International Study Validates Veredus 'Lab-on-Chip' Multi-Drug Resistant TB Test

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Premium

NEW YORK (GenomeWeb) – A new assay system for multi-drug resistant Mycobacterium tuberculosis purports to address cost and versatility issues affecting currently available TB tests.

The assay, called VereMTB, was developed by Singapore-based Veredus Laboratories, and enables simultaneous detection of different mycobacterium species as well as assessment of resistance to rifampin and isoniazid, two first-line TB drugs. Resistance to these two medicines defines "multi-drug resistant" TB, or MDR TB.

Veredus is hoping to be able to offer the test for $100 or less, depending on the target customer, according to company officials.

In a study published online last week in the Journal of Clinical Microbiology, researchers at hospitals and universities in five European countries and in Tanzania collaborated to evaluate the performance of VereMTB on 91 clinical isolates harboring different resistance-conferring mutations.

They reported a diagnostic accuracy of about 98 percent compared to sequencing and another assay, GenoType MTBDRplus from Hain Lifescience.

The VereMTB test is based on a platform called VerePlex that was originally developed by Geneva-headquartered STMicroelectronics, and is now licensed to Veredus.

"We started working on this platform almost eight years ago," Daniela Cirillo, head of the emerging bacterial pathogens unit at IRCCS San Raffaele Scientific Institute in Milan and corresponding author on the JCM study, told GenomeWeb in an interview. But funding was not sufficient to push the full development of the device and the automization of the sample processing, Cirillo added.

The earliest work on VerePlex pre-dated availability of Cepheid's Xpert MTB/Rif test, which has been widely distributed in developing countries with a high TB burden.

Xpert MTB/Rif has been a boon for global health, but some have noted that the assay lacks sufficient

sensitivity to detect extra-pulmonary TB, as well as TB in children. Cepheid has said that a new assay, called TB Ultra, will have a multi-copy TB target to boost sensitivity by about 10- to 15-fold, which may ameliorate these problems. That test is expected to launch in 2016.

Another recent report highlights a potential issue with the flexibility of Xpert MTB/Rif in terms of in target selection, however.

Researchers working with Médecins Sans Frontières/Doctors Without Borders recently showed the Cepheid assay was likely to have missed about 30 percent of TB cases in Swaziland in 2009 due to occurrence of a mutation the assay was not designed to detect. This is particularly tragic because of the 80 percent HIV co-infection rate in that country and the fact that more than a quarter of the adult population there is infected with HIV.

Although the new Xpert assays are expected to have increased sensitivity, Cirillo noted that "the capacity to detect rifampin-resistant strains mutated outside the hotspot will be improved only if the specific regions are targeted by the assay."

Cepheid's cartridge for so-called extreme drug-resistant TB will test more targets than the 20 or so in the MTB/Rif and Ultra cartridges. The XDR test is currently in field trials and should be released in 2017, but modifying it to accommodate any additional mutations could delay its release, the firm has suggested previously.

The VerePlex assay, meanwhile, is a sort of hybrid between PCR and microarrays, and this enables adding or removing targets more easily.

One of the first assays developed using the system was VereFlu, during the 2009 H1N1 influenza outbreak.

The speed of test development at that time might reflect the potential for flexibility and versatility of the device, Robert Hodges, chief operating office at Veredus Labs, suggested in an email to GenomeWeb.

"Once we had the sequences we were able to design the new primers and probes in two days and had chips for testing within two weeks, so the process can be very fast if necessary," he said.

Veredus has now developed six assays using the VerePlex system. These include VereFlu, VereMERS, and the VereMTB that is the subject of the JCM study.

The firm also has an assay for simultaneous qualitative detection and identification of food-borne pathogens called VereFoodborne. Its VereThreat assay detects four viral biological threat agents in a single sample, while its VereTrop test can identify a number of tropical disease pathogens including malaria, dengue, West Nile, chikungunya, and typhoid fever.

All of these products are commercially available, and the firm has customers in Asia, the Middle East, and South America, Hodges said.

The firm is also part of a collaborative effort to develop an Ebola assay, as previously reported.

"The value of VereMTB assay is in multiplexing capability and therefore the amount of information we are able to provide in a single test," Hodges explained.

"In addition to the detection of MTB, we are able to detect nine relevant non-tuberculous Mycobacterium, and first-line drug resistance to both rifampin and isoniazid," he noted.

Verdus plans to launch the MTB assay as a CE-IVD product in the second quarter of 2016. The company has a target price of $100 for non-HBDC customers, Hodges said, depending on volumes, and the HBDC price will be announced after the product launch.

The company does not plan to pursue US Food and Drug Administration clearance for any of its current assays, but is evaluating future assays for possible FDA submission, Hodges said.

Veredus is also evaluating options to evolve the platform into a sample-to-answer system which will utilize microarray printing technology to enable a menu of highly multiplexed next-generation assays, he said.

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