Expression of Interest

Invitation to diagnostic manufacturers to submit an Expression of Interest (EOI) for the development and manufacturing of *Plasmodium knowlesi* malaria diagnostic

PATH

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EOI #2026-116: Invitation to diagnostic manufacturers to submit an Expression of Interest (EOI) for the development and manufacturing of *Plasmodium knowlesi* malaria diagnostic

1. Expression of Interest schedule

Activity	Date and title
EOI released	November 10, 2026
Clarifying questions due	November 18, 2026
Answers uploaded	November 25, 2026
Deadline for submission in response to the EOI	December 11, 2026

Note: PATH reserves the right to modify dates at its discretion.

2. PATH statement of business

PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Visit www.path.org to learn more.

3. EOI Description

Background

Plasmodium knowlesi (*P. knowlesi*) is the leading cause of zoonotic malaria in Southeast Asia and is endemic in several countries across the region. According to the World Health Organization's World Malaria Report, in 2024, 2,164 *P. knowlesi* cases were reported globally, of which 89% were reported in Malaysia.

The ADVANCE program, funded by the Australian Department of Foreign Affairs and Trade, is working to bring forth a portfolio of high-quality diagnostics responsive to the needs of malaria programs in the Indo-Pacific region. In alignment with the ADVANCE program, PATH is seeking to identify manufacturers interested in collaborating on the development and production of a diagnostic tool for *P. knowlesi*. Potential collaboration opportunities may include technical and operational support across areas such as research and development, clinical evaluation,

regulatory pathway planning and dossier development, quality management systems, supply chain strengthening, and commercialization strategy. The scope and nature of support will be determined based on project needs and partner capabilities.

Purpose and respondent

This EOI targets diagnostic manufacturers with an interest in exploring a potential product development partnership with PATH for the development and production of a *P.knowlesi* diagnostic tool. Respondents should be committed to manufacturing quality-assured, fit-for-purpose, affordable diagnostic products.

We encourage applicants from companies and partners that:

- Focus on In Vitro Diagnostics, especially RDTs/Rapid Test Kits (RTKs)
- Have malaria diagnostic products commercialized or in the pipeline
- Are interested in expanding their infectious disease diagnostic portfolio through a collaborative development effort

Disclaimer

This EOI is issued solely for information-gathering and planning purposes and does not constitute a commitment by PATH to enter into a partnership, provide funding, or offer technical support to any respondent.

PATH **will not** reimburse any costs associated with the preparation or submission of information in response to this EOI. Information submitted will be treated as confidential and will not be shared outside PATH without the respondent's prior written consent. Aggregated and anonymized information may be shared with potential funding organizations to inform discussions related to future partnership or financing opportunities.

PATH reserves the right, at its sole discretion, to evaluate all responses and determine whether further engagement with any respondent is warranted.

4. Submission

Interested manufacturers are invited to complete the survey linked below: EOI: Partner for the development and manufacturing of malaria diagnostic – Fill out form

The survey is intended to collect information on your organization's manufacturing capabilities, operational capacity, diagnostic product portfolio, regulatory and commercialization experience, and market presence in Southeast Asia and other regions.

It should take approximately 45-60 minutes to fill out the survey. To complete the survey, you may require the following information:

- Company strategy
- Product portfolio including technology description, regulatory status, health area
- Marketing and sales authorization information for diagnostic products within last 5 years
- Geographic sales information for diagnostic products within last 5 years

The respondent shall complete and submit the survey in the link above **by 11:59:59 p.m. (ET) on December 11th, 2026.** All responses must be submitted in English and completed by an authorized representative. PATH may request clarification or additional information and may conduct follow-up discussions with selected respondents.

*Note: Please refer to Annex 1 for an overview of the information requested in the survey. Kindly note that **all survey responses must be submitted via the link provided above.***

5. Questions and answers

All clarifying questions regarding this solicitation must be sent via email to the contact listed below **by 11:59:59 p.m. (ET) on November 18th, 2026.** Answers to all questions will be updated here on **November 25th, 2026.**

To uphold transparency principles, all clarifying questions and PATH's responses will be shared publicly. Questions will be anonymized and answered if PATH reasonably determines that responding does not disadvantage any potential supplier and does not involve commercially confidential information. Commercially confidential questions will be handled in accordance with PATH's policy on information and data.

Please kindly note that it will not be possible to engage in telephone inquiries.

Technical/program contact: **Chi Nguyen, Market Dynamics Officer, PATH (cllnguyen@path.org)**

Annex 1: Data collection form

The data form below is provided **for reference** and to give respondents an overview of the information that will be requested in the survey. Please note that all responses **must be submitted through the survey link** provided in **Section 4: Submission**.

EOI #2026-116: Partner for the development and manufacturing of malaria diagnostic

Company consent

1. Do you consent to participate in this survey to provide us with some high-level information about your company?

Note: The information that solely for information-gathering and planning purposes only and does not constitute a commitment by PATH to enter into a partnership, provide funding, or offer technical support to any respondent.

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*

- Yes
- No

Company information

2. Company name *
3. Website *
4. Contact name *
5. Contact Designation *
6. Contact email *
7. Contact phone number *
8. Headquarter Country *

Interest in partnership

Plasmodium knowlesi (Pk) is the most common cause of zoonotic malaria and is present in many countries in Southeast Asia. In 2024, according to WHO's World Malaria Report, 2164 Pk cases were reported globally, with 89% of cases found in Malaysia.

PATH has identified antibodies that selectively recognize *P.knowlesi* (Pk) antigen and not other malaria parasite antigens. PATH is exploring to develop either an RDT (as an antigen detection RDT) or a lab-based ELISA for Pk antigen detection. We are looking for manufacturers interested in

partnering with PATH to co-develop the product. Reagents and technical assistance will be provided by PATH for the development of either a RDT or an ELISA.

9. Would your company be interested in partnering with PATH to develop a *P.knowlesi* diagnostic, if the reagent is provided by PATH? *
    - Yes
    - No
    - Maybe. We will need more information
10. Which product would you be interested in developing? *
    - P.knowlesi RDT
    - P.knowlesi ELISA
    - Both
    - Other
11. Please describe the types of support (technical, financial, commercial etc…) that your company would be interested in for the development of this diagnostic product? *
12. Please provide a statement explaining why your company would be interested in developing a test for *P.knowlesi* malaria. *
13. Can we reach out to you to discuss this partnership opportunity to develop Pk diagnostic or other future partnership opportunities to develop other diagnostic products? *
    - Yes
    - No

Company overview

14. Please provide an overview of your company, including subsidiaries and ownership, key product lines (e.g. medical devices, pharmaceuticals, etc…), key customers and key market served geographically *
15. Please describe your company's current in-house manufacturing, assembly, and kitting capabilities including infrastructure, production capacity, and efficiency rates for IVDs *
16. Which products in your diagnostic product portfolio do you currently manufacture and/or assemble? **[list product names or product categories]** *
17. Where are your manufacturing facilities located? *
18. Please provide an overview of your research and development structure, capabilities, and product pipeline. *
19. Please provide an overview of your organizational structure, including key departments and number of staff. *
20. Please provide a brief statement on your company's areas of growth and expansion for the future *
21. Please provide a brief statement of your company's past work and future plans with government, NGO, and global health organizations as those partnerships relate to specific diagnostic products and commitments aimed at improving healthcare access. *

Company portfolio

22. For **how many diagnostic products** do you have regulatory and marketing/sales authorization? *
23. For **which diagnostic products** do you have regulatory and marketing/sales authorization and in which countries? *
24. In which countries do you have sales and manufacturing presence and/or distribution networks?

*

25. Into which countries are you interested in expanding your sales and/or distribution presence? *
26. Approximately what percentage of all products are sold or distributed within local market vs. globally? *

27. What types of regulatory approvals (for 1+ products other than COVID-19) and quality management systems or certifications do you have in place (for products other than COVID-19)? *Please select all that apply* *

- Product – WHO PQ
- Product – EU CE Marking Product – US FDA
- Product – Australian TGA
- Product – Japan PMDA
- Product – Other (please list below)
- Manufacturing – cGMP (current good manufacturing processes)
- Manufacturing – cGLP (current good laboratory processes)
- Manufacturing – ISO 13485
- Manufacturing – ISO 9001
- Manufacturing – Other (please list below)

28. Please list any additional product-specific regulatory approvals you hold *
29. Please list any additional quality management systems or manufacturing certifications you hold *
30. Which health areas does your company product portfolio address? *Select all that apply* *

- Cancer
- Cardiovascular
- CD4 count
- Chagas disease
- Cholera
- COVID-19
- Dengue
- Diabetes
- Hepatitis A
- Hepatitis B
- Hepatitis C
- HIV/AIDS
- Influenza
- Malaria
- Meningitis
- Neonatal (including CRP, Sickle Cell, TORCH, and Procalcitonin)
- Respiratory infections (including RSV and pneumonia)
- Sepsis
- Syphilis
- Sickle cell
- Tuberculosis
- Typhoid
- Yellow fever

- Other

31. What product types does your company manufacture or distribute? *Select all that apply* *

- Raw and intermediary materials
- Reagents
- Test kits
- Equipment
- Consumables
- Combo tests (please list in the next question diseases detected by combo test)
- Other (please list in the next question)

32. What other, if any, product types or combo tests does your company manufacture or distribute?
33. What types of technologies are part of your company's product portfolio? *Select all that apply* *

- Molecular
- Immunoassay
- Point of care
- Rapid test
- Flow cytometry
- Hameostasis
- Clinical chemistry
- Hameotology
- Nephelometry
- Serology
- Multiplexing
- Other

34. If your portfolio includes malaria related products, please provide additional information on the specific malaria products that your company manufactures and the types of regulatory approvals that these products hold. If there's no malaria-related products with your portfolio, please response with "N/A" *
35. Into which countries do you currently have sales for your malaria-related products? *