Non-Instrumented Isothermal Nucleic Acid Amplification Device

Health need

Many infectious diseases that affect global health are most accurately diagnosed through nucleic acid amplification and detection. Existing nucleic acid amplification tests are too expensive and complex for most low-resource settings. The small numbers of centralized laboratories that exist in developing countries tend to be in urban areas and primarily cater to the affluent. In contrast, rural area health care facilities commonly have only basic equipment, and health workers lack the necessary training to maintain equipment and handle reagents. Reliable electric power is a common infrastructure shortfall in low-resource health clinics.

Technology solution

To address this need, PATH has been leading development of technologies that facilitate electricity-free, instrument-free nucleic acid amplification. The development of the prototype non-instrumented nucleic acid amplification (NINA) heating device represents the first example of using an exothermic chemical reaction and engineered phase-change material in a nucleic acid amplification test. In the NINA heater, we use the exothermic reaction of magnesium iron alloy and saline to generate the necessary heat.

Current status and results

We have demonstrated the use of this configuration to stabilize heat mixtures within narrow temperature ranges (58°C to 60°C; 60°C to 63°C; 63°C to 65°C) suitable for several isothermal amplification strategies. NINA heater prototypes have been used to demonstrate proof of principle by amplifying genomic malaria DNA, HIV-1 RNA, and Ralstonia solanacearum (an agricultural pathogen) DNA using loop-mediated amplification.[1] Additionally, we have received design feedback from potential users in low-resource setting clinics in India, Kenya, and Zambia.

PATH continues to assess the performance of NINA with a variety of infectious disease pathogens and isothermal amplification strategies. Next-generation prototypes will improve ease of activation, miniaturization, and disposable design approaches. We are actively seeking partners with novel isothermal amplification strategies and relevant infectious disease primers. We are also working on non-instrumented solutions such as simple sample preparation and naked-eye detection that when used together with NINA, will complete a fully functional, electricity-free, molecular diagnostic kit. We recently initiated a National Institutes of Health-funded collaboration with the US Centers for Disease Control and Prevention that merges scientific and engineering capabilities to adapt the NINA platform into a point-of-care HIV test. The NINA device could enable diagnosis of acute HIV-1 infection and/or infant HIV that might have gone undetected by existing point-of-care rapid HIV tests currently in use in low-resource settings.

1. LaBarre P, Hawkins KR, Gerlach J, et al. A simple, inexpensive device for nucleic acid amplification without electricity—toward instrument-free molecular diagnostics in low-resource settings. PLoS ONE May 2011;6(5):e19738.

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A prototype NINA device is demonstrated in a clinic in Kenya.

The non-instrumented isothermal nucleic acid amplification device can enable highly accurate diagnosis at the periphery where there is no access to electricity.

Availability

For more information regarding this product, contact Paul LaBarre at plabarre@path.org.

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