

“We plan to manufacture one million tests of VANSCAN Typhoid RT PCR test in our first year in India”

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Indian firm Vanguard Diagnostics recently launched the VANSCAN Typhoid RT PCR Test, which is India's first Typhoid RT PCR test based on patented technology. With typhoid fever being common in developing countries, India is an endemic country for typhoid with a burden of approximately 4.8 million cases per year. Veena Kohli, Chief Executive Officer, Vanguard Diagnostics spoke, at length, with BioSpectrum about the growing cases of typhoid in the country and how the new diagnostic solution can solve this problem.

Please share some details about the global Typhoid Diagnostics market. Where does India stand in terms of disease cases, diagnostic tests R&D and manufacturing, when compared to other countries?

Typhoid fever is prevalent in tropical regions such as India, China, Bangladesh, Nepal, Vietnam, and Africa. These countries report more than 75 per cent of typhoid cases around the world. During the year 2019, 9.2 million cases of typhoid fever and 110,000 deaths were reported worldwide with the highest incidence in South East Asia, Eastern Mediterranean and African regions. More than half the deaths were in children under 15 years of age. On average, 12.5 million people are infected with the infection every year. The key limitations to ascertaining the true burden of this disease are the lack of reliable diagnostic tests, systematic surveillance in most countries and masking of the infection by the widespread use of antibiotics.

Although typhoid can prove to be a fatal infection yet there has been negligible focus on the development of reliable diagnostics tests for its detection. The infection is rare in the developed regions of the world, and thus typhoid has never been featured as a disease of focus for these countries.

The conventional WIDAL test was developed by a French physician 125 years ago and it continues to be deployed as one of the most commonly used tests for the detection of typhoid fever. But the results obtained with the WIDAL test are largely unstandardised and inconclusive.

Then there are rapid card tests that were introduced in the early 2000s and they detect the presence of IgM and /or IgG antibodies to *Salmonella typhi*, a causal organism for typhoid. These antibodies take 10 to 14 days to become detectable in the blood. Both these tests have been widely reported to suffer from the limitations of poor sensitivity and specificity. The current gold standard for typhoid detection is the blood culture test, however, it is cumbersome and time-consuming. Additionally, the results of a blood culture test can be affected by the intake of antibiotics.

Despite these limitations in the diagnosis of typhoid, there has been negligible focus on the development or manufacturing of novel tests for its detection either in India or any other part of the world. Early and accurate diagnosis of typhoid fever is imperative to initiate treatment by administering the right antibiotics and reducing the risk of Antimicrobial Resistance (AMR).

So, Vanguard Diagnostics has recently developed the first RT PCR Test for typhoid detection based on a patented technology – VANSCAN Typhoid RT PCR Test, in collaboration with Graphic Era University, Dehradun.

How did the idea of VANSCAN Typhoid RT PCR test development germinate, in collaboration with Graphic Era University? Please share more details about its technology.

During the month of June 2020, Vanguard Diagnostics tied up with the Defence Research & Development Organisation (DRDO), under the Department of Defence Research and Development in the Ministry of Defence of the Government of India, for the development of an IgG antibody test for COVID -19 using an ELISA format. During our interactions with the team, we had the opportunity to meet two scientists from Graphic Era University, Dehradun who had worked with DRDO in the past. They happened to share with us about their patented technology for the detection of *Salmonella typhi* and paratyphi – and there was therefore an instant connection and a perfect match with them.

Soon thereafter we signed an agreement with the Graphic Era University and began pursuing our dream of launching a novel test for the early and reliable detection of typhoid fever. The R&D team at Vanguard Diagnostics successfully transformed this patented technology into a marketable product.

VANSCAN Typhoid RT PCR Test is a nucleic acid diagnostic assay for the detection of *Salmonella typhi* and paratyphi based on a patented technology. It uses DNA isolated from the whole blood of infected humans and works on the principle of nucleic acid amplification through Real-Time Polymerase Chain Reaction (RT PCR). It uses a specific set of primers targeting a signature DNA, and its detection by a specific probe. It can be used with any open RT PCR system.

During a multicentric study conducted at three sites, the VANSCAN Typhoid RT PCR Test was found to have 100 per cent sensitivity and specificity.

The teams at Vanguard Diagnostics and Graphic Era University utilised their complementary skill sets to deliver a noteworthy example of industry – academia collaboration in an area that had a far-reaching unmet need in the diagnostics space.

What are the production and marketing plans for this product in 2023 and later?

Production of the VANSCAN Typhoid RT PCR Test will be one of our top priorities this year. We have taken an internal target of manufacturing one million tests. We would want this test to reach as many people as possible given that it could potentially play a crucial role in the accurate diagnosis of typhoid and in slowing down the emerging threat from AMR in India.

Marketing efforts will be channelised towards generating awareness about the benefits of early and reliable diagnosis of typhoid fever with a focus on Tier 1 and Tier 2 cities and towns in equal measure, in order to ensure equitable access to the test across the nation.

After fulfilling the domestic requirements, we plan to export the test to other regions such as South East Asia, where typhoid is endemic.

What new launches are in the pipeline this year and next? Are you exploring new partnerships, investments?

2023 is shaping up to be quite an exciting year for us with a lot currently in the works. We are looking to move more into the instrumentation market with some potential opportunities in that sphere. We at Vanguard believe that technology is the future, so we are also working on a project that explores how technology and digitisation can be harnessed for the diagnostics industry.

What are the current challenges facing the growth of the Indian diagnostic industry? What is the way forward?

The IVD industry has been suffering on account of no official access to positive and negative clinical samples from path labs and hospitals. The industry requires access to such samples for the preparation of in-house QC panels for testing manufactured products and in R&D projects for the development of new products. The international QC panels supplied by just a handful of global companies, are exorbitantly expensive and not affordable by the Indian IVD manufacturers, a majority of whom are SMEs.

Government bodies like NIPER, academic and research institutes such as the IITs, AIIMS, CCMB, ICGEB have a treasure trove of technologies which when utilised by the industry could drive innovation through industry-academia collaborations. The COVID-19 pandemic did provide a lot of opportunities for such tie-ups and showed evidence of how they can be successful.

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