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"Truenat diagnostic tests will be available for 30 more diseases in next 2 years"

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Established in 2000, Molbio Diagnostics is working aggressively to strengthen its presence in the molecular diagnostics space in India. The company has recently opened a new manufacturing unit for its innovative molecular diagnostic platform - Truenat Real-Time PCR, spread across 1,35,000 sq ft, in Verna, Goa, in the backdrop of increasing demand for point-of-care molecular testing, in India and across the world. Sriram Natarajan, Director & Chief Executive Officer, Molbio Diagnostics, Goa spoke to BioSpectrum in detail about the company's growth plans and new launches in-store. Edited excerpts;

How is the Truenat Real-Time PCR making a difference in diagnosing infectious diseases such as tuberculosis (TB) and dengue?

Truenat MTB is the only World Health Organisation (WHO) and Indian Council of Medical Research, (ICMR) approved point-of-care platform for Tuberculosis (TB) detection recommended as a replacement to smear microscopy. It has been adopted by the Indian National Tuberculosis Elimination Programme (NTEP) as a frontline tool for the diagnosis of TB and Rifampicin resistance. The Government of India has already deployed over 1,760 Truenat machines at a sub-district level across all states and Union Territories and its introduction by the National Programme is already showing a huge impact by a significantly increased rate of case detection. Global rollout of Truenat for TB has also begun through various international agencies including United Nations, Global Funds, Global Drug Facility, and the United States Agency for International Development (USAID) etc. On the other hand, Truenat Dengue is being used by the state governments and the private sector effectively for early and timely diagnosis of dengue. A study in Sri Lanka has shown the superiority of Truenat Dengue over NS1 antigen ELISA in early and accurate diagnosis of the infection.

How can your molecular diagnostics platform make an impact on India's overburdened healthcare system?

With a turnaround time of one hour from sample to result, Truenat ensures early and accurate diagnosis and appropriate

initiation of treatment on the same day of presentation. This not only helps in better patient outcomes but also prevents the further spread of the disease. The portable, battery-operated, rugged machines, the ready to use room temperature stable reagents and the fully automated protocols ensures that testing can be done by minimally trained technicians. The in-built data transfer capability further enables remote interventions and remote monitoring. Truenat tests are priced very affordably and cost much lower than conventional reagents. However, the overall cost-benefit of the early point of care diagnosis and the resulting impact on reduced morbidity and mortality, improved disease management and consequently reduced burden on the health care system far outweighs the cost of testing.

What is so unique about the technology used in the molecular diagnostics platform?

Understanding the limitations of conventional molecular platforms, Molbio Diagnostics and its R&D subsidiary Bigtec Labs had to completely re-engineer the conventional Real-Time PCR technology into a point of care solution. It was done through leveraging on technologies such as Micro Electro Mechanical Systems (MEMS), micro and meso fluidic cartridges, nanotechnology, low power thermal cycling using disposable intelligent ceramic chips, lyophilisation and other drying techniques and special sealing techniques. The platform was made rugged by minimising moving parts, miniaturised to occupy little floor space, enabled for portability and battery operation, with onboard memory, touchscreen interface and wireless data transfer capability. The reagents were designed for single testing capability, ready to use and stable at room temperature (up to 30°C) for two years and the intelligent chip carries a lot of information and standard curve values for generating quantitative results. The intelligent chip also ensures that wrong chips, previously run chips and expired chips are not run again. The system requires no special environmental conditions, no specific maintenance or calibration requirements has inbuilt diagnostic features and error reporting features.

Are you planning to launch more diagnostic tests for other infectious diseases, following the opening of your new facility?

Truenat tests for over 30 infectious diseases are already available on the Truenat platform, while tests for another 30 new diseases are in development, expected to be launched over the next two years. A range of open format reagents by the name Truemix are also planned, again in ready- to-use, room temperature stable format.

The new facility of Molbio was conceptualised due to the increasing demand for point of care testing in India, partially driven by COVID-19 and partially by the growing awareness of the importance and efficacy of this model for other diseases like TB, Dengue etc.

This new facility will be used to increase the manufacturing capacity of existing and upcoming Truenat kits and reagents in addition to the Truemix range. The manufacturing capacity has been increased 5-fold, from the existing 80,000 tests per day to 3.5 lakh tests per day. Over 700 employees are currently working in Molbio Diagnostics and Bigtec Labs.

What are your plans for the next five years both for the domestic and the global market?

Truenat is already being viewed as a multi-disease platform and in addition to the TB programme, we expect other programmes such as the Viral Hepatitis programme, National AIDS Control Organisation (NACO) and vector-borne diseases programme to add to the wider deployment and usage of the technology at the grass-root level. The Indian private sector is also able to use the Truenat platform for delivering high-quality diagnostics for the full range of tests available.

There is also a much larger and growing global demand for high quality molecular diagnostic tools that can be specially deployed at the point of care. We expect to establish ourselves as a major player in the global molecular diagnostics market in the coming years. At the same time, we are also working on other ‘point of care’ technologies for providing better solutions for Antimicrobial resistance (AMR) and non-infectious disease testing applications.

How do you view the evolution and growth of the molecular diagnostics market in India?

Molecular diagnostics was an underserved segment in the Indian scenario for a very long time despite being regarded as the most reliable for infectious diseases testing, especially Real-Time PCR that was invented several decades ago and is

considered the gold standard for diagnosing many diseases. The primary reason for this was due to the highly centralised nature of molecular diagnostic platforms owing to a high level of infrastructure and skill dependence, high capex and opex costs, the need for batch testing, logistics issues of sample transportation and the consequent long turnaround time for results. Delayed diagnosis denies access to appropriate and timely medical aid resulting in deterioration of patient health, thus increasing the risk of complications and mortality. Their usage was also limited to confirmatory testing which was available at only a few centralised laboratories and hospitals in major Indian cities. The outbreak of COVID-19 dramatically increased the need for RT PCR tests that have resulted in the market size suddenly growing many folds.

With the growing awareness, the demand for early diagnosis of infectious diseases is high, and various public and private organisations are investing funds to accelerate R&D in the field of molecular diagnostics. Recently, the infectious disease application segment accounted for the largest market share and will grow in the coming years.

The increasing prevalence of infectious diseases such as tuberculosis, hepatitis B, and hepatitis C, coupled with tests for sexually transmitted diseases/infections like HIV and HPV will propel the segment's growth. Molecular testing is expected to become more of a routine clinical diagnostics tool not only for COVID-19 but for a wide range of infectious diseases in the near future.

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