

Hand-held Point-of-care Test Device for the Rapid Detection of Viral Infections

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Background/Objective

Most point-of-care test (POCT) devices detect antigens or antibody; however, these assays are insensitive compared with nucleic acid detection methods. Therefore there is an urgent need for nucleic acid amplification based POCT tests for the detection of infectious diseases. We describe here an instrument-free, hand-held, point-of-need test device that can detect viruses on a swab providing an answer in 20 minutes.

Method

The POCT device is self-contained and requires no additional equipment. A patient swab is inserted into the hand-held POCT device which performs the following procedures: elution of the material off the swab, lysis of viral and bacterial pathogens, isothermal amplification of nucleic acid gene targets, and detection of amplified DNA by either a visible color change or by electrochemical methods providing a test result in 20 minutes.

Result

We have developed 35 different assays for use in the device all of which have a lower limit of detection of 1-10 genome equivalents including influenza, RSV, Dengue virus, Ebola virus and MERS-CoV. To date our POCT device has been used to detect Influenza A and B, RSV A and B in nasal swabs, Norovirus in rectal swabs, and Hemorrhagic fever viruses (Ebola, Dengue and Marburg) in spiked body fluid specimens. This hand-held device provided an accurate identification of the infectious agent in each case.

Conclusion

We have developed a hand-held POCT device that accepts a patient swab and detects specific infectious agents in 20 minutes. The device is completely self-contained, disposable and does not require an analyzer. This hand-held device can be used by non-health care workers in clinical and non-clinical settings where there is no laboratory diagnostic support providing a swab-to-result diagnosis in 20 minutes. A rapid, point-of-need diagnosis of specific infections using this hand-held, disposable test device will facilitate the immediate treatment of infected patients thereby saving lives.