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Longhorn Vaccines & Diagnostics LLC Receives FDA Emergency Use Authorization (EUA) for the First 2009 H1N1 Influenza Assay to Include a Molecular Transport Medium (MTM)

Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay(TM) is the First Collection-to-Detection Assay for the 2009 H1N1 influenza virus.

SAN ANTONIO, Feb. 22 /PRNewswire/ -- Longhorn Vaccines & Diagnostics today announced it has been granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay™ in CLIA high complexity laboratories. . The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay™ is a ready-use assay that requires no mixing prior to use and has been authorized for use on the ABI 7500. The device includes PrimeStore MTM, a clinical collection and transport solution that preserves the released nucleic acids, including labile RNA for testing and contains an internal positive control, providing the first specimen collection solution to contain an internal RNA control capable of tracking the degradation of the sample from the point of collection.

"Sample integrity, and the ease and economy of transporting collected samples are key components to testing during outbreaks," said Gerald Fischer, MD, Longhorn Vaccines & Diagnostics' Chief Executive Officer. "An infectious disease physician and a molecular biologist designed The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay™ to generate rapid, high quality PCR results, in as little as two hours while improving safety, and reducing laboratory preparation time."

2009 H1N1 is a new influenza virus that was detected in the United States in April 2009. As such, children and younger adults are less likely than older people to have immunity to this virus, and illness may be more severe and widespread as a result (1). In June 2009, the World Health Organization (WHO) announced that the spread of the novel 2009 H1N1 virus had reached pandemic phase 6, the highest level of pandemic alert designated by the organization (2).

"Influenza-like-illness puts a significant strain on Emergency Departments during the standard Influenza season. The atypical epidemiology of H1N1-09 has magnified the impact on healthcare systems around the world. The principal morbidity and mortality of H1N1-09 was in young, previously healthy patients who accessed the system in large numbers. We were quite fortunate this time around that it came early, during relatively mild weather. Having access to reliable, rapid testing will significantly improve the quality and timeliness of care we can provide -- in both hospital/ED, and community health settings," stated international health expert, R. Scott Altman MD, MPH, MBA, FACEP, Assistant Professor of Clinical Emergency Medicine at the Northwestern University Feinberg School of Medicine.

Longhorn Vaccines and Diagnostics will continue the development of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay™ and expects to submit a separate 510(k) in 2010.

About the FDA's Emergency Use Authorization

The US Secretary of Health and Human Services has declared a public health emergency because of the outbreak of the pandemic flu virus. The FDA has issued emergency use authorizations to make diagnostic and therapeutic tools available to public health and medical personnel for use in the diagnosis of 2009 H1N1 influenza virus under certain circumstances.

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. The emergency use authorization authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved and uncleared medical products following a determination and declaration of emergency, provided certain criteria are met. The FDA can only grant emergency use authorization for the duration of the emergency, which is currently set to expire on April 26, 2010, unless it is terminated sooner or renewed. The FDA may also revoke an EUA prior to the termination of the emergency.

About Longhorn Vaccines & Diagnostics

Longhorn Vaccines & Diagnostics is a private a biotech company located in San Antonio, TX that develops, and commercializes platform neutral RRT-PCR assays and develops vaccines for infectious diseases.

While initially focused on influenza diagnostics, Longhorn Vaccines & Diagnostics is working to develop PrimeMix assays for malaria, tuberculosis, dengue, and adenovirus. The company's proprietary molecular transport medium allows researchers to collect specimens from around the world and safely ship them to laboratories without expensive and cumbersome cold chain packaging including dry ice. The PrimeStore MTM will facilitate standard sequencing and meta-genomic analysis of samples by improving the quality of the microbial nucleic acids in the collected specimens when they finally arrive in the laboratory.

Longhorn Vaccines & Diagnostics is developing a proprietary universal influenza vaccine. This vaccine is designed to provide broad protection against influenza viruses. Its unique properties may make it easier, quicker, and less expensive to manufacture compared with standard influenza vaccines

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References

(1) CDC: Facts About Novel H1N1 Influenza; May 2009

(2)
http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html
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