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# Game Changing Tuberculosis Assay Validated for Illumina's MiSeq® Platform

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**Longhorn Vaccines and Diagnostics LLC →**

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*Next Generation Sequencing (NGS) Kit to Improve Speed and Accuracy of M. Tuberculosis (MTB) Drug Sensitivity Testing (DST) at a Fraction of the Current Cost of Sequencing*

BETHESDA, Md., Sept. 24, 2018 /PRNewswire/ -- Longhorn Vaccines and Diagnostics LLC (LHNVD), a private pre-analytical systems and molecular solutions company, is pleased to announce the validation of its newest technology, PrimeSeqMDR™, across a wide range of well characterized clinical strains of MTB from the Ukraine and South Africa. PrimeSeqMDR™ is a proprietary reagent set that allows users to conduct targeted gene sequencing for up to five genes per sample in less than 24 hours. The development of PrimeSeqMDR™ was made possible by LHNVD's revolutionary FDA cleared sample collection system, PrimeStore® Molecular Transport Medium (PS-MTM), which allows biological samples to be shipped and processed without need for special containment.

As the United Nations opens a high level meeting this week to seek an urgent global response to end TB, embracing new molecular diagnostic and sequencing products and technologies will be crucial. With more than 10 million people falling sick with TB globally every year and more than four million of these being missed (StopTB Partnership), every aspect from sample collection to diagnosis, drug sensitivity analysis to treatment regimens, needs to be optimized and supported if the world is truly to end the MTB epidemic by 2030.

Pyrazinamide (PZA) is an important component of current, and newly embraced drug regimens for multi-drug resistant tuberculosis (MDR-TB). PZA resistance can occur at multiple points along the *pncA* gene. MTB can be resistant to PZA alone or resistant to PZA and other standard MTB drugs. Direct testing of PZA sensitivity is therefore crucial however it is very difficult to impossible by most methods other than gene sequencing. The *pncA* gene target is the cornerstone of the PrimeSeqMDR™ kit. The additional gene targets can/will be selected based on current and future drug regimens. Regionally specific kits can also be manufactured to target circulating strains of concern in different parts of the world.

PrimeSeqMDR™ has been developed and optimized from samples transported in PS-MTM, the first FDA cleared sample collection, transport, and storage device for samples suspected of containing MTB. Direct clinical specimens, as well as samples from culture, can be transported in PS-MTM at ambient temperature to a laboratory with an Illumina MiSeq® for rapid analysis and since PS-MTM inactivates/kills microbes, special handling or containment procedures are not required. Facilities with containment and special handling capabilities can use PrimeSeqMDR™ with samples that are not transported in PS-MTM.

LHNVD is in the process of establishing distribution and manufacturing for PrimeSeqMDR™, PS-MTM, and its other MTB products in large MTB endemic countries and regions.

**About PrimeSeqMDR™**

PrimeSeqMDR™ is a targeted gene sequencing (TGS) kit developed for the Illumina MiSeq® Next Generation Sequencing system to determine *M. tuberculosis* drug sensitivity from clinical and cultured specimens. It is optimized to reduce time and cost and is most effective when used with the PrimeStore® MTM collection and transport device and the highly sensitive, open platform PrimeMix® TB qPCR reagent set.

**About PrimeStore® MTM**

PS-MTM is FDA cleared and intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza A virus RNA. PS-MTM is also intended for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing *M. tuberculosis* DNA from human samples.

Peer reviewed journal articles, abstracts, posters, and vaccine development clinical trials have demonstrated PS-MTM's ability to generate highly sensitive results with multiple pathogens and sample types on several Real-Time PCR platforms to include Roche's LightCycler and Thermo Fisher's ABI 7500, as well as next generation sequencers including Thermo Fisher's Ion Torrent and Illumina's MiSeq®. PS-MTM has been demonstrated to be compatible with manual and high-throughput extractions systems from LHNVD, Qiagen, Thermo Fisher, bioMérieux, and Roche. Published studies have shown it to be compatible with Cepheid's GeneXpert MTB/RIF test using a fraction of the sputum necessary for the standard workflow.

**About LHNVD**

Longhorn Vaccines and Diagnostics is a closely-held, veterans' owned, Limited Liability Company headquartered in Bethesda, MD with laboratories in San Antonio, TX and Gaithersburg, MD. LHNVD diagnostic division develops technologies to optimize molecular testing in the developed and developing world.

[www.lhnvd.com](http://www.lhnvd.com)

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