

Cepheid to establish manufacturing footprint for Xpert MTB/RIF tests in India

13 July 2018 | News

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US-based leading molecular diagnostics company, Cepheid Inc. (a wholly owned subsidiary of Danaher) unveiled its newest configuration in the GeneXpert® family of systems, the GeneXpert® Edge, in the country today. The company also announced its 'Make in India' initiative by announcing plans to establish their manufacturing footprint in the country for Xpert® MTB/RIF test cartridges which run on the GeneXpert® System. More than 1,200 Cepheid's GeneXpert Systems have been installed in the last 2 years at various Revised National Tuberculosis Control Program (RNTCP) sites in the country and more than 2.5 million cartridges were supplied last year at various centres of Central TB Division (CTD). The GeneXpert® Edge is expected to be available in India later this year.

The GeneXpert® Edge is a portable, easy-to-use system, developed specifically for near-patient testing, to help support a one visit test-and-treat approach. With almost 17,000 systems in 182 countries, the GeneXpert System is the world's most popular molecular diagnostics system. Its modular configuration makes it the most scalable platform available, delivering the ability to process from one to eighty tests simultaneously — enabling accurate, fast, and cost-effective test results in both lower volume point-of-care settings and higher volume reference laboratories.

Unveiling the GeneXpert Edge, Mr. Peter Farrell, Executive Vice President, Worldwide Commercial Operations, Cepheid said, "The published data point out that Tuberculosis leads to over 400,000 deaths in India every year due to delayed diagnosis and inadequate treatment and there are above 2.5 million new cases of TB every year. Cepheid recognises the need for technological advancement and is committed to contributing significantly to India's goal of TB eradication. Our 'Make in India' plans are a testimony to our commitment towards supporting the Indian Government's vision of TB eradication by 2025. With this announcement, we aim to establish a manufacturing footprint for Xpert® MTB/RIF test cartridges, thus bringing our global expertise in TB diagnostics to India. Today, we also unveil our latest system innovation, the GeneXpert Edge, which further demonstrates our resolve to participate in India's fight against TB. We are hopeful that this portable, easy-to-use testing system will help eliminate delays in TB diagnostics by providing definitive results within hours and facilitating fast and easy last-mile delivery even in the remote villages of India."

Mr. Jai Shankar Krishnan, President and CEO, India and Southeast Asia, Danaher said, "Cepheid brings cutting-edge technology and innovation to the molecular diagnostics platform. The launch of the GeneXpert® Edge underscores our commitment to localization and to the eradication of TB in our country. Today Danaher has a strong manufacturing footprint in India. Cepheid's "Make in India" initiative reflects our continued desire to invest and address local market needs. I am delighted to reinforce Danaher's and Cepheid's commitment to India."

Cepheid's Xpert MTB/RIF test can simultaneously detect tuberculosis (MTB) and rifampicin-resistance mutations, which are markers for MDR-TB strains in under two hours. Xpert MTB/RIF tests have excellent negative predictive value, which allows clinicians to manage TB-negative patients more effectively to prevent unnecessary and costly respiratory isolations. With unprecedented sensitivity for detecting MTB, even in smear negative, culture positive specimens Xpert MTB/RIF provides on-demand results enabling physicians to treat their patients rapidly and effectively.

Another version of Cepheid's test cartridges - Xpert® MTB/RIF Ultra - raises the standard for TB diagnosis by producing test results in less than 80 minutes. It ensures fast active-case finding in HIV-positive patients. It leads to a lower number of culture confirmations due to the high negative predictive value. Xpert® MTB/RIF Ultra has enhanced sensitivity over smear microscopy of MTB-complex in pulmonary samples. The test is CE-IVD approved and is currently in the process of being registered with the regulatory authorities in India. Cepheid's GeneXpert system can run 27 CE-IVD approved tests, including tests addressing the global epidemics, HIV and HCV, on the same platform.

Cepheid has been an active participant in the global fight against TB and is bolstering that commitment by being a part of the 'Make in India' initiative. Cepheid is committed to enhancing its presence in India by localising many of its functions, and bringing products customised to the needs of the Indian market. It works closely with the key departments of the government like the Central TB Division, and important stakeholders like the World Health Organization, The Union, FIND, CHAI, stakeholders from private sector and corporations to bring best-in-class products and solutions to India.