

PrimeStore® MTM opens Sputum-free Molecular Screening for M. tuberculosis Infection

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South Africa pilot study demonstrates new broad approach to identifying M. tuberculosis infected patients for further clinical investigation and treatment

BETHESDA, Md., April 23, 2019 /PRNewswire/ -- The results of a pilot study using Longhorn Vaccines and Diagnostics's patented sample collection technology, PrimeStore® MTM, were presented at the 29th European Congress of Clinical Microbiology & Infectious Diseases in Amsterdam, Netherlands, by Professor Bernard Fourie PhD of the University of Pretoria, South Africa.



PrimeStore MTM

Healthcare workers sampled household members living in a high burden TB/HIV area of South Africa. Oral salivary specimens were collected using a flocked swab from adults with cough and one or more risk factors for TB, including previous TB, or asymptomatic individuals residing in a home with someone diagnosed with TB. The swabs were immediately placed into a tube of PrimeStore® MTM for microbial inactivation and DNA stabilization and transported to a nearby lab at ambient temperature for qPCR analysis. This approach detected *M. tuberculosis* (MTB) DNA in about one third of persons that otherwise would not be detected by currently used first-line methods. Individuals that tested positive for MTB were referred to clinics so that they could go through the current standard protocol for testing and treatment. Larger studies are underway to further evaluate the effect that oral screening using PrimeStore® MTM and qPCR can have on the goal to eliminate MTB as a global disease threat.

The role of PrimeStore® MTM is crucial to ensuring the MTB DNA is completely released and undamaged prior to qPCR. Similar results were seen in a study of asymptomatic family members of influenza patients using PrimeStore® MTM and qPCR. PrimeStore® MTM is the only FDA cleared product for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing *Mycobacterium tuberculosis* DNA and the stabilization, transportation and inactivation of infectious unprocessed nasal washes and nasal oral/nasopharyngeal swabs suspected of containing Influenza A virus RNA for molecular testing.

As many individuals potentially infected with MTB struggle to produce any or enough sputum for current molecular testing, the World Health Organization has prioritized non-sputum approaches for new rapid tests. Screening by qPCR from oral swabs transported by PrimeStore® MTM would provide a mechanism to conduct routine testing of large populations likely to be exposed to MTB, such as prisoners, miners, and individuals in high density living conditions.

The qPCR process is well suited for high volume screening. Many key manufacturers sell high volume automated machines that can test hundreds of samples per day. Major diagnostic companies such as Abbott Laboratories, Roche Diagnostics, and ThermoFisher have a significant amount of equipment capacity already in place in high MTB burden countries and are actively adding newer, faster, and higher volume equipment. Each of these manufacturers has or are developing their own TB tests, and there are many open platform tests such as PrimeMix® TB that can be run a wide range of existing qPCR machines. PrimeStore® MTM allows samples to be shipped safely to laboratories that can perform qPCR.

About PrimeStore® MTM

PrimeStore® MTM is FDA cleared for the stabilization, transportation and inactivation of infectious unprocessed nasal washes and nasal oral/nasopharyngeal swabs suspected of containing Influenza A virus RNA and for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing *Mycobacterium tuberculosis* DNA from human samples.

Peer reviewed journal articles, abstracts, posters, and vaccine development clinical trials have demonstrated PrimeStore® 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. PrimeStore® MTM has been demonstrated to be compatible with manual and high-throughput extractions systems including those from LHNVD, Qiagen, Thermo Fisher, bioMeriue, 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. The company is a commercial stage diagnostic company and a preclinical stage vaccine and antibody company focused on Universal Influenza and *M. tuberculosis*.

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