PP13 CD

# The Field Validation of a New Brugia Rapid Test (BT+) for the Detection of Lymphatic Filariasis in Malaysia: A Study Protocol

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## INTRODUCTION

Lymphatic filariasis (LF) is a vector-borne disease caused by the parasitic nematodes *Wuchereria bancrofti, Brugia malayi*, and *Brugia timori*. A sensitive point-of-care rapid test is essential for LF surveillance to monitor infection and recrudescence and interrupt disease transmission in endemic localities [1,2]. Currently, the Brugia Rapid test (BRT) is used for detecting LF in Malaysia [3,4]. This study aims to validate and assess the performance of a new rapid test (BT+) for the same purpose.

## METHODOLOGY

- Study design: Cross sectional study design
- Study Site(s): 8 (eight) LF endemic localities in Beluran and Pitas, Sabah Malaysia. (Fig 1)
- The study is registered with MOH: NMRR-23-01957-TQZ and already obtained ethics approval from the Medical Research Ethics Committee, MOH.

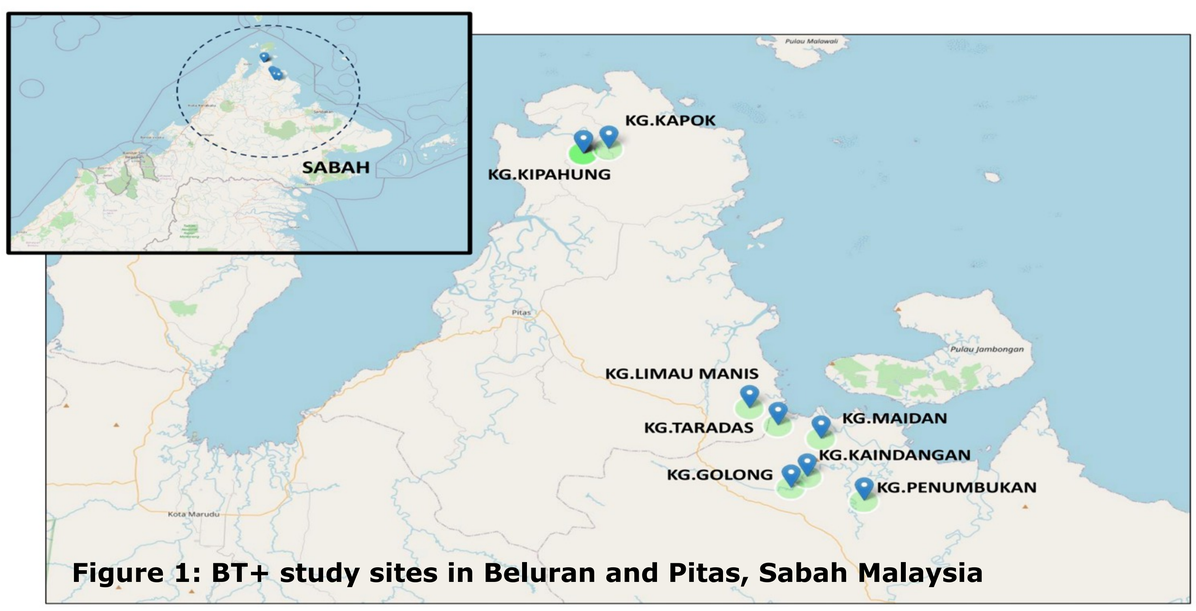


**Figure 1: BT+ study sites in Beluran and Pitas, Sabah Malaysia**

## RESULT/ DATA ANALYSIS PLAN

- The study will recruit 1,125 respondents with 30% attrition rate.

**Quantitative data analysis:**

- BT+ diagnostic SN will be calculated and compared with BRT, using the results of real-time PCR and/or TBS as reference.
- Kappa statistics will be used to determine the agreement between BT+ and BRT.
- Antibody seroprevalence will be compared between the two rapid tests.

**Qualitative data analysis:**

- On-site test performance of BT+ on selected individuals using the Likert Scale that measures on ease of performing the test and interpreting the results.
- Compare the test and control line intensities of BT+ at 20, 30 and 60 minutes after the last step (after adding 3 buffer drops.

## REFERENCE TEST

- For diagnostic sensitivity determination, the positive reference test is positivity by NBS AND/OR real-time PCR.
- Positive sample: **Either** TBS OR/AND real-time PCR is considered positive.
- Negative sample: **Both** TBS AND real-time PCR is considered negative

Data Collection Method:

On-site – Day time (8am to 4pm)

House visits for household listing

Obtain information on eligible respondents age >=5 years old

Brief participants on the study

Set appointment for blood sampling in the evening

### Inclusion criteria:

i. Individuals residing in the selected localities for at least six months.
ii. Individuals who are at least five years old. For the minors, parental guidance consent is required.

### Exclusion criteria:

Pregnant woman.

i. Breastfeeding mother.
ii. Immunocompromised or medically unfit individuals, e.g., cancer patients on treatment, patients with renal failure.

On-site Activities (6 pm-12 am)

House visits for blood sampling based on appointment

Obtain consents and assents (minors)

Finger-prick blood of adults and children > 12 years
- three-line TBS
- perform on-site BT+ on 50 random adult samples

Venepuncture on adults & children ≤12 years
- transfer ~ 3ml blood into EDTA-tube
- three-line TBS using children's venous blood (from syringe)

Transport EDTA-blood to field lab in a cold box

**Field Lab activities**

Transfer EDTA-blood Into screw-cap tube for PCR

Giemsa staining of dried TBS

Perform BT+ using EDTA-blood
-score test line
- 20 pos and 20 neg will be read at 20, 30 and 60 mins

Perform BRT using EDTA-blood
-score test line

Prepare dried blood spots on Trop-Bio filter papers

Centrifuge EDTA-blood to separate plasma

**Activities at other Institutions (UMS, MKA KK, UKM)**

Real-time PCR (UMS)

Microscopic examination
-Mf count & species ID
(MKA KK)

BT+ using eluted DBS
- 50 pos, 10 neg
(UKM)

BT+ on plasma
- 50 pos, 10 neg
- read at 20, 30 & 60 min
(UKM)

**Figure 2: Field data collection and Lab activities for the BT+ study**

## CONCLUSION

Findings from this study can be used as evidence for future use of BT+ in the national LFEP control program.

## LIST OF ABBREVIATIONS

| | |
|---|---|
| BRT | Brugia Rapid test |
| BT+ | Brugia Test plus |
| DBS | Dried Blood Spot |
| LFEP | Lymphatic Filariasis Elimination Program |
| LF | Lymphatic Filariasis |
| NBS | Night Blood Smear |
| RDT | Rapid Diagnostic Test |
| SN | Sensitivity |
| TBS | Thick Blood Smear |

References:

1. Noordin, R. Lymphatic filariasis and the global elimination program. *Malays. J. Med. Sci.* **14**, 1–3 (2007).
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