India's MolBio Brings Tuberculosis MDx to Point of Care With Help From FIND

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NEW YORK (GenomeWeb) – MolBio, a Goa, India-based molecular diagnostics manufacturer, is bringing tuberculosis testing closer to patients in its home country, potentially competing with imported testing. MolBio's point-of-care real-time PCR system and infectious disease assays are currently commercially available in India, and the Foundation for Innovation of New Diagnostics (FIND) is now assisting the firm with clinical trials of its TB test system prior to review by the World Health Organization for potential prequalification.

Claudia Denkinger, head of the tuberculosis program at FIND, said that the MolBio technology has a unique ability to be used closer to the patient than other systems that are currently available. FIND has been working with MolBio since 2012. "We have supported them along the way with studies and technical advice, and now we are taking it forward into the WHO process," Denkinger said in an interview.

The MolBio system, called TrueLab, is composed of two instruments and two consumables.

There is a small instrument called TruePrep which performs a 25-minute sample prep step, a fixed volume micropipette to transfer sample, and Truenat PCR consumables containing the molecular diagnostic assays. The firm currently sells Truenat assays for TB and rifampin resistance to detect active TB from sputum samples, as well as assays for hepatitis B and C viruses, HIV, chlamydia, gonorrhea, trichomonas, H1N1, dengue, chikungunya, malaria, rabies, and salmonella.

Sample is transferred from the TruePrep instrument to the consumable using the transfer pipette, and the consumable is placed in the reader element of the TrueLab system, called the TrueLab Uno Dx Real Time Micro PCR analyzer.

This instrument can perform 40-cycle real-time PCR in 35 minutes, and can detect three wavelengths of fluorescent signal, allowing for tests to be multiplexed. For multiplexed tests, MolBio currently offers combined dengue/chikungunya, and chlamydia/gonorrhea assays. The instrument also provides quantitative results, so it can be used to detect viral loads for HBV, HCV, and HIV. It has a rechargeable

battery, weighs a little over three pounds, and is 10 inches deep, seven inches wide, and about four inches tall.

Tuberculosis is highly infectious, and in India it often affects rural populations where most patients must travel to get diagnosed. "We needed a platform that could be placed at the first point of contact," said Sumit Mitra, marketing manager at MolBio.

MolBio developed the TrueLab technology with subsidiary BigTec, an instrument developer based in Bangalore, India that was funded by the Gates foundation in 2011 under the Point-of-Care Diagnostics Initiative. MolBio was officially founded in 2012, but work began back in 2000, Mitra said, supported by the government of India under the New Millenia India Technology Leadership Initiative, as well as by India's Human Council of Medical Research, and Department of Biotechnology.

Patient care in India can be separated into public and private sectors. Testing in public labs is frequently subsidized, but private labs can choose which tests to offer their customers.

In both sectors, patients themselves are often responsible for bringing their own samples to labs and transporting the results back to their physicians, which can be a challenge.

And yet, MolBio is "the only point-of-care system at this point that allows every laboratory to do real-time PCR routinely," Mitra said. The system can help labs eliminate outsourcing of TB testing, which takes about seven days and involves transportation that could impact sample viability.

"We give options to the laboratories, and say 'you don't have to outsource, we have a system that does things just as well as any of the big guys, so do it yourself ... you can give the correct treatment to the patient almost immediately,'" Mitra said. This could also prevent so-called "loss to follow-up," since asking patients to come back for results after seven days is "asking too much" in rural areas, Mitra said.

Overall, Mitra estimated that about 90 percent of the IVD market in India is made up of imports from Europe, US, Japan, and Taiwan. For TB molecular testing, the Cepheid GeneXpert has a large part of the public sector market, while firms like Roche, Abbott, and Qiagen, are also players in larger public and private labs.

MolBio saw a "tremendous opportunity because platforms that were in the market were very conventional ... central lab machines, where the hardware and consumables were capital intensive," Mitra said.

The MolBio system is unique from various perspectives. It was designed with the ASSURED criteria from WHO in mind, Mitra said. These criteria include affordability, sensitivity and specificity, user friendliness, rapidity and robustness, being relatively equipment-free, and being deliverable to end users who need it most.

The system was designed to be used at the point of care with the affordability element of the ASSURED criteria as a focus, and the cost of the system is "reasonable and competitive," Mitra said.

An estimated 60 percent of people in India get their healthcare in the private sector, where testing can be more costly. For TB testing, however, organizations like the Initiative for Promoting Affordable and Quality TB Tests (IPAQT) impact pricing by offering a public sector price on WHO-endorsed TB tests performed in certified private labs that meet WHO criteria.

Denkinger said that the MolBio system is also the first TB test system that has clinical data from what are called microscopy centers, where many patients initially present for care. "In that, it is very exciting," she said.

Now, FIND is helping MolBio gather the necessary clinical data so that the system can be reviewed by WHO, which would then also make it eligible for IPAQT use. Along with FIND, MolBio is "doing a multi-country evaluation in South Africa, India, Peru, and Uganda, toward ultimate WHO endorsement," Mitra said.

Competition

When MolBio started in 2012, Cepheid already had a six-year head start, having come into the Indian market in 2009, Mitra said.

However, "Within the last five years in the private market, not taking the public sector or government business into account, our number of installations outnumber those of Cepheid," he said, such that now the firm is "one of the few Indian companies in the market competing with the big guys."

Mitra said that MolBio currently has around 350 installations in the private sector market, compared to around 200 in that space from Cepheid. In the public sector, Cepheid has been around longer and has WHO endorsement and subsidized pricing, and has placed about 900 GeneXperts, Mitra said, numbers that are slightly higher than numbers published last year in *The Lancet Global Health* documenting GeneXpert use for HIV testing in India.

Additionally, the government of India recently purchased 350 MolBio systems and the firm will be installing 225 TrueLabs in the state of Andhra Pradesh, in Eastern India, over the next month, Mitra said.

Denkinger noted that the Cepheid Omni is certainly the next POC molecular TB test expected on the market, and it is likely to have advantages over MolBio's system in terms of being fully integrated.

However, she also said that the transfer step in the MolBio system did not pose any problems for users in operational studies, and "there was overall good feedback from operators" in the settings of intended use.

"I honestly believe that MolBio is the closest to being a Cepheid competitor of any other molecular device company currently working on TB," Denkinger said. "What I'm particularly excited about is they are from India and they are producing a diagnostic that serves a need in a high-burden country."

Indeed, local manufacturing may reduce costs, perhaps explaining why firms like Cepheid and Co-Diagnostics have recently setting up manufacturing facilities in India.

The MolBio system has been evaluated in two published studies performed in collaboration with the company. One evaluated the performance, and found specificity and sensitivity of 91 percent and 100 percent, respectively, compared to an in-house nested PCR assay. Another compared the assay to the Cepheid GeneXpert, showing high concordance.

Denkinger also noted that FIND conducted an evaluation in 10 microscopy centers all over India, and that the Indian Center for Medical Research did an evaluation in 100 microscopy centers. "Overall, there was very positive feedback from users on the acceptability of the device and the process, to make it a useful instrument in the point of care," she said.

Mitra said MolBio does not see Cepheid or the other "big guys" as competition. "We see them to be good friends in the industry. They've done a lot of good work, so we have been selling on our merits rather than their demerits," he said. "They are all good systems, but we sell because we can show clients the value proposition" of point-of-care, he added.

Furthermore, "The fact that companies like Cepheid, or Roche with the Liat system, are thinking of bringing [testing] nearer to the patient, tells you that our initial decision to have a platform at the point of care was spot on," Mitra said. He noted that he is aware of POC platforms in the real-time PCR domain in

development in Korea, Taiwan, and Europe. "These systems will come, and it is better for the market because customers get to choose," he said.

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