab that just does next-gen sequencing,” Musser said.

Musser said that the FDA’s own lab has already used next-gen sequencing to do geo-tracing of food-borne organisms such as *Salmonella*, so the goal will be to first test the technology in this capacity.

For example, said Musser, if *Salmonella* is detected in a food item, whole-genome sequencing would be done to identify the geographical location of the strain, which would help in subsequent testing of food products to try and prevent an outbreak.

A second application, said Marc Allard, research area coordinator for genomics, will be to help build up databases of refer-

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ence genomes of pathogens.

Over the last 20 years, both state and federal laboratories have been collecting isolates of organisms from outbreaks and food inspections, he said. So another facet of the project will be to start sequencing the whole genomes of all of these isolates.

These sequences will contribute to an effort announced earlier this year called the 100K Genome Project, a five-year project involving the University of California, Davis; Agilent; and the FDA, to sequence the genomes of 100,000 food-borne pathogens such as *Salmonella*, *Listeria*, and *Escherichia coli*.

All of the data generated from this effort will be submitted to the National Center for Biotechnology Information and made freely available.

“One reason [the FDA] got into using next-gen sequencing is that [in current databases] there are only about two dozen *Salmonella* isolates,” Allard said. “That’s not enough data to build robust tests.” Building a more complete database will be a key goal of using sequencing, he said.

Finally, the MiSeq systems could be used alongside traditional technology for any other situation that may come up, such as to track an outbreak. Because whole-genome se-

quencing has not been validated for these applications, the data generated would be used to evaluate its performance relative to existing approaches.

The goal will be to see how these systems operate in traditional regulatory microbiology labs, as opposed to laboratories that use sequencing on a regular basis and to see if whole-genome sequencing could be used to provide investigational leads in regulatory labs.

“If we put [next-gen] into labs that are not currently using sequencing, can they generate good sequence and use them in high-pressure situations like an outbreak?” said Musser.

Additionally, “what are the problems, what are the benefits, what are the things that don’t work, what are the things that need to be improved?” he added. The labs will evaluate all facets of the sequencing, including performance, capacity, cost, software, and the validation of protocols.

If this initial two-year pilot project goes well, the technology could be adopted more broadly in FDA labs throughout the country, said Musser, but that will depend on a number of factors, including funding and how well these initial test sites integrate the instruments.