

## **Rapid identification of melioidosis agent by an insulated isothermal PCR on a field-deployable device**

### **ABSTRACT**

**Background.** *Burkholderia pseudomallei* causes melioidosis, a serious illness that can be fatal if untreated or misdiagnosed. Culture from clinical specimens remains the gold standard but has low diagnostic sensitivity. **Method.** In this study, we developed a rapid, sensitive and specific insulated isothermal Polymerase Chain Reaction (iiPCR) targeting *bimA* gene (*Burkholderia* Intracellular Motility A; BPSS1492) for the identification of *B. pseudomallei*. A pair of novel primers: *BimA*(F) and *BimA*(R) together with a probe were designed and 121 clinical *B. pseudomallei* strains obtained from numerous clinical sources and 10 ATCC nontargeted strains were tested with iiPCR and qPCR in parallel. **Results.** All 121 *B. pseudomallei* isolates were positive for qPCR while 118 isolates were positive for iiPCR, demonstrating satisfactory agreement (97.71%; 95% CI [93.45– 99.53%];  $k = 0.87$ ). Sensitivity of the *bimA* iiPCR/POCKIT assay was 97.52% with the lower detection limit of 14 ng/ $\mu$ L of *B. pseudomallei* DNA. The developed iiPCR assay did not cross-react with 10 types of non-targeted strains, indicating good specificity. **Conclusion.** This *bimA* iiPCR/POCKIT assay will undoubtedly complement other methodologies used in the clinical laboratory for the rapid identification of this pathogen.