

DEVELOPMENT OF A NOVEL HAND-HELD POINT-OF-CARE TEST (POCT) DEVICE FOR DIAGNOSING INFECTIOUS DISEASES

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Nucleic acid amplification tests (NAATs) have become the cornerstone of clinical laboratories providing a same day diagnosis for a wide range of infections. Although polymerase chain reaction (PCR) has served laboratories well, PCR has significant disadvantages as it is labor intensive, requires a thermal cycler, and is relatively slow compared with newer isothermal amplification methods. Isothermal amplification methods such as loop-mediated isothermal amplification (LAMP) are rapid, have excellent sensitivity and can provide results in 20 minutes, which is required for next generation POC tests. Other requirements for next generation POC tests include low cost and ease-of-use for resource poor settings including developing countries. We have developed a hand-held next generation POCT device that employs microfluidics, a novel isothermal amplification method and on-plate nucleic acid detection to provide a rapid and visible test result without the need for any instrumentation. This fully integrated, hand-held POCT device performs pathogen lysis, specific pathogen target amplification and detection providing a swab-in, result-out answer in 20 minutes. The device can be used with a variety of clinical specimens including nasal, throat and vaginal swabs. The isothermal amplification method employs cleavable bivalent primers which provide excellent sensitivity with limit of detection of 100 copies and excellent specificity without primer-dimer amplification and false positive results. The POCT device includes both a positive and negative control channel and later versions will have up to 10 channels and the ability to detect multiple infectious agents on a single swab using a single test device. This low cost, one-time use, disposable test device is being manufactured for use in resource-poor settings in both developed and developing countries to provide a rapid test result for the detection of infectious agents in a range of clinical settings providing physicians with a rapid, actionable result leading to improved patient management.

BIOGRAPHY

James Mahony is currently working as a Professor Emeritus in Pathology and Molecular Medicine at University of Toronto, Canada. He is teaching within the faculty of health sciences includes medical microbiology/infectious diseases and pathology residency training programs, graduate course in clinical virology (MS763) and medical sciences. He completed his fellowship in Microbiology at American Academy of Microbiology as well as in Canadian College of Microbiology. He has decorated his career with several publications with local, international, industrial collaboration with Drs Mark Loeb, Jenny Johnstone, Marek Smieja, Peter Timms (Brisbane), Phil Hansbro (Newcastle, Australia), Lee Ann Campbell (Seattle), Theo Moraes (Toronto) and Luminex Molecular Diagnostics, Qiagen, Pro-L. The major focus area of his research is the pathophysiology of acute respiratory infections caused by specific viruses (influenza, RSV) and bacteria (*Chlamydia pneumoniae*, *P. aeruginosa* and *C. difficile*). One of the major focuses of his laboratory is the development of new antimicrobial agents for both respiratory viruses and bacteria. In addition to the development of novel therapeutics the other focus of his clinical research is in the areas of diagnostics.

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