



Drug-Resistant Tuberculosis Test From China's Zeesan Biotech Performs Well in Clinical Validation

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Premium

NEW YORK (GenomeWeb) –A group led by researchers from the Chinese Centers for Disease Control and Prevention has published a clinical validation of Zeesan Biotech's MeltPro TB assay for the detection of multidrug-resistant (MDR-) and extensively drug-resistant tuberculosis (XDR-TB) in patient sputum samples.

With this key validation completed, Zeesan now plans to market the test, which runs on its MeltPro system, in China, Pakistan, and Indonesia, according to Qingge Li, a professor at China's Xiamen University who works closely with Zeesan on commercial projects.

The company believes MeltPro TB "should be welcome in these neighboring countries considering [its] cost effectiveness and the similar endemic situation of drug-resistant TB," Li told GenomeWeb in an email. The test may thus add an interesting nuance to the Southeast Asia TB testing market, where some firms appear to have been struggling to some degree.

MeltPro TB uses melting curve analysis with dually labeled probes, which makes it possible to cover two fragments of more than 20 continuous nucleotides per fragment associated with drug resistance in one assay, the researchers noted in a paper describing the validation and published in [Scientific Reports](#) earlier this month.

The MeltPro system comprises an automated DNA extraction instrument and a multi-color real-time PCR analyzer equipped with automated read-out software. Interestingly, the test can also perform [spoligotyping](#) to provide epidemiologic information on strain identities. "This system not only can detect the drug-resistant status of nearly all TB drugs but it also can detect the adverse response effects found in using these drugs," Li said.

The firm validated a precursor of the test called the MeltPro TB/INH in 2014, as [previously reported](#).

In the recent evaluation of the latest version of MeltPro TB, researchers from China CDC and non-profit organizations PATH and the Bill and Melinda Gates Foundation examined smear-positive sputum from 2,057 patients in two Chinese hospitals specializing in tuberculosis: Guangzhou Chest

Hospital and Shandong Chest Hospital. They compared the MeltPro test to a reference standard of drug susceptibility testing with Becton-Dickinson's Mycobacterial Growth Indicator Tube 960.

MDR-TB is defined as resistance to at least isoniazid and rifampicin, both considered first-line treatments for the infection. XDR-TB is essentially MDR-TB plus resistance to any fluoroquinolone drug as well as the drugs kanamycin, amikacin, or capreomycin.

China contributes about one third of the global MDR cases per year, according to the [World Health Organization](#).

For first-line treatments, MeltPro TB showed a sensitivity of about 94 percent for detecting resistance to rifampicin and 85 percent for detecting resistance to isoniazid.

It also showed an 83 percent and 75 percent sensitivity for ofloxacin and amikacin resistance, both of which are considered second-line drugs. For another second-line treatment, kanamycin, the test had an overall sensitivity of 64 percent for detecting resistance, but the authors noted that this varied by site, with a sensitivity of 53 percent in Guangdong and about 82 percent in Shandong.

The MeltPro system also has the ability to detect heteroresistant TB, or co-existing drug-susceptible and resistant TB in a single sample. And, "as low as a 1 percent mutation rate can be detected, which is close to the traditional drug sensitivity testing," said Li.

Market acceptance

Tuberculosis has received a great deal of emphasis from policy makers in China, Li said, adding that the "anti-TB" network of chest, pulmonary, and infectious diseases hospitals tend to follow common protocols and guidelines.

Zeesan's test has been approved by the the Chinese Food and Drug Administration (CFDA), and once it is validated by a few hospitals it can be "easily accepted by other hospitals" in the anti-TB network, Li said.

He further noted that the product was developed with the support of the Chinese government and all the gene mutations included are based on large-scale epidemiological studies conducted in China.

Various nucleic acid-based tests have been approved by the CFDA. A test from Germany's Hain Lifescience called Genotype MTBDR is a primary competitor, Li [previously said](#).

Qiagen's QuantiFeron-TB, which detects interferon gamma release as a proxy for early detection of latent tuberculosis, was [approved](#) by the CFDA in 2013. In the first quarter of this year, Qiagen [reported](#) overall sales for the QuantiFeron-TB test grew over 25 percent and now represent about 10 percent of total sales at the company.

Cepheid's MTB/RIF test was CFDA [approved](#) in 2014, and the firm expected to ship more than 700 GeneXpert systems to China during the second quarter that year. But in a conference call recapping the firm's 2015 earnings, the systems were described as "still to a large extent sitting around," but also, "starting to get some movement" in terms of assay utilization.

Cepheid's CEO John Bishop also noted that there was new management overseeing Chinese

operations and that a second menu offering in China, a *Clostridium difficile* test, could help testing uptake. He further contrasted the situation in China with what the firm sees in India, describing China as a "one-off opportunity," and adding, "the government there was not fully ready yet to implement a program, so that's the [cause of the] delay that we've seen." He also said that the firm now expects the Chinese units are going to be used on a routine basis going forward.

Cepheid's MTB/RIF test detects non-resistant TB as well as rifampin-resistant strains. The firm previously [described](#) an upgraded MDR test, called TB Ultra, scheduled to launch early 2016, as well as [an XDR test](#).

Zeesan's marketing approach in China will now include working through the China CDC at both the city and province levels, Li said. That agency is responsible for supervising TB control in local areas, and, "Although their major work is to conduct epidemiological studies, they also recommend testing protocols and products to the local hospitals."

Zeesan also has [a growing number of tests](#) on its MeltPro system. Its HPV assay was [CE marked](#) last year, and will be [distributed](#) by QuanDx in Europe. The firm also makes multiplex tests for [alpha-](#) and [beta-thalassemia](#).

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