




DIATHERIX Laboratories, Inc

*DIAGNOSTIC INNOVATION  
CHANGING HEALTHCARE*

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# Michigan Homeland Security Conference

Bio-Preparedness, Pandemic  
Response, Military Application and  
Healthcare Solutions in Infectious  
Disease Identification through  
Molecular Multiplex Differential  
Detection Technology (Tem-PCR)



# Target Enriched Multiplex PCR (Tem-PCR)

- Tem-PCR is a breakthrough molecular multiplex technology provided by Diatherix Laboratories Inc.
- Tem-PCR allows for true multiplexing for viral, bacterial and fungal pathogens
- Tem-PCR testing identifies multiple pathogens in a single sample
- Tem-PCR allows for Molecular Differential Diagnostics or MDD
- Tem-PCR has a low false positive rate and almost no cross reactivity
- Tem-PCR testing provides a result for multiple pathogens both viral and bacterial in 4-5 hours from sample receipt to patient result
- Tem-PCR not only identifies pathogens, but also identifies genetic drug resistance



# Bio-Preparedness

- Early response capability to a Biological Outbreak in a mobile unit
- Technology that is capable of detecting 25 pathogens simultaneously in 1-2 hours from a single sample
- Ability to detect infectious agents through BSL-4
- Ease of use molecular multiplex technology automated system that can be performed by properly trained personnel



# Pandemic Response

- **Accurate Early detection of Pandemic Influenza is required to control spread of the virus**
- **Detection of actual strain of the pandemic virus (H5N1, H1N1-09) is vital for containment, triage and proper treatment**
- **Ability to detect the pandemic strain of the virus and co-infection simultaneously is important for proper treatment and reducing mortality**
- **Accurate diagnosis can ease public concern and potential panic**



# Military Application

- Detection of multiple infectious agents in regions associated with military action can prepare troops with preventive measures
- Prior to deployment knowing the infectious agents endemic to the area can help in maintaining troop health in the field
- Ability to detect infectious agents from multiple environmental sample types
- A technology that is not temperature dependent is vital for military application
- Rapid technologies do not provide the sensitivity or specificity required for accuracy of detection



# Healthcare Solutions

- Identifies Pathogens in the presence of antibiotics
- Differentiates between viral and bacterial infection and co-infection
- Provides results in 24hrs or less that can change empiric treatment
- Assists in confirmation of complex pneumonias
- Assists in the de-escalation of drug therapy through fast and accurate pathogen identification
- Faster identification of pathogens links to proper initial antimicrobial therapy
- Identifies up to 25 pathogens in a single test including genetic drug resistance
- Tem-PCR provides test results at a minimum two days faster than culture reducing LOS



# History of Tem-PCR

- Dr. Jian Han developed Tem-PCR during the SARS outbreak in 2003 and received Chinese SDA approval
- Fast and accurate diagnosis using the Tem-PCR technology assisted health officials in Asia to identify SARS during the outbreak
- Since 2003 the technology has been expanded to identify multiple pathogens including virus, bacteria, fungus and bacterial genetic drug resistance
- Tem-PCR was used to identify the bird flu (H5N1) in Asia in partnership with the Chinese CDC resulting in a publication in 2007
- Tem-PCR testing is performed on panels developed to test for a group of pathogens that may give a patient similar symptoms.
- The Staphylococcus Panel differentiates subtypes of Staphylococcus including MRSA, genetic drug resistance and is able to identify the Mec-A and PVL genes

# Recognition of the Technology

- The invention of Tem-PCR technology has broken a 25 year scientific barrier in Molecular based testing
- In 2006 Dr. Jian Han and his development company was awarded the runner up for the *Wall Street Journal* Medical Technology Innovation of the Year Award
- In 2006 Dr. Jian Han was awarded the **Frost and Sullivan Award** for Technology Innovation and Leadership of the Year Award in Molecular Diagnostics in the European Union
- In August 2009 Diatherix Laboratories was issued an award for the First Commercially available H1N1-09 test performed in a CLIA certified laboratory





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## Thank You!