

Vietnam-Japan joint pilot project for nurturing new industries

# **Production and sales demonstration of STH-PAS, genetic testing kit in Vietnam**

TBA Co. Ltd.,



# Introduction of TBA, Co. Ltd.

TBA Co., Ltd. is startup company of Tohoku University, doing production and sales of PAS (Printed Array Strip) which enables on-site testing for target gene causing infectious disease.

【Director】 CEO Mitsuo Kawase Prof.

【Capital】 63.5 Million yen

【Employee】 9people

【Establishment】 July 2013

【Business Contents】

- C-PAS(Printed Array-Strip)
- Custom Printing
- STH reagent

【Facility】

- GENESHOT : Ink-Jet DNA Printer

【Address】

- 6-6-40 Aramaki-Aoba, Aoba, Sendai  
T-Biz 307 980-8579 Japan
- [TEL:+81-22-721-7822](tel:+81-22-721-7822)
- URL:t-bioarray.com

## Product



C-PAS Series

## Facility



*GENESHOT(Developed by NGK )*

## Office



*Business incubator in Tohoku university*

# STH-PAS for multiplex Pathogen Detection

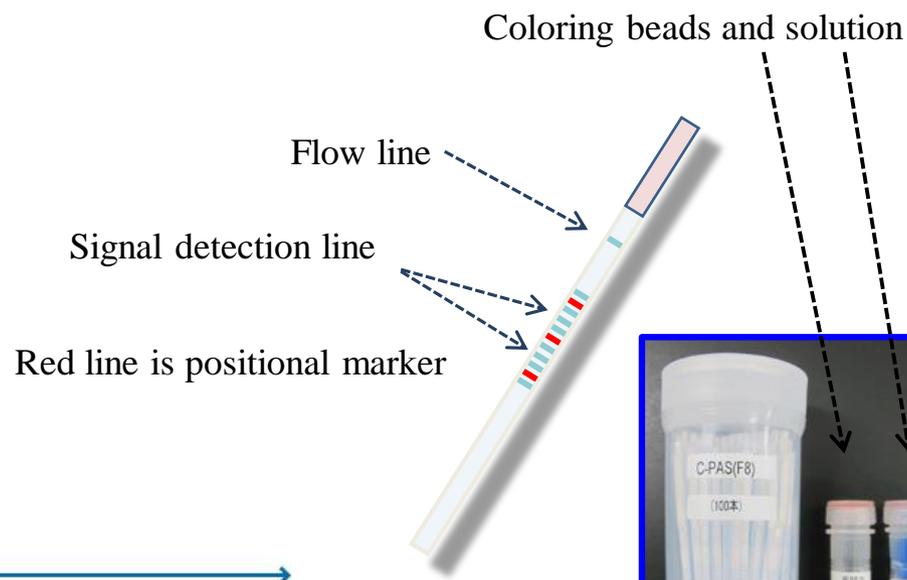
“PAS” : Strip with several lines immobilized complementary tag DNA

➤ Using STH primers(tagged primer) patent-licensed from NGK, PAS can be available for various genetic tests.

➤ Line-up

- C-PAS(F4) : For 4 targets test
- C-PAS(F8) : For 8 targets test
- C-PAS(F12): For 12 targets test

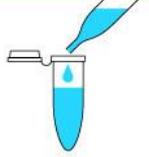
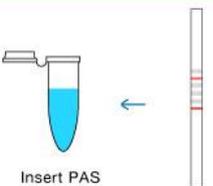
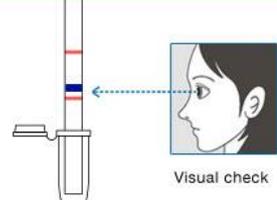
➤ PAS is manufactured by ink-jet DNA printer.



C-PAS(F8)

C-PAS(F8)

————— 15 minutes for test results —————➔

STEP 1	STEP 2	STEP 3	STEP 4
 <p>Test sample    PCR amplification</p>	 <p>Add developer reagent</p>	 <p>Insert PAS</p>	 <p>Visual check</p>
Put a mixture of test sample and STH reagent into PCR tube and perform PCR.	Add developer reagent into PCR tube and mix them.	Insert PAS into the mixture and perform chromatography.	Visual check

# Candidates of STH-PAS Applications

Research, Others

- Genetic research
  - Marker research
- Disease risk research
  - Adiposity, Cancer, etc
- For pet
  - Adiposity, Cancer, etc

Food testing

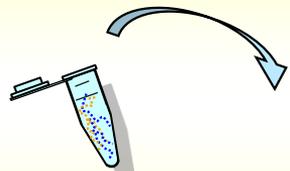
- Pathogen inspection
  - Food poisoning
- Species inspection
  - Meat, Grain, etc.



Diagnosis

- Infection diagnosis
  - Tuberculosis, Malaria, Dengue, etc.
  - HPV, HIV, HBV, HCV, Other Virus.
  - STD, Oral Microbe, etc.

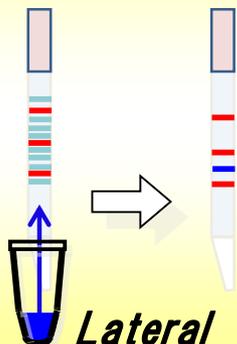
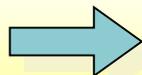
**Simple and convenient genetic testing  
for anyone anywhere !!**



Sample



**PCR**

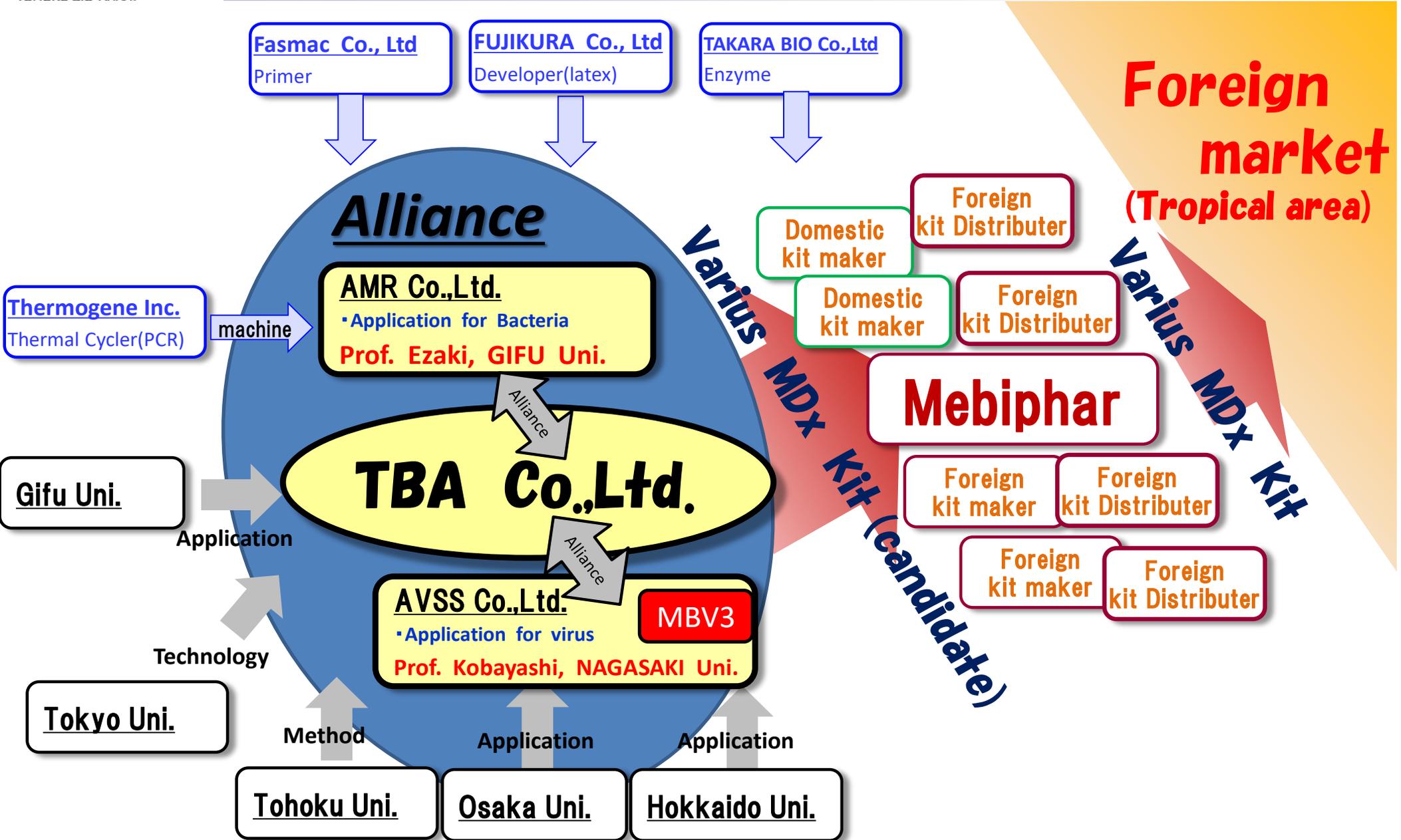


**Lateral flow assay**

Marketing towards  
developing countries



# Business Alliance for MDx kit Development



# Mosquito-Borne Viruses 3 Kit

## -Dengue, Chikungunya, and Zika viruses At Once-

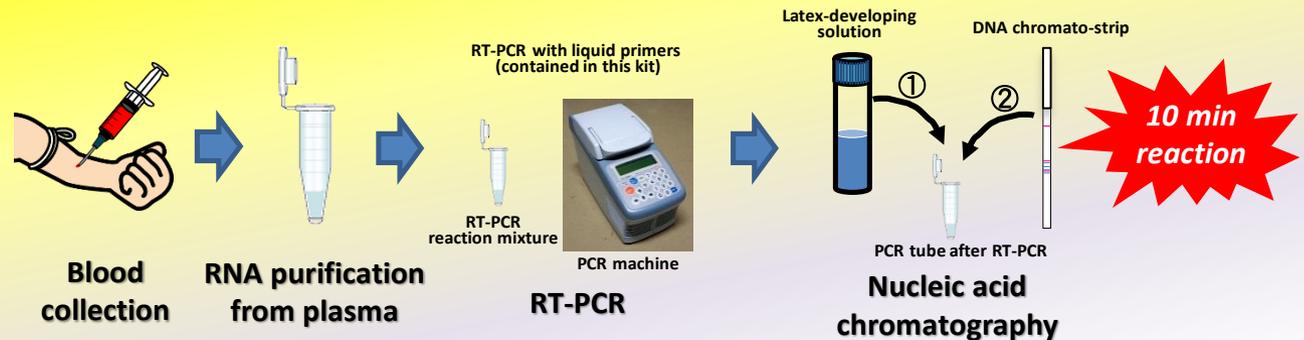
### High-sensitive detection at early phase of infection

Dengue, Chikungunya, and Zika fevers are mosquito-borne viral infectious diseases which are developed with the sudden onset of high fever after 2-14 days from an infection. These diseases are difficult to distinguish due to their similar clinical manifestations.

Our product uses high-sensitive PCR methods that can distinguish these 3 different viruses visually. These advantages will enable rapid and exact treatments for viral infectious diseases.

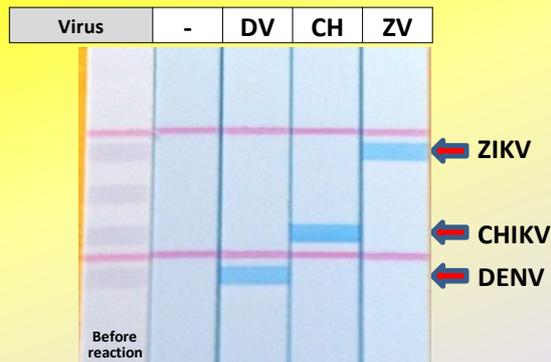
### Easy and short-time

- Easy nucleic acid chromatography kit.
- No need to buy expensive realtime PCR or perform electrophoresis.
- 10 min to determine the existence of virus after RT-PCR.



### Distinguish 3 different viruses

- We can distinguish between these 3 viruses corresponding to the different positive line position.



- Lanes
  - ; Ultra pure water
  - DV ; Dengue virus (DENV)
  - CH ; Chikungunya virus (CHIKV)
  - ZV ; Zika virus (ZIKV)

\* This product uses nucleic acid chromatostrip (C-PAS), which is produced and patented by TBA, co., Ltd. Japan.

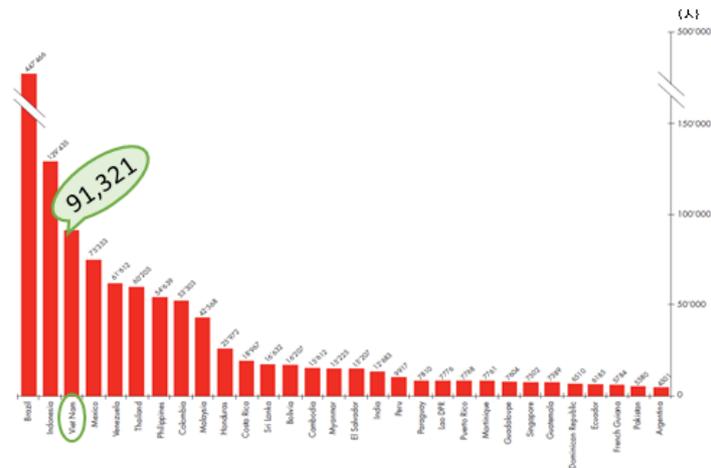
# Background

1) Early symptom of mosquito borne infection (Dengue fever, Zika fever, etc.) looks like similar (fever), so early diagnosis is difficult, it has caused delay in treatment and expanding infection.

2) Immuno-chromato testing is current popular method for infectious disease, but is locally considered to have issues such as low accuracy.

3) Genetic testing is popular for confirmed diagnosis of infectious disease, but requires **expensive instrument and skilled expert**, so that is hardly becoming popular in medical sites of Southeast Asian countries.

4) Number of Dengue patients in Vietnam is the third largest in the world, but the rate of infected patients per population is higher than Indonesia where the number of infected patient is the second largest in the world.



: WHO Global Strategy for Dengue Prevention and Control 2012-2020

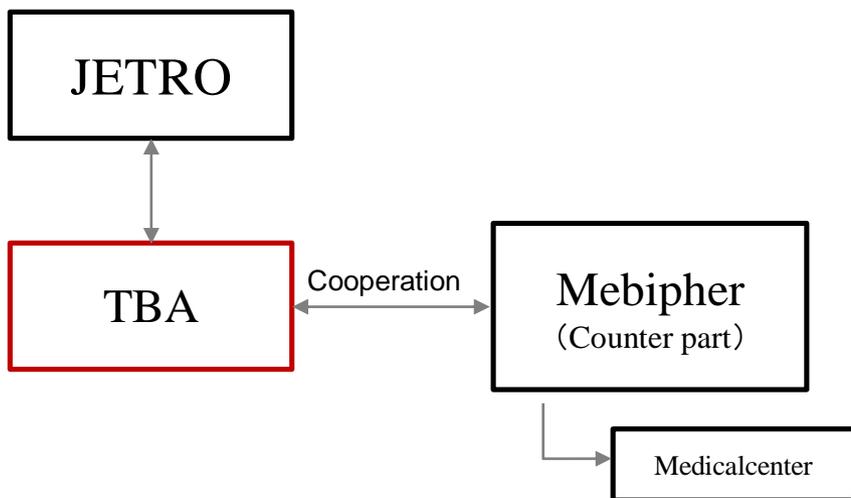
Our Mosquito-Borne Viruses 3 Kit is effective tool for infectious disease in Vietnam.

# Project summery

## Implementation

- 1) Establishment of Production Platform
- 2) Kit performance evaluation at Medical Center
- 3) Demonstration of sales and marketing
- 4) Verification of STH-PAS testing kit standardization

## Organization



## Mebiphar

(Medical Biomaterial & Pharmaceutical stock company)

Annual turnover: approx. JPY 7,000M, Staff: 207

Manufacturer and sales of pharmaceuticals and medical equipments

Current production: 8 main product line (beta-lactam antibiotics, vitamin, cardiovascular, neurologic, herbal, etc.)

Intent to expand medical equipment production

Experience to manufacture and sell urine strip kit product (similar to STH-PAS kit)

Sales network for 63 province in Vietnam

Experience to export to Myanmar

Experience of technology transfer from overseas (introduction of new technology)

## Progress to date

### 1) Establishment of Production Platform

- meeting of project schedule → finished
- trial export of bulk kit components → finished
- establish Quality Control platform → finished
- Quality Control training → finished

### 2) Kit performance evaluation at Medical Center

- Choice the hospital (Medical center) → finished
- Contact to hospital → finished
- Sample collection and measurement → ongoing

### 3) Demonstration of sales and marketing

- Investigation of permission and regulation concerning manufacture and sale of medical examination equipment in Vietnam → ongoing
- Sales network and marketing survey in Vietnam → ongoing

### 4) Verification of STH-PAS testing kit standardization

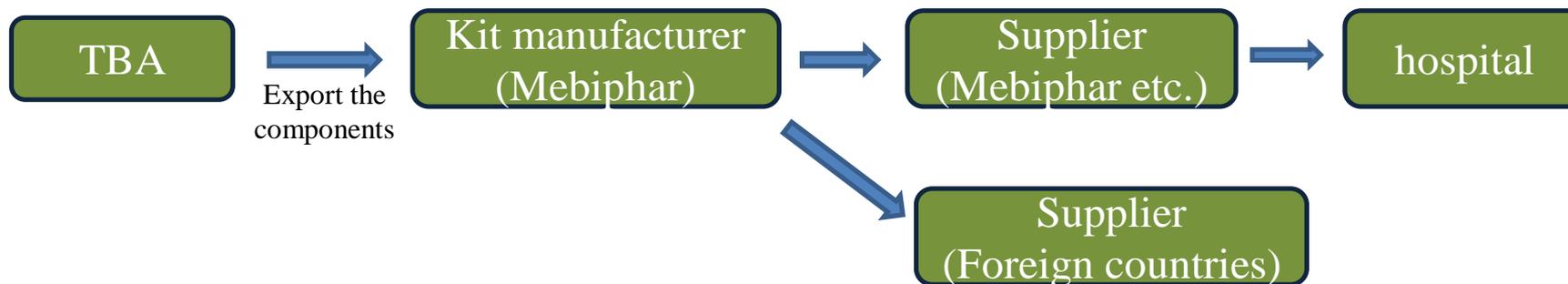
- Investigation of other application development of genetic testing kit in Vietnam → ongoing
- Survey on sales channel expansion to ASEAN countries centered on neighboring Indochina countries → ongoing

# Future plan after the project

## 1) Application and approval of diagnostic reagents

- Mebipahr will assemble the kit under their own brand and conduct clinical trial.
- Apply the kit and after approval, Mebiphar will sell the kits.
- Expand the kit items.

## 2) Build supply chain



## 3) Expand the technology to other application development in Vietnam

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Thank you !