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UNIVERSITI SAINS MALAYSIA

APEX™

INTRODUCTION

Malaria is a serious global health concern caused by five species of human Plasmodium, with Plasmodium falciparum being the most widespread and deadly. Effective diagnostic strategies are necessary for disease prevention and control, but technical issues such as the limited shelf life of capture and detecting antibody reagents have been documented. This problem is particularly significant for rapid diagnostic tests (RDTs) deployed in remote tropical areas, as it could lead to inaccurate diagnoses and inappropriate drug use. Sharks produce an exceptional antibody called VNAR, which has a much longer CDR3 region than conventional antibodies, as well as an unusual cysteine content that contributes to its superior heat stability. SalamAB, or Shark Artificial Loops Advanced Monoclonal Antibody, is a trademarked antigen binder that can identify biomarkers associated with infectious diseases. SalamAB-malaria is a reagent designed to target malaria biomarker P. falciparum HRP2. This innovative single-domain antibody has excellent thermal stability, making it a valuable tool in malaria diagnostics. The outcome of this work could potentially provide a new solution for the current malaria diagnostic platform by allowing kits to be stored at room temperature and ensuring appropriate drug use in remote areas where traditional storage methods may not be feasible.

NOVELTY AND INVENTIVENESS

- The world's first report of using shark VNAR conjugated with gold nanoparticles is presented in this study.
- The VNAR produced in this study has the potential to be used as a new reagent for malaria diagnosis, without the need for cold chain storage.

APPLICABILITY & BENEFITS

Applicability

- Clinical laboratories
- Hospitals
- Diagnostic
- Public health agencies
- Research institutions
- Biologics and biotech industries

Benefits

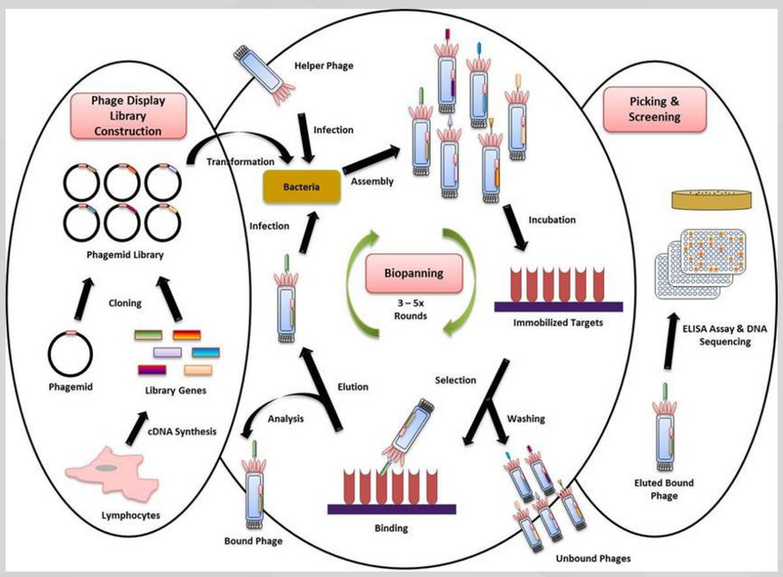
- Heat stability proven
- 99% accuracy identified
- Lower production cost
- Innovative product

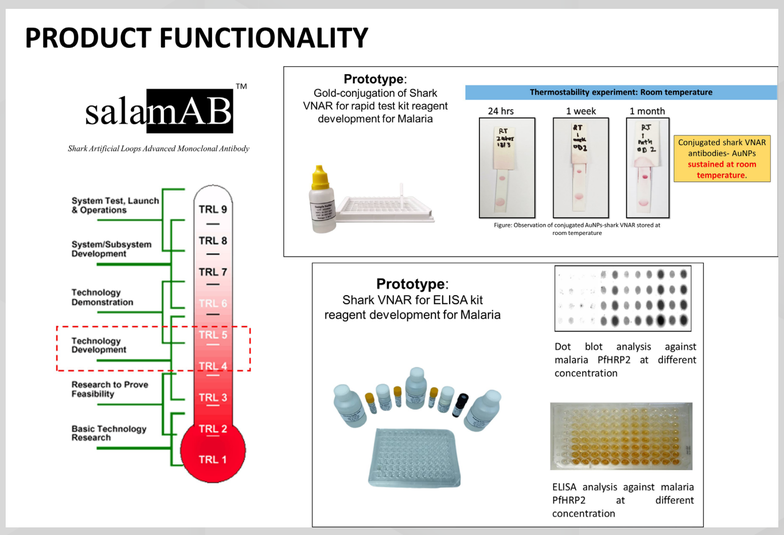
salamAb

An advanced Themostable Reagent for Malaria Diagnostic

STATUS OF INVENTION

TRL 4





PROBLEM STATEMENT

- The World Health Organization (WHO) reported over 100,000 cases of malaria annually across the globe in 2020.
- The current diagnostic reagent for malaria is vulnerable to degradation due to heat and humidity, which can cause a reduction in its sensitivity and shelf-life.

RESEARCH ACHIEVEMENT

- Grants type and amount – 2
  - USM Short Term 2014 (RM 45,000)
  - PRGS 2019 (RM 261,000)
- Journal/books/magazine/book chapter – 5
  - Malaria Journal
  - Journal of Preparative biochemistry & biotechnology
  - International Journal of Biological Macromolecules
  - Analytical Biochemistry
  - Antibody Engineering
- No of Students fyp/msc/phd – 4
  - 1 PhD
  - 3 MSc

INTELLECTUAL PROPERTY STATUS

- Copyright: 1 (Reg no: CRLY2021P03874)
- Trademark: 1 (Reg no: TM2022017448TM)
- Patent: 1 (Reg no: PI2022005962)

COMMERCIALIZATION POTENTIAL AND INDUSTRIAL PARTNER

- 1,000,000 cases X USD5 = USD5 million
- 10% = USD500k, so RM2.5 million is expected to generate per year
- Elsamogen Ltd, UK (NDA signed)

IMPACT OF INNOVATION

- **Society** - Prevent misdiagnosis and provide early intervention and treatment for better quality of life
- **Academia** - Technology development of new antibody enhance healthcare system and reduce the cost of medication
- **Government** - Avoiding an outbreak of disease that could burden a nation's healthcare system and incur substantial medical costs
- **Industry** - Enable the development of new targeted therapeutics, improved diagnostic testing for pharmaceutical and biotechnology industries
- **Environment** - Reduce the large amount of energy required to maintain a consistent temperature, which leads to increased greenhouse gas emissions
- **Product Impact - In line with national and international goals and policies**
  - MySTIE: Advances materials and Medical healthcare
  - Sustainable goal: (3) Good health and well being; (9) Industry, Innovation and Infrastructure
  - Shared prosperity vision 2030: (14) Advanced and modern services
  - Twelfth Malaysia Plan 2021-2025: Increasing of Well-being