Docket #: S15-236

Real-time RT-PCR for the Detection of Chikungunya Virus

Stanford virologists have developed a quantitative and sensitive assay to detect chikungunya virus (CHIKV). In addition, it may be multiplexed with assays for other pathogens to detect and differentiate CHIKV infection. CHIKV infection presents with symptoms similar to other viral infections, including dengue virus infection. Accurate differentiation and diagnosis of infection is important to ensure proper clinical care and treatment. Molecular tests have been developed to diagnose dengue or CHIKV in the acute setting, but the available tests require performance of several separate PCR reactions and do not detect and differentiate CHIKV from other agents. This can result in misdiagnosis and unnecessary interventions. To overcome these limitations, the inventors have developed this real-time RT-PCR assay which provides sensitive and quantitative detection of CHIKV. In addition, this test can be multiplexed with other assays developed by the inventors to provide a single reaction test that can detect and differentiate a variety of pathogens including dengue, Zika, Leptospira, and Plasmodium species. This test can improve detection and differentiation of pathogens that have similar clinical presentation, thereby improving diagnostic accuracy and ensuring proper clinical care.

Stage of research

The inventors have validated the assay using 182 clinical samples from Nicaragua.

Related technology

The inventors have also developed an assay to detect Zika virus (see <u>Stanford</u> Docket S15-234).

In addition, the researchers have developed an assay to detect Dengue virus that works in combination with the assay to detect CHIKV. The Dengue virus assay, however, is not currently available for licensing.

Applications

- Diagnosis of patients with chikungunya fever
- Include in multiplex assays to detect and differentiate CHIKV infections from a number of other pathogens that cause similar symptoms

Advantages

- Sensitive and quantitative detection of CHIKV, even when evaluated in multiplex with detection of dengue virus
- Detects all lineages of CHIKV
- CHIKV assay has a wide linear range (5 orders of magnitude)
- CHIKV assay has demonstrated equivalent clinical sensitivity to WHO/CDC recommended molecular tests for CHIKV while also providing detection of dengue virus
- Assay in multiplex:
 - Single reaction test
 - Improves detection
 - Decreases testing cost
 - Streamlines molecular workflow

Publications

- Jesse J. Waggoner, Gabriela Ballesteros, Lionel Gresh, Alisha Mohamed-Hadley, Yolanda Tellez, Malaya K. Sahoo, Janaki Abeynayake, Angel Balmaseda, Eva Harris, Benjamin A. Pinsky, "Clinical Evaluation of a Single-Reaction Real-Time RT-PCR for Pan-Dengue and Chikungunya Virus Detection," Journal of Clinical Virology 78, pp. 57-61, May 2016.
- Joanna Nelson, Jesse J. Waggoner, Malaya K. Sahoo, Philip M. Grant and Benjamin A. Pinsky, "Encephalitis Caused by Chikungunya Virus in a Traveler from the Kingdom of Tonga," Journal of Clinical Microbiology, published online June 23, 2014; 52(9):3459. DOI:10.1128/JCM.01288-14.

Patents

• Published Application: WO2017124054

• Published Application: 20230295750

• Issued: 11,591,660 (USA)

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