October 2025

# Next Generation Malaria RDT workshop for Chinese manufacturers

# 中国生产商疟疾快速诊断检测研讨会

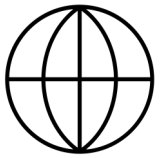
Market trends and key processes to support development and commercialization of high-quality malaria RDTs for LMIC markets

面向中低收入国家市场的高质量疟疾快检试剂：市场趋势及支撑其研发与商业化的关键流程

PATH

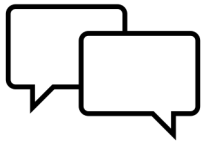
The Hong Kong Jockey Club Global Health Institute
香港賽馬會環球衞生研究院

# Webinar Information 会议须知



**Language & Interpretation 语言与同声传译**

- This webinar offers simultaneous interpretation in Chinese and English
  本次研讨会提供**中文与英文**的同声传译。
- To access, click the globe “Interpretation” icon on your Zoom toolbar 请点击工具栏上的“口译”功能
- Select your preferred language and adjust audio settings as needed 并选择你希望听到的语言频道

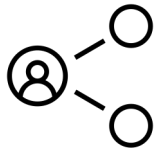


**Question & Feedback 提问与反馈**

- Use the Zoom Chat to submit comments, feedback, or questions throughout the webinar
  (Note your name, organization, and who your question is posed to (if specific) for any questions raised)
  请通过聊天提交评论或问题，注明姓名、机构和提问对象。
- Questions will be monitored and shared during the Q&A sessions 问题将在问答环节汇总分享。

**Interactive Participation 互动参与**

- Mentimeter will be used for polls and reflections during the webinar. More information to follow
  研讨会将使用投票工具收集意见，详情稍后说明。



**Recording & Materials 录制与资料**

- Recording of the webinar and material presented will be shared with participants after the webinar
  会议将录制，会后分享录音和资料。

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# Agenda 议程

## Day 1 第一天

| Session<br>场次 | Speaker<br>演讲者 | Duration<br>时长 |
|---|---|---|
| Webinar Information 会议须知 | PATH | 5m |
| Welcome and Day 1 opening remarks<br>欢迎辞及第一天开幕致辞 | Gates Foundation, HKJCGHI, PATH | 10m |
| Introduction to Next-Generation mRDTs<br>新一代疟疾快检试剂介绍 | PATH | 15m |
| Key considerations for mRDT product development and clinical study design<br>疟疾快检产品开发及临床研究设计的关键考量因素 | PATH | 20m |
| Reagent resources available to support manufacturers<br>可用于支持生产商的试剂资源 | Fapon Biotech | 20m |
| Break茶歇 | | 10m |
| Regulatory pathways and strategy监管途径与策略 | PATH | 15m |
| WHO PQ overview世卫组织预认证概述 | PATH | 20m |
| Manufacturer experience with WHO PQ<br>生产商在世卫组织预认证（WHO PQ）方面的经验 | InTec | 20m |
| Research resources available to support manufacturers<br>可用于支持生产商的研究资源（预录版） | HKJCGHI | 20m |
| Q&A问答 | PATH, HKJCGHI | 20m |
| Day 1 closing remarks第一天结束语 | PATH, HKJCGHI | 5m |

## Day 2 第二天

| Session<br>场次 | Speaker<br>演讲者 | Duration<br>时长 |
|---|---|---|
| Welcome and Day 2 opening remarks<br>欢迎辞及第二天开幕致辞 | Gates Foundation, HKJCGHI, PATH | 10m |
| Public sector market insights<br>公共部门市场洞察 | PATH | 20m |
| Private sector market insights<br>私营部门市场洞察 | PATH | 20m |
| Participant survey参会者调查 | PATH, All | 10m |
| Break茶歇 | | 10m |
| Manufacturer experience with LMIC markets<br>生产商在中低收入国家市场的经验 | Wondfo | 20m |
| Partner experience with mRDTs<br>合作伙伴在疟疾快速诊断检测方面的经验 | Centre Pasteur du Cameroun | 30m |
| Q&A问答 | PATH, HKJCGHI | 30m |
| Day 2 (final) closing remarks<br>第二天（最后一天）结束语 | Gates Foundation, HKJCGHI, PATH | 20m |

# Mentimeter Survey Questions 互动调查问题

The webinar will feature interactive survey questions.
网络研讨会将设置互动式调查问题

When prompted, please go to www.menti.com with your **phone or laptop** and **enter the code displayed on the slide**.
当系统提示时，请用手机或笔记本电脑访问 www.menti.com 网站，并输入幻灯片上显示的代码。

All questions and responses will be anonymous.
所有问题及反馈均为匿名形式。

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# Mentimeter Survey Questions 互动调查问题

Let's give it a try! 我们来试试看

Please go to www.menti.com with your **phone or laptop** and **enter the code displayed on the slide below**.
当系统提示时，请用手机或笔记本电脑访问 www.menti.com 网站，并输入幻灯片上显示的代码。

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所有问题及反馈均为匿名形式。

Mentimeter Code:
**7350 7193**

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# Welcome & Opening Remarks

# 欢迎辞及开幕致辞

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# Introduction to Next Generation Malaria RDTs

# 新一代疟疾快检试剂介绍

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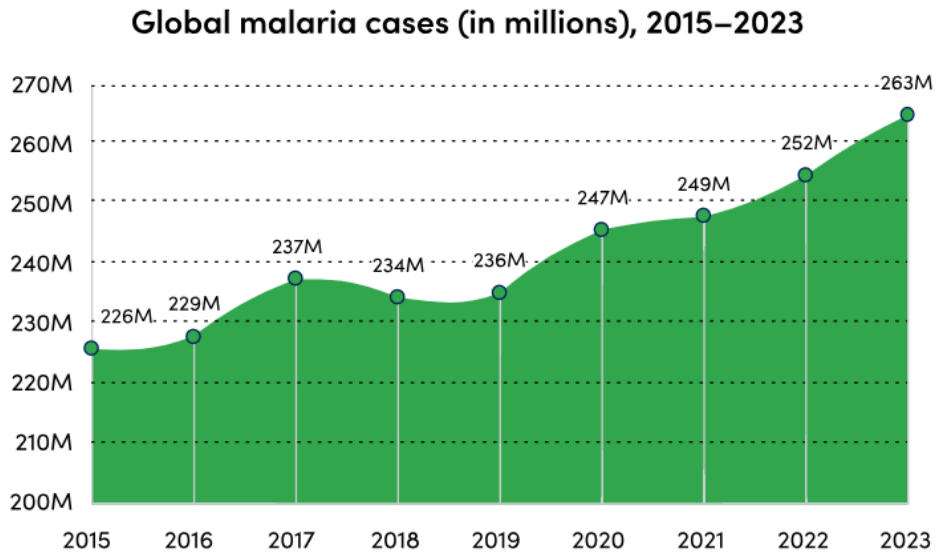
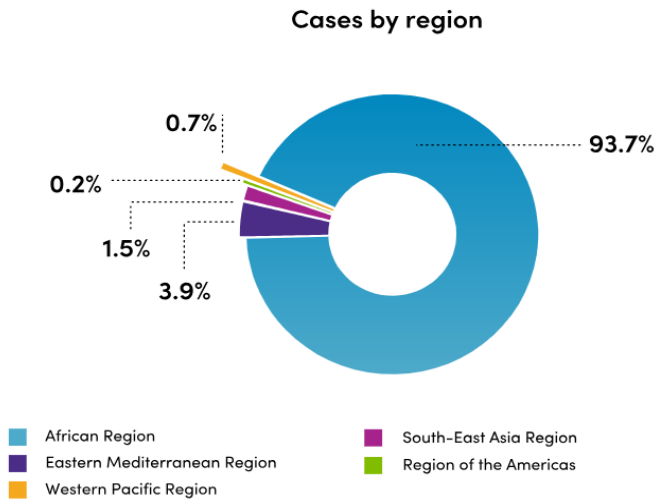
# Background on global malaria burden 全球疟疾负担背景




**Malaria species 疟原虫种类**

- There are five species of Plasmodium, which can infect and be spread by humans: *P. falciparum, P. vivax, P. ovale, P. malariae, and P. knowlesi.*
  感染人类并在人群中传播的疟原虫共有五种，分别是：恶性疟原虫(Pf)、间日疟原虫(Pv)、卵形疟原虫(Po)、三日疟原虫(Pm)和诺氏疟原虫(Pk)。
- P*. falciparum* makes up most of the cases; the second most common being P*. vivax*
  Pf 引发的病例占比最高，Pv 则是第二常见疟原虫种类。

## Global cases of malaria (2023)　2023年全球疟疾病例

- In 2023, there were an estimated 263 million new malaria cases in 83 countries worldwide
  2023 年，全球 83 个国家估计新增疟疾病例 2.63 亿例。
  - 93.7% of the burden can be attributed to the Africa region.
    93.7% 的疟疾负担可归因于非洲地区。

SOURCE: WHO malaria report 2024

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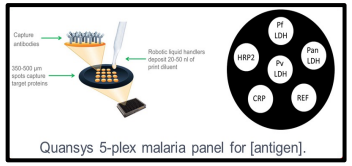
# Diagnosis and detection of malaria 疟疾的诊断与检测

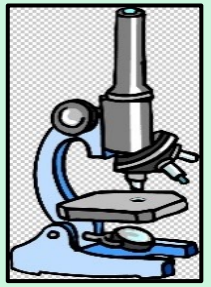
**Ultra-sensitive PCR**
超敏聚合酶链式反应


**LAMP** 环介导等温扩增技术

**Loopamp malaria kits**
环介导等温扩增技术疟疾检测试剂盒




**Multiplex platforms for detection of malaria antigen**
疟疾抗原检测多重平台



**Microscopy 1880**
**显微镜检查法（1880 年）**

**Microscopy and Rapid Diagnostic Tests (RDT) are the accepted / recommended standard of care to aid clinical diagnosis of malaria.**
显微镜检查法与快检试剂是公认/推荐的标准诊疗辅助手段，可用于协助疟疾的临床诊断。

**Parasite density** 寄生虫密度



***P.Falciparum*** **RDT**
恶性疟原虫快速诊断检测 (HRP2)

***P.Vivax*** **RDT**
间日疟原虫快速诊断检测 (LDH)

**1990's**

**Increasing sensitivity 提高灵敏度**

# How does a rapid diagnostic test for malaria work? 疟疾快检的工作原理?

Malaria RDTs detect the presence of specific proteins produced by the malaria parasites on the lateral flow platform. 疟疾快检试剂通过侧流平台检测疟原虫所产生特定蛋白质的存在。


***P. falciparum* RDTs *Pf* 快速诊断检测**

Histidine Rich Protein (HRP2): Only expressed by *P.falciparum.* 富含组氨酸蛋白(HRP2)：仅由Pf表达。

- Is highly expressed and confers good sensitivity… 表达量高，且具有良好的灵敏度……
- **…but *P. falciparum* parasites can live without it. 但 Pf 在没有HRP2的情况下也能存活。**

Lactate dehydrogenase (LDH): Expressed by all malaria species. 乳酸脱氢酶(LDH)：所有疟原虫种类均会表达。

- Is an essential enzyme for the survival of the parasite.是疟原虫存活所必需的一种酶。
- Antibodies target *P.falciparum* -specific epitopes 抗体靶向Pf特异性表位。

***P.vivax* RDTs *Pv* 快速诊断检测**

Lactate dehydrogenase (LDH): Expressed by all malaria species. 乳酸脱氢酶 (LDH)：所有疟原虫种类均会表达。

- Is an essential enzyme for the survival of the parasite. 是疟原虫存活所必需的一种酶。
- Antibodies target *P.vivax* -specific epitopes 抗体靶向 Pv 特异性表位。

***Pan* RDTs 泛疟原虫快速诊断检测**

Lactate dehydrogenase (LDH): Expressed by all malaria species. 乳酸脱氢酶(LDH)：所有疟原虫种类均会表达。

- Is an essential enzyme for the survival of the parasite. 是疟原虫存活所必需的一种酶。
- Antibodies target epitopes that are conserved across species. 抗体靶向所有疟原虫种类中均保守的表位。

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# The vast majority of malaria RDTs target the histidine-rich-protein 2 (HRP2) antigen
# 大多数疟疾快检试剂以HRP2抗原为检测靶点。

- ~450 million RDTs sold in 2023

  2023 年售出约 4.5 亿份疟疾快检试剂。

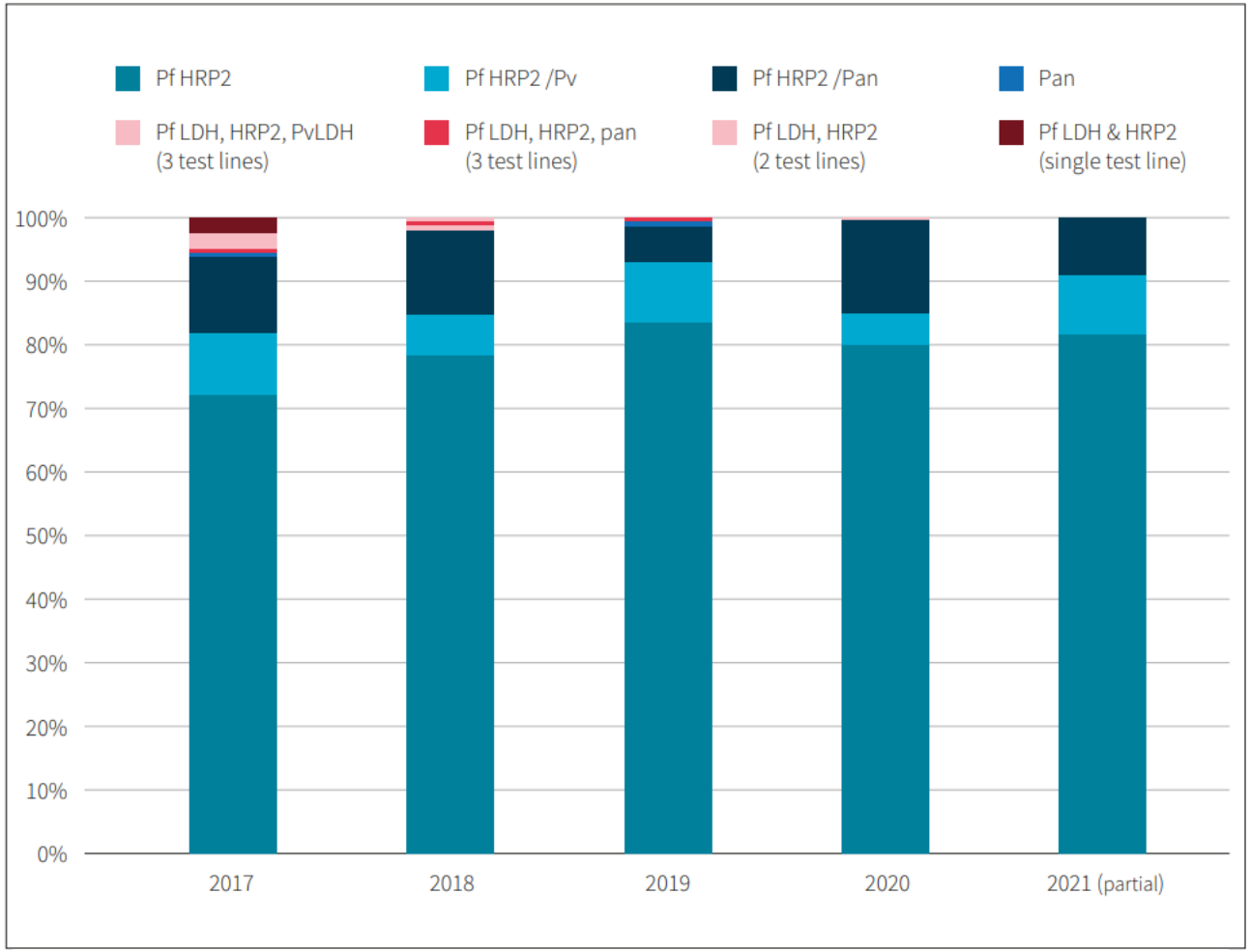
- 90% in sub-Saharan Africa

  90% 销往撒哈拉以南非洲地区。

- Nearly all detect *P. falciparum* based on HRP2

  几乎所有检测试剂均基于HRP2来检测 Pf。

**RDT market share by type快检试剂市场份额**（按类型划分）




**Sources:** [1]World Malaria Report 2024, Unitaid Malaria Market and Technology Landscape 2022
来源：《2024 年世界疟疾报告》，《2022 年全球基金疟疾市场与技术现状报告》

# *P.falciparum* infections in which HRP2 is not detected
# 未检测到HRP2的恶性疟原虫感染

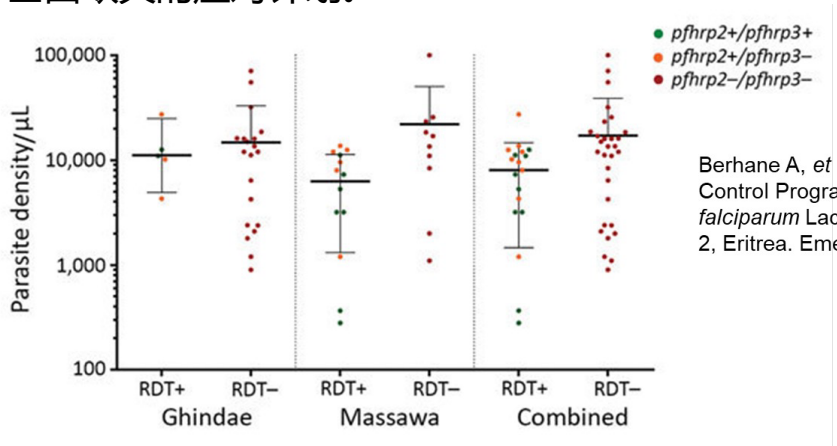
In several countries now, HRP2 detection cannot be used as a reliable test for *P.falciparum* infection due to: 如今在多个国家，HRP2检测已无法作为诊断 Pf 感染的可靠方法，原因如下：

- A rise in infections with not detectable HRP2. 无法检测到HRP2的感染病例增多。
- This is due deletions of the *pfhrp2* (and *pfhrp3)* genes in viable *P.falciparum* parasites. 这是由于具有活性的恶性疟原虫中 *pfHRP2*（及 *pfHRP3*）基因发生缺失所致。

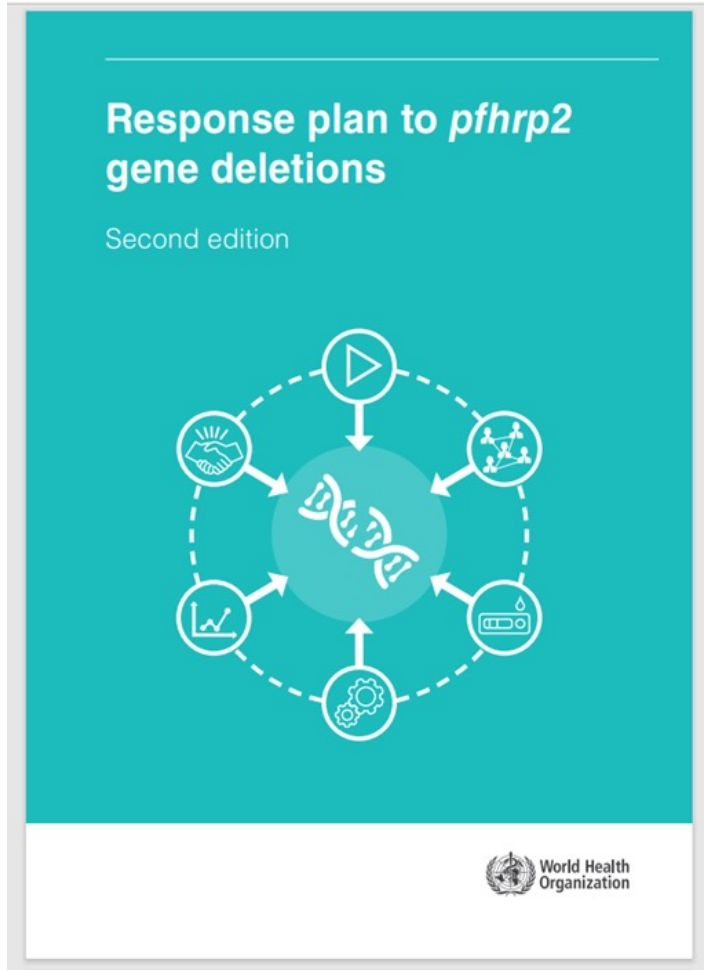
***PfHRP2* gene deletions can result in febrile cases with high parasite densities are missed by RDTs *PfHRP2* 基因缺失可能导致快检漏检寄生虫密度高的发热病例。**

The WHO considers pfhrp2/hrp3 gene deletions, as one of four biological threats to malaria control and elimination.
WHO将 pfHRP2/pfHRP3 基因缺失列为疟疾防控与消除工作面临的四大生物威胁之一。

As a result, WHO has published a response plan for *pfhrp2* deletions.
WHO已发布针对 *pfHRP2* 基因缺失的应对计划。


Berhane A, *et al.*, Major Threat to Malaria Control Programs by *Plasmodium falciparum* Lacking Histidine-Rich Protein 2, Eritrea. Emerg Infect Dis. 2018

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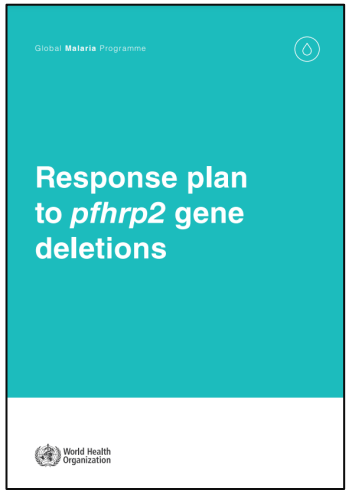
# Resources on hrp2/hrp3 deletions in P.falciparum
# 关于恶性疟原虫中 hrp2/hrp3 基因缺失的相关资料

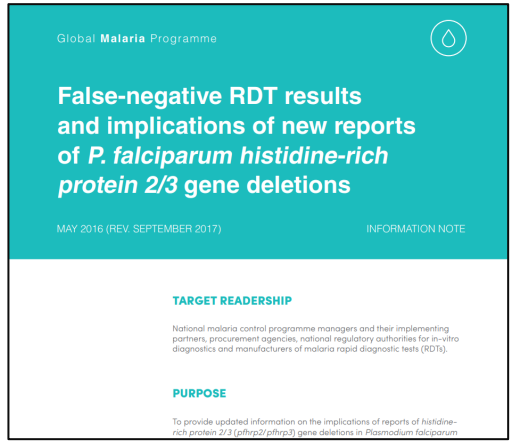
**The WHO Global Malaria Program (GMP) has developed multiple resources:**
**WHO全球疟疾规划（GMP）已编制多项资源材料，具体包括：**

**Video:** *Malaria Diagnosis: Addressing the issue of HRP2 gene deletions (UPDATED VERSION).*
**视频：** 疟疾诊断：应对 HRP2 基因缺失问题（更新版） Watch here.

**Guidance materials:指导材料：**

- Response plan to *pfhrp2* gene deletions.
  应对 *pfhrp2* 基因缺失的行动计划 here.
- Recommended selection criteria for procurement of mRDTs.
  疟疾快检试剂采购推荐选择标准
- False-negative RDT results and implications of new reports *of Pfhrp*2/3 deletions.
  快检假阴性结果及*pfhrp*2/3基因缺失新报告的启示
- Template protocols to support surveillance and research for *pf*hrp2/3 deletions.
  支持 *pfhrp2/3* 基因缺失监测与研究的标准操作流程模板




**Selecting and procuring malaria RDTs选择和采购疟疾快检试剂**

https://www.who.int/teams/global-malaria-programme/case-management/diagnosis/rapid-diagnostic-tests/selection-and-procurement

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# WHO already recommends commercially available LDH-based tests for settings with 5% or more *hrp2/3* deletions causing false-negative HRP2 RDTs

世卫组织已建议在 hrp2/3 基因缺失率达到 5% 或以上，导致 HRP2 快速诊断测试出现假阴性的地区，使用市面可获取的基于LDH的检测试剂。

The table below summarizes the alternative testing options for areas were ≥5% of *P. falciparum* cases are missed by HRP2-RDTs due to *pfhrp2/3* deletions.

| | |
|---|---|
| **Detect *P. falciparum*** | • pan-LDH-only RDTs<br>• combination of HRP2 and pf-LDH[a] |
| **Detect and discriminate Pf from Pv or non-Pf infections** | • Combination of pf-LDH, HRP2 and pan-LDH[a]<br>• Combination of pf-LDH, HRP2 and pv-LDH[a]<br>• Combination of pf-LDH, pv-LDH<br>• Combination of pf-LDH and pan-LDH |

[a] pf-LDH and HRP2 may be on the same test line or separate test lines

**Selecting and procuring malaria RDTs**

选择和采购疟疾快检试剂

https://www.who.int/teams/global-malaria-programme/case-management/diagnosis/rapid-diagnostic-tests/selection-and-procurement

World Health Organization

Health Topics Countries

Global Malaria Programme

**List of currently eligible products**

*WHO-prequalified*

There are currently no WHO -prequalified products meeting requirements.

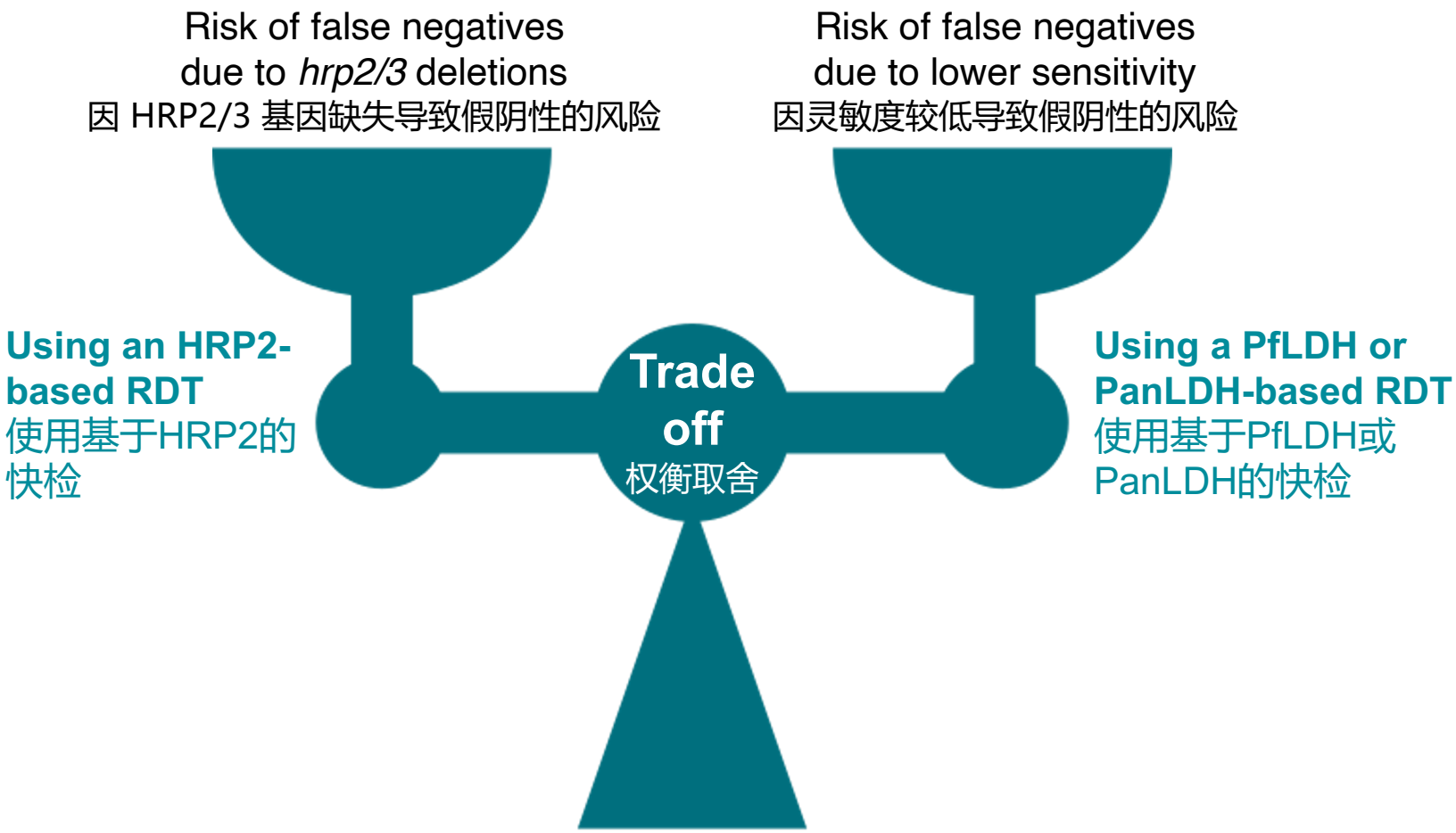
*Non WHO-prequalified tests meeting critical criteria* [a]

| Product name | Product code | Manufacturer name |
|---|---|---|
| Biocredit Malaria AG Pf (pLDH) | C14RHG25, C14RHH25 | Rapigen Inc. |
| Biocredit Malaria AG Pf (pLDH/HRP2) | C13RHG25, C13RHH25 | Rapigen Inc. |
| Biocredit Malaria AG Pf/Pv (pLDH/pLDH) | C61RHG25, C61RHH25 | Rapigen Inc. |

[a] Valid ISO 13485:2003, submission of application for WHO prequalification, and acceptable diagnostic performance against both HRP2 expressing and HRP2 non-expressing at 200p/µL (*pfhrp2/3* single or double deletions) based on the most recent WHO laboratory assessment, performed at the United States Centers for Disease Control and Prevention.

# LDH-based RDTs have lower analytical sensitivity compared to HRP2-based tests, resulting in a clinical trade off

# 基于LDH的快检试剂其分析灵敏度低于基于HRP2的检测，导致了临床应用中的权衡取舍

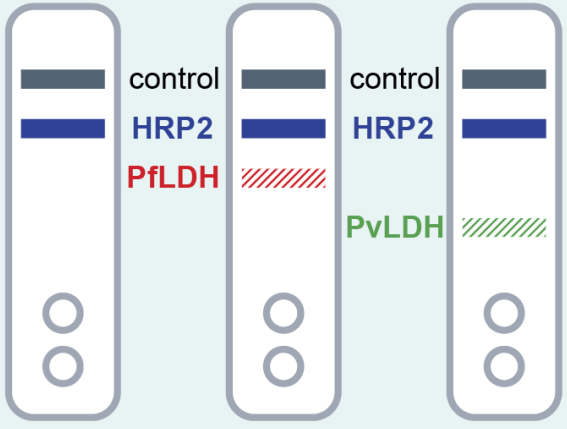


# Development of new malaria RDTs 新型疟疾快检试剂的研发

| *Status quo 现状* | *Near term solutions 短期解决方案* | *Longer term solutions 长期解决方案* |
|---|---|---|
| **HRP2**<br>基于 HRP2 开发的检测 | **HRP2 + pLDH**<br>HRP2+ 疟原虫乳酸脱氢酶 | **New antigens**<br>新抗原 |
| ***ADVANTAGES优势*** | | |
| Abundant biomarker for P. falciparum<br>恶性疟原虫的丰富生物标志物<br><br>Sensitive detection of P. falciparum when expressed<br>表达时可实现对Pf的灵敏检测 | Combination of HRP2 with pLDH allows detection of deletion mutants, and other Plasmodium species and is essential to the parasite<br>HRP2 与 pLDH 联合使用，可实现对pfHRP2/3缺失突变株、其他疟原虫种类的检测，且对疟原虫的识别至关重要 | Longer term solutions include new malaria protein antigens with key features: 长期解决方案包括具有以下关键特征的新型疟疾蛋白抗原：<br>• High abundance in blood 在血液中含量丰富<br>• Stability 稳定性<br>• Resistance to mutation抗突变性<br>• Clinically and epidemiologically-relevant expression profile 具有临床和流行病学意义的表达谱 |
| ***CHALLENGES挑战*** | | |
| False negative test results in patients with *pfhrp2/3* deletions *pfHRP2/3*<br>基因缺失患者的检测假阴性结果 | Risk of false negative results if PfLDH sensitivity not improved<br>若PfLDH检测灵敏度未得到提升，则存在假阴性结果风险 | Requires new antibodies and robust validation of the markers across multiple clinical settings<br>需要研发新型抗体，并在多种临床场景下对这些标志物进行可靠验证。 |

# Near term solutions: RDT form and pipeline
# 短期解决方案：快速诊断检测的形式与研发管线

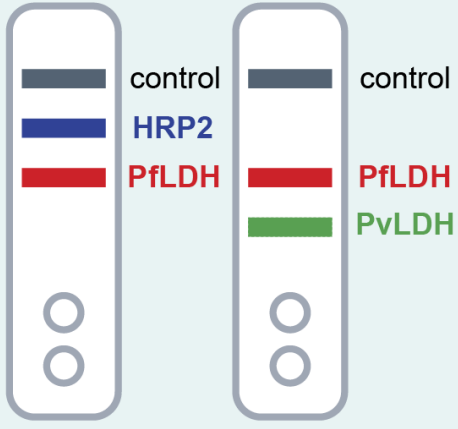
## Status quo
现状




- **HRP2**-only tests are the majority of the market
- **PfLDH** has lower sensitivity
- **PvLDH** has lower sensitivity

Multiple manufacturers and products available and WHO Prequalified
有多家生产商及多款产品可供选择，且这些产品均通过了WHO PQ。

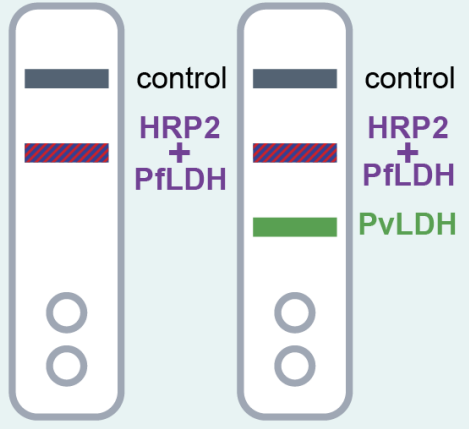
## Current improved
当前经过改进的检测试剂




- Addresses ***hrp2/3*** deletion risk
- Improved **PfLDH** sensitivity
- Improved **PvLDH** sensitivity
- Without **HRP2**, there is less sensitivity even with improved PfLDH

ERPD approved RDTs available
有经 ERPD（诊断学专家审查小组）批准的快检试剂可供使用。

## Next-generation
下一代快检试剂




- Addresses ***hrp2/3*** deletion risk
- Improved **PfLDH** sensitivity
- Improved **PvLDH** sensitivity
- Higher usability with only one Pf-line

Over 15 products in multiple stages of development
超过 15 款产品处于不同研发阶段。



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# New RDTs address need for more sensitive tests and detection of *P.f* with *hrp2/3* deletions 新型快检试剂可满足两方面需求：一是检测方法更灵敏，二是能检出 hrp2/3 基因缺失的恶性疟原虫

**Pf antigen standard (NIBSC code: 16/376)**
**恶性疟原虫抗原标准品 (NIBSC code: 16/376)**

| Based on dilution: IU/mL | Quansys* measured pg/mL | | Current PQ RDTs | | More sensitive pLDH detection RDTs | | Next-gen RDTs |
|---|---|---|---|---|---|---|---|
| | HRP2 | PfLDH | HRP2 | PfLDH | HRP2 | PfLDH | HRP2+ PfLDH |
| 200 | 20454 | 45433 | | | | | |
| 100 | 10550 | 26060 | | | | | |
| 50 | 4637 | 11223 | | | | | |
| 30 | 2866 | 6165 | | | | | |
| 20 | 1304 | 2990 | | | | | |
| 15 | 981 | 2931 | | | | | |
| 10 | 700 | 1871 | | | | | |
| 8 | 510 | 1350 | | | | | |
| 5 | 351 | 873 | | | | | |
| 3 | 183 | 502 | | | | | |
| 1.5 | 108 | 239 | | | | | |

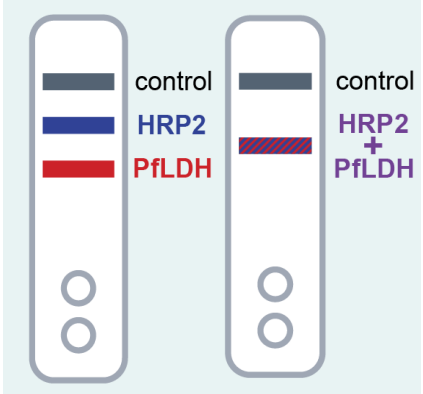
*WHO International Standard for Pf antigen (NIBSC code:16/376). Reconstituted material is further diluted into pooled negative whole blood. NIBSC WHO恶性疟原虫抗原国际标准品（NIBSC code:16/376）。复溶后的物质需进一步稀释至混合阴性全血中。*
*Highlighted cells show where the majority of replicates tested were positive by test line.高亮单元格显示的是大多数重复检测样本在检测线处呈阳性的区域。*
** Antigen quantification conducted at PATH using the Quansys Q-plex:抗原定量分析由PATH采用 Quansys Q-plex 检测技术完成。*
https://www.quansysbio.com/products-and-services/multiplex-assays/human-malaria-5-plex/

**Cultured *P. falciparum* 3BD5 (hrp2-/3-)**
**体外培养的恶性疟原虫 3BD5 株（hrp2 / 3基因缺失）**

| Parasites/ µL | Quansys* measured pg/mL | | Current PQ RDTs | | More sensitive pLDH detection RDTs | | Next-gen RDTs |
|---|---|---|---|---|---|---|---|
| | HRP2 | PfLDH | HRP2 | PfLDH | HRP2 | PfLDH | HRP2+ PfLDH |
| 4500 | 4 | 24934 | | | | | |
| 2250 | 4 | 12639 | | | | | |
| 1125 | 3 | 5718 | | | | | |
| 563 | 2 | 2753 | | | | | |
| 338 | 2 | 1783 | | | | | |
| 225 | 1 | 1129 | | | | | |
| 113 | 2 | 604 | | | | | |
| 56 | 1 | 301 | | | | | |

International Pf standard detection limits:
国际Pf标准品检测限：

- Higher sensitivity tests can detect < 5 IU/mL
  高灵敏度检测可检出（浓度）< 5 IU/mL的恶性疟原虫。
- Target 1 ng/mL PfLDH or lower
  目标检测限为 1 ng/mL 恶性疟原虫乳酸脱氢酶（PfLDH）或更低



# Clinical performance depends on limit of detection and the distribution of antigen 临床性能取决于检测限和抗原分布

| NIBSC Pf Ag | | | | | | | |
|---|---|---|---|---|---|---|---|
| Based on dilution: IU/mL | Quansys measured pg/mL | | Current PQ RDTs | | More sensitive PLDH detection RDTs | | Next-gen RDTs |
| | HRP2 | PfLDH | HRP2 | PfLDH | HRP2 | PfLDH | HRP2+ PfLDH |
| 200 | 20454 | 45433 | | | | | |
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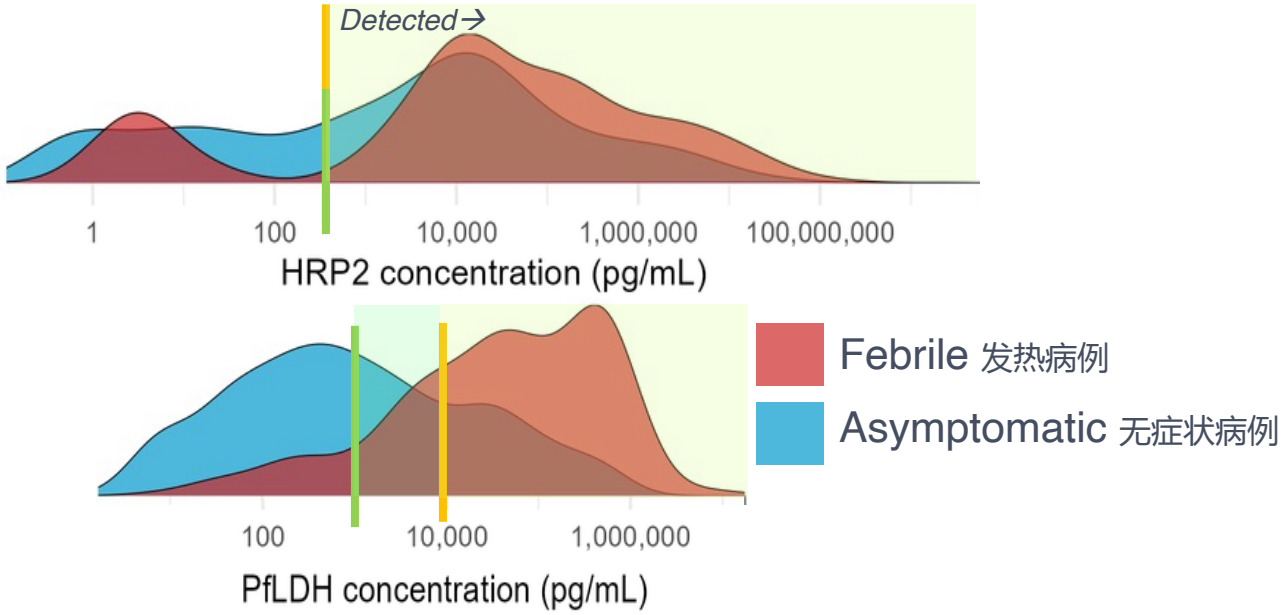
| 50 | 4637 | 11223 | | | | | |
| 30 | 2866 | 6165 | | | | | |
| 20 | 1304 | 2990 | | | | | |
| 15 | 981 | 2931 | | | | | |
| 10 | 700 | 1871 | | | | | |
| 8 | 510 | 1350 | | | | | |
| 5 | 351 | 873 | | | | | |
| 3 | 183 | 502 | | | | | |
| 1.5 | 108 | 239 | | | | | |
| 0.75 | 50 | 107 | | | | | |

**LODs can be compared to clinical antigen distributions 检测限可与临床抗原分布进行比较。**
**RDTs with improved PfLDH sensitivity may detect more febrile and asymptomatic cases**
**PfLDH 灵敏度提升的快检试剂可能检出更多发热病例和无症状病例。**

*Distributions adapted from Ref. 2*




## Correlation of analytical sensitivity to clinical performance分析灵敏度与临床性能的相关性


1. Analytical Sensitivity Analysis and Clinical Impact Modeling of Rapigen Rapid Diagnostic Tests for Malaria https://doi.org/10.4269/ajtmh.24-0003
   Rapigen 疟疾快检的分析灵敏度分析与临床影响建模
2. Performance and usability evaluation of three LDH-based malaria rapid diagnostic tests in Kédougou, Senegal https://doi.org/10.1101/2024.12.12.24318945
   在塞内加尔凯杜古地区开展的三款基于LDH的疟疾快检试剂的性能与易用性评估
3. Performance of a novel *P. falciparum* rapid diagnostic test in areas of widespread *hrp2/3* gene deletion https://doi.org/10.1093/cid/ciaf212
   一款新型恶性疟原虫快检试剂在 hrp2/3 基因广泛缺失地区的性能表现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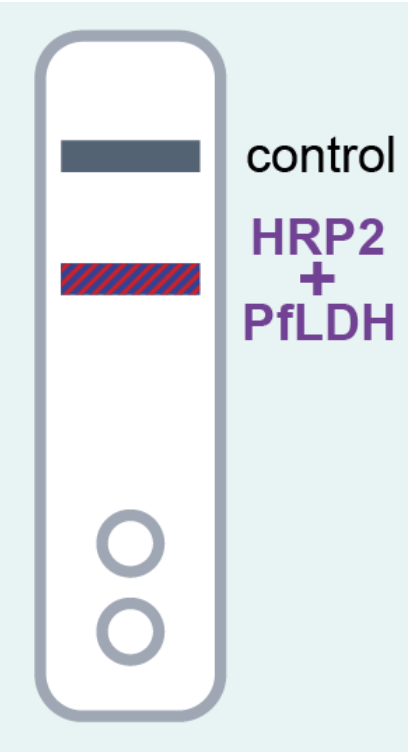
# Feasibility of detecting P. falciparum infections with hrp2/3 deletions using next-generation RDTs　使用新一代快检试剂检测hrp2/3缺失的Pf感染的可行性




| All study participants* 所有研究参与者 | | |
|---|---|---|
| **RDT 快速诊断检测** | **Sensitivity 灵敏度 (PCR)（聚合酶链式反应）** | **Sensitivity灵敏度 (microscopy +ve and PCR +ve) 显微镜检测阳性且聚合酶链式反应检测阳性** |
| Conventional [HRP2] (Abbott) 传统型 | 55.9% (95% CI: 51.7-60.1) | 68.5% (95% CI: 63.9-72.8) |
| Combo Line [HRP2+LDH] (Abbott) 联合检测线 | 77.4% (95% CI: 73.7-80.8) | 94.8% (95% CI: 92.3-96.7) |
| **Study participants with confirmed *hrp2* + *hrp3* dual deletions (n=146) 经确认存在 hrp2 与 hrp3 双基因缺失的研究参与者（样本量 = 146）** | | |
| **RDT快速诊断检测** | **Sensitivity (PCR)** | **Sensitivity (microscopy +ve and PCR +ve)** |
| Conventional [HRP2] (Abbott) | 15.8 (95% CI:10.3-22.7) | 26.1% (95% CI: 17.3-36.6) |
| Combo Line [HRP2+LDH] (Abbott) | 54.1% (95% CI: 45.7-62.4) | 89.8% (95% CI: 81.5-95.2) |

**489 Pf positive by microscopy and 549 by PCR.显微镜检测确诊Pf阳性的有489 例，PCR检测确诊阳性的有549 例。*

Performance of the conventional RDT vs Combo line RDT for *P. falciparum* across two clinics in Oromia and Bahir Dar.  Manfredo et al., Golassa L. *Clin Infect Dis. 2025:* 10.1093/cid/ciaf212

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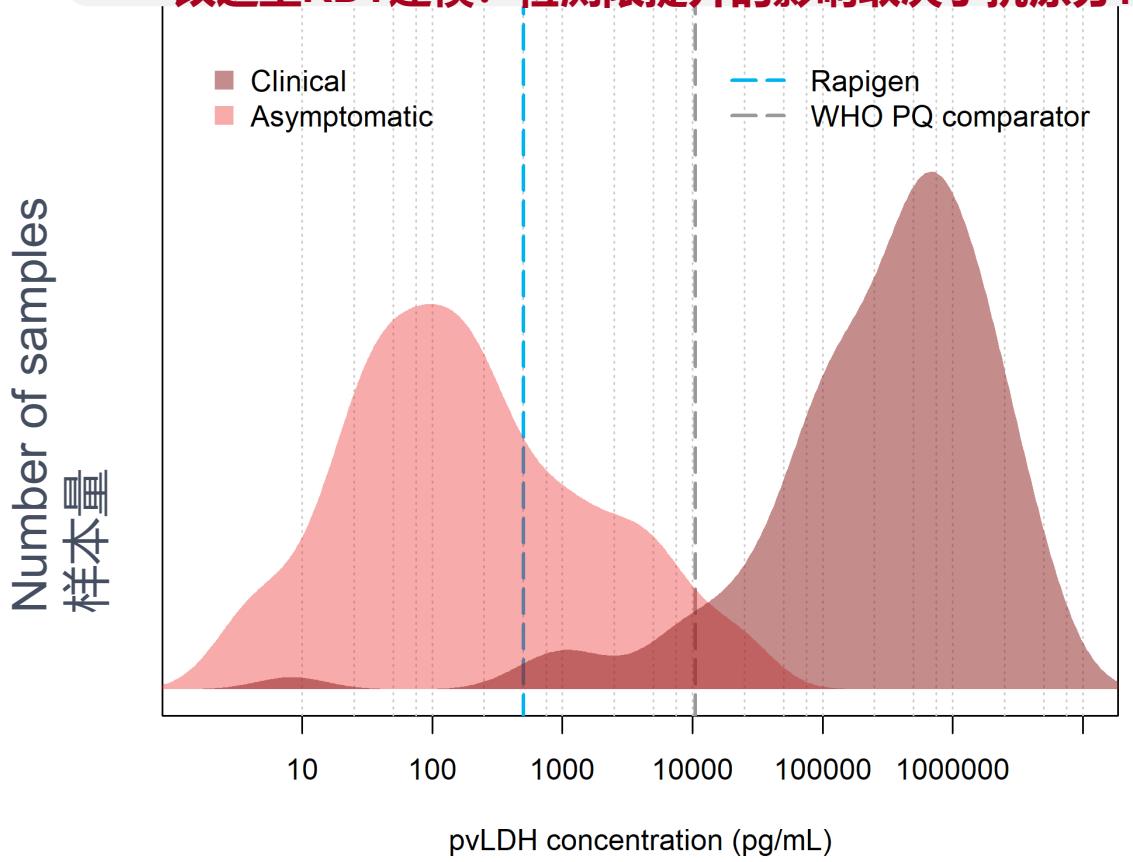
# Estimating performance based on antigen concentration for *P. vivax*
# 基于间日疟原虫(Pv)抗原浓度估算检测性能

## NIBSC Pv antigen standard
## NIBSC Pv 抗原标准

| NIBSC Pv antigen NIBSC# 19/116 | | Rapigen Pf/Pv | Pf/Pv PQ comp. |
|---|---|---|---|
| Units | Q-Plex measured pg/mL | PvLDH test line | PvLDH test line |
| IU/mL | PvLDH | Positive/total replicate tests | |
| 4,000 | > ULQ | 5/5 | 5/5 |
| 400 | 99,553 | 5/5 | 5/5 |
| 200 | 45,480 | 5/5 | 5/5 |
| 100 | 23,196 | 5/5 | 5/5 |
| 50 | 13,506 | 5/5 | 5/5 |
| 25 | 4,122 | 5/5 | 3/5 |
| 15 | 2,534 | 5/5 | 0/5 |
| 10 | 1,807 | 5/5 | 0/5 |
| 5 | 927 | 5/5 | 0/5 |
| 2.5 | 484 | 3/5 | 0/5 |
| 1 | 191 | 2/5 | |

*NIBSC WHO International Standard for Pv antigen (NIBSC code: 19/116). Reconstituted material is further diluted into pooled negative whole blood. Highlighted cells show where the majority of replicates tested were positive. NIBSC* WHO间日疟原虫（Pv）抗原国际标准品（19/116）。复溶后的物质需进一步稀释到混合阴性全血中。高亮显示的单元格代表在多数重复检测中呈阳性的情况。

## Modeling of improved RDT: improved limit of detection impact depends on distribution
## 改进型RDT建模：检测限提升的影响取决于抗原分布




PvLDH distribution example shown above:上述所示为PvLDH分布示例:

- 349 samples: ultrasensitive PCR-positive Pv-positive
  - Asymptomatic, Eastern Myanmar (Landier et al. 2018)
- 114 samples: febrile patients, microscopy Pv-positive
  - FIND, Discovery Life Sciences

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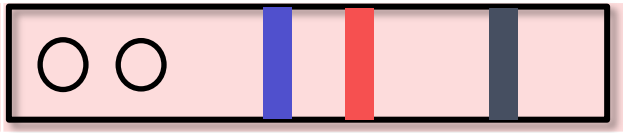
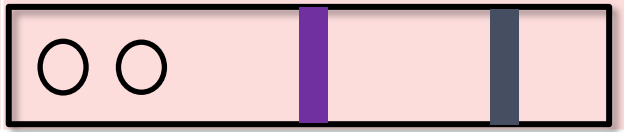
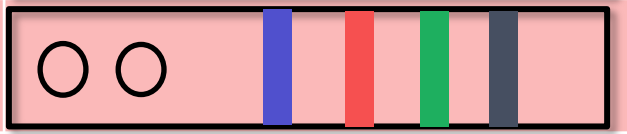
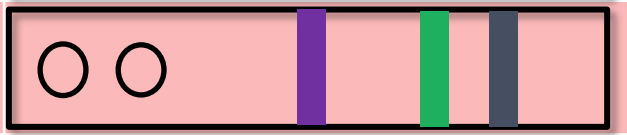
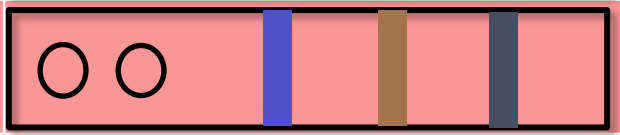
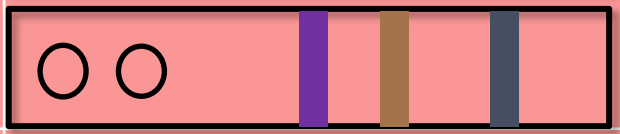
# Next-Gen formats 新一代快检方式

Near term solutions of Next-Gen RDTs for *P. falciparum* need to include detection of BOTH HRP2 and PfLDH. **New tests need to have higher sensitivity for pLDH.** **恶性疟原虫新一代快检的近期解决方案需同时包含对HRP2和PfLDH的检测。新型检测试剂需对pLDH具备更高的灵敏度。**

HRP2 | PfLDH | HRP2 + PfLDH | PvLDH | PanLDH | HRP2 + PanLDH | control

| Test 检测 | Description 描述 | Test lines* 检测线 |
|---|---|---|
| Pf only | Separated HRP2 and **higher sensitivity PfLDH** line<br>分离的HRP2检测线与更高灵敏度的PfLDH检测线。 |  |
| | Combined HRP2 and **higher sensitivity PfLDH** in single test line<br>在单条检测线中整合HRP2与更高灵敏度的PfLDH检测功能。 |  |
| Pf/Pv | Separated HRP2 and **higher sensitivity PfLDH** line with higher sensitivity PvLDH line. Multi-line test has poorer usability.分离的HRP2检测线、更高灵敏度的PfLDH检测线，以及更高灵敏度的PvLDH检测线。多线检测（试纸条）的易用性较差。 |  |
| | Combined HRP2 and **higher sensitivity PfLDH** in single test line with higher sensitivity PvLDH line.<br>在单条检测线中整合HRP2与更高灵敏度PfLDH的检测功能，同时配备更高灵敏度的PvLDH检测线。 |  |
| Pf/Pan or Pan | Separated HRP2 and **higher sensitivity PanLDH line.** Option to also include a PfLDH line, though with poorer usability 分离的HRP2检测线与更高灵敏度的PanLDH检测线。也可选择额外增设一条PfLDH检测线，但会导致易用性下降。 |  |
| | Combined HRP2 and **higher sensitivity PfLDH** in single test line with higher sensitivity PanLDH line. Differentiate Pf with deletions from PanLDH. 在单条检测线中整合HRP2与更高灵敏度的PfLDH检测功能，同时配备更高灵敏度的PanLDH检测线。通过PanLDH检测区分存在（基因）缺失的恶性疟原虫。 |  |
| | Combined HRP2 and **higher sensitivity PanLDH** in single test line. All malaria detection<br>在单条检测线中整合HRP2与更高灵敏度PanLDH检测功能。（可实现）所有疟疾类型的检测。 |  |

◆ *Preferred format for market for usability*
*市场上兼顾易用性的优选方式*

**Specific line order based on manufacturer R&D*
*基于生产商研发的特定检测线顺序*

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# Summary概要

- There is an immediate and growing need for diagnostic tests that detect *P.falciparum* infections REGARDLESS of whether they express the HRP2 and HRP3 proteins (*hrp2/3* gene deletions) 对于能够不受Pf是否表达 HRP2和 HRP3（即是否存在 hrp2/3 基因缺失）影响、均可检出其感染的诊断检测方法，存在迫切且日益增长的需求。
    - Solution: Next-Gen mRDTs - malaria RDTs that do not rely only on HRP2 to detect *P.falciparum* infections. 解决方案：新一代疟疾快检试剂— 此类试剂并非仅依赖HRP2检测Pf感染。
- HRP2 is still an important target antigen since most *P.falciparum* infections still express HRP2. HRP2仍是一种重要的靶抗原，因为大多数Pf感染仍会表达HRP2。
    - HRP2 assays tend to have better analytical sensitivity and HRP2's relative abundance enhances clinical sensitivity. HRP2检测法通常具有更优的分析灵敏度，且其相对较高的丰度可提升临床灵敏度。
- Some manufacturers are already developing Next-Gen mRDTs. 部分生产商已着手研发新一代疟疾快检试剂。
    - As Next-Gen mRDTs become more available, it is likely that they will have a market advantage over malaria RDTs that ONLY use HRP2 to detect P.falciparum infections. 随着新一代疟疾快检试剂的供应愈发充足，相较于仅依靠HRP2检测Pf感染的传统试剂，前者很可能具备市场优势。
    - In the short term, for Pf detection, the easiest marker to include to mitigate *hrp2/3* deletion risk is Pf-LDH. 短期内，在Pf检测中，若要降低hrp2/3基因缺失带来的检测风险，最易纳入检测体系的标志物是Pf-LDH。

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# Key considerations for mRDT product development and clinical study design

# 疟疾快检产品开发与临床研究设计的关键考量因素

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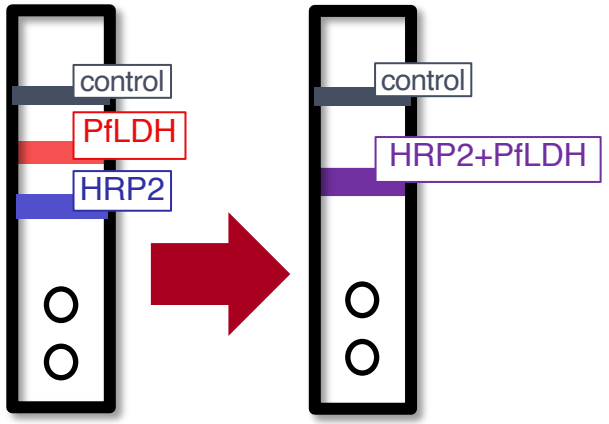
# Developing high quality tests that meet performance targets
# 开发符合性能指标的高质量检测试剂

- **Use high quality reagents to maximize sensitivity**
  **使用高质量试剂以最大限度提高灵敏度**
  - Antibodies which have high on-target sensitivity and high specificity. 具有高靶向灵敏度和高特异性的抗体
  - High quality antigen reagents高质量抗原试剂
- **Improve usability with combined target Pf line　通过组合型Pf靶标线提升易用性**
  - HRP2 and PfLDH detection combined into a single test line
    将HRP2与PfLDH的检测整合到同一条检测线中
  - Test isolated HRP2 and PfLDH antigen **检测分离出的HRP2和PfLDH抗原**
    - Combined should meet or exceed sensitivity to HRP2 and PfLDH as compared to the individual lines **组合后的试剂对 HRP2和 PfLDH的灵敏度应达到或超过各单条检测线对二者的灵敏度。**




- **Use International Standards to understand limit of detection**　使用国际标准了解检测限
  - WHO International Standard for Pf antigens (NIBSC code: 16/376)　恶性疟原虫抗原国际标准品
  - WHO International Standard　for Pv antigens (NIBSC code:19/116)　间日疟原虫抗原国际标准品
  - Traceability for antigen reagents: WHO encourages quality control specimens traceable to a validated reference material 抗原检测试剂的溯源性：WHO鼓励使用可溯源至经验证标准物质的质量控制样本
  - Antigen quantification method　抗原定量方法
- **Include single/double *hrp2* and *hrp3* deletions**　包含 HRP2 和 HRP3 的单/双基因缺失情况
  - Confirm reactivity to PfLDH in the absence of HRP2 (*and HRP3*)　验证在无 HRP2（及 HRP3）存在时，对 PfLDH的检测反应性
  - Understand test reactivity to HRP3　明确检测方法对 HRP3 的检测反应性

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# Current tests, recommended for use in regions with Ihrp2/3 *deletions,* can detect pLDH with higher sensitivity
# 目前推荐在 HRP2/3 基因缺失地区使用的检测试剂，能够以更高灵敏度检测 pLDH

Rapigen Biocredit Pf and Pf/Pv RDTs have met critical criteria by WHO for use in regions with elevated *hrp2/3* deletions.
Rapigen Biocredit 品牌的Pf及Pf/Pv快速诊断试纸条符合WHO针对高 HRP2/3 基因缺失地区使用的关键标准。

- Benchmarking indicates higher analytical sensitivity against PQ'd comparators.
  基准测试表明，相较于预认证的对照品，该检测方法/试剂对Pf的分析灵敏度更高。
- Include PfLDH detection　包含PfLDH检测。

Benchmarking and impact modeling of analytical performance: "Analytical Sensitivity Analysis and Clinical Impact Modeling of Rapigen Rapid Diagnostic Tests for Malaria" 分析性能的基准与影响建模:Rapigen疟疾快检试剂的灵敏度分析与临床影响建模
https://doi.org/10.4269/ajtmh.24-0003

| Test | Antigen Concentration at Which Test has 90% Probability of Positivity | | | |
|---|---|---|---|---|
| | HRP2 (pg/mL) | | PfLDH (pg/mL) | |
| | Median Estimate | 95% Credible Interval | Median Estimate | 95% Credible Interval |
| Rapigen Pf (pLDH/HRPII) | 525 | (407–661) | 1,318 | (1,175–1,479) |
| Rapigen Pf/Pv (pLDH/pLDH) | – | – | 525 | (447–589) |
| WHO PQ comparator HRP2/PfLDH RDT | 1,072 | (955–1,202) | 5,754 | (5,012–6,607) |
| WHO PQ comparator HRP2/PvLDH RDT | 891 | (741–1,047) | – | – |

HRP2 = histadine-rich protein 2; LDH = lactate dehydrogenase; Pf = *Plasmodium falciparum*; pLDH = *Plasmodium* lactate dehydrogenase; PQ = prequalified; Pv = *Plasmodium vivax*.

# Analytical performance targets for next-generation tests 新一代检测试剂的分析性能目标

## NIBSC Pf Ag 16/376

| Based on dilution: IU/mL | Quansys* measured pg/mL | | Current PQ RDTs | | More sensitive PLDH detection RDTs | | Next-gen RDTs |
|---|---|---|---|---|---|---|---|
| | HRP2 | PfLDH | HRP2 | PfLDH | HRP2 | PfLDH | HRP2+ PfLDH |
| 200 | 20454 | 45433 | | | | | |
| 100 | 10550 | 26060 | | | | | |
| 50 | 4637 | 11223 | | | | | |
| 30 | 2866 | 6165 | | | | | |
| 20 | 1304 | 2990 | | | | | |
| 15 | 981 | 2931 | | | | | |
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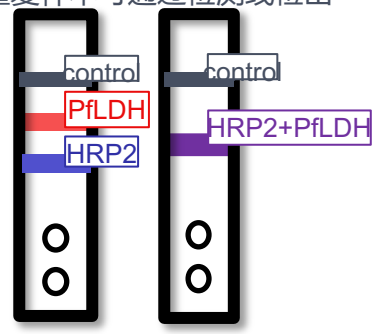
| 8 | 510 | 1350 | | | | | |
| 5 | 351 | 873 | | | | | |
| 3 | 183 | 502 | | | | | |
| 1.5 | 108 | 239 | | | | | |

## 3BD5 culture** (hrp2-/hrp3-)

| Para/ µL | Quansys* measured pg/mL | | Current PQ RDTs | | More sensitive PLDH detection RDTs | | Next-gen RDTs |
|---|---|---|---|---|---|---|---|
| | HRP2 | PfLDH | HRP2 | PfLDH | HRP2 | PfLDH | HRP2+ PfLDH |
| 4500 | 4 | 24934 | | | | | |
| 2250 | 4 | 12639 | | | | | |
| 1125 | 3 | 5718 | | | | | |
| 563 | 2 | 2753 | | | | | |
| 338 | 2 | 1783 | | | | | |
| 225 | 1 | 1129 | | | | | |
| 113 | 2 | 604 | | | | | |
| 56 | 1 | 301 | | | | | |

Majority replicates detected by test line
多数重复样本可通过检测线检出




*Quantification at PATH conducted using Quansys Qplex PATH 采用 Quansys Qplex（技术/平台）进行定量分析
https://www.quansysbio.com/products-and-services/multiplex-assays/human-malaria-5-plex/

**3BD5 strain donated to PATH by NIAID
**3BD5 菌株由NIAID捐赠给PATH

**Understand detection limits of current higher sensitivity tests** to set standard for performance:
明确当前高灵敏度检测试剂的检测限，以设定性能标准：

- **Higher sensitivity tests can detect < 5 IU/mL of International Standard Pf antigen 16/376 and Pv antigen 19/116**
  **高灵敏度检测试剂可检出低于 5 IU/mL的Pf抗原国际标准品 16/376 及Pv 抗原国际标准品 19/116。**
- **Higher sensitivity tests can detect approximately 1 ng/mL PfLDH or lower**
  **高灵敏度检测试剂可检出约 1 ng/mL 或更低浓度的PfLDH。**
- **Higher sensitivity tests can detect approximately 1 ng/mL PvLDH or lower**
  **高灵敏度检测试剂可检出约 1 ng/mL或更低浓度的PvLDH。**

PATH

# Reagents and Resources 试剂和资源

- Antibodies for malaria antigen targets　疟疾抗原靶向抗体
- Recombinant antigens　重组抗原
- International standards　国际标准
- Culture strains and clinical specimens　培养菌株与临床标本
    - PATH is planning to establish a biorepository of specimens (mid-2026).
      PATH计划于 2026 年中建立一个标本生物样本库。
- Evaluation Panels 评估组合
    - PATH is working to provide benchmarking panels accessible to manufacturers (early 2026)
      PATH 正致力于为生产商提供可获取的基准测试组合（2026 年初）
- Independent Evaluation　独立评估
    - Analytical benchmarking: PATH can conduct testing using panels developed from the reagent resources (cost-recovery fee）分析基准测试：PATH可使用基于试剂资源开发的测试组合开展检测（收取成本回收费）
    - In addition to BEI-sourced single and double-deletion Pf strains, PATH cultures Pf strain 3BD5 (hrp2-/3-) and *P. knowlesi* for benchmarking**.　除了来自 BEI（生物危害评估研究所）的Pf单和双基因缺失菌株外，PATH 还培养了用于基准测试的恶性疟原虫 3BD5 菌株（hrp2/hrp3 基因缺失）和诺氏疟原虫。



**3BD5 strain donated by NIAID, *P. knowlesi* donated by Francis Crick Institute

# Antibodies 抗体

| Antibody Supplier name<br>抗体供应商 | Location<br>地区 | Antibodies to malaria proteins offered<br>提供的疟疾蛋白抗体 | Website<br>网站 |
|---|---|---|---|
| Fapon | Dongguan, China and MA, USA<br>中国东莞和美国马萨诸塞州 | HRP2, PfLDH, PvLDH, PanLDH | https://en.faponbiotech.com/ |
| Vista | WA state, USA 美国华盛顿州 | HRP2, PfLDH, PvLDH, PanLDH, PoLDH | https://vistalaboratoryservices.com/ |
| Arista | PA state, USA 美国宾夕法尼亚州 | HRP2, PfLDH, PvLDH, PanLDH | https://www.fortislife.com/arista-biologicals/ |
| Bio Matrix Research Inc. | Japan 日本 | HRP2, PfLDH, PvLDH, PanLDH | http://www.biomatrix.co.jp/en/product.html |
| NBI | Pinetown, South Africa 南非派恩镇 | HRP2, aldolase | https://nbisa.org.za/ |

*Many suppliers have additional antibodies in development or available – ask about new part numbers available*
*许多供应商还有更多处于研发阶段或能提供的抗体 —— 可咨询最新可用的产品编号。*

| | Reactivity Towards LDH from:<br>针对以下来源LDH的反应性 | | | | | |
|---|---|---|---|---|---|---|
| Target Line<br>检测线 | P. falciparum LDH | P. vivax LDH | P. malariae LDH | P. ovale LDH (curtisi & wallikeri) | P. Knowlesi LDH | Human LDH |
| P. falciparum LDH | O | X | 1 | 2 | 1 | X |
| P. vivax LDH | X | O | 2 | 1 | 2 | X |
| Pan LDH | O | O | O | O | O | X |

| | |
|---|---|
| X | **Not acceptable** - should not react with high concentration non-target **不可接受** —— 不应与高浓度非目标物质发生反应 |
| O | **Target affinity** – should be highly reactive 靶标亲和力 —— 应具备高反应性 |
| 1 | **Acceptable** cross reactivity based on treatment decisions 基于治疗决策的可接受交叉反应性 |
| 2 | **Acceptable** but not preferred cross-reactivity based on treatment decisions基于治疗决策的可接受但非优选的交叉反应性 |

# Antigens and International Standards 抗原与国际标准

| Antigen Supplier 抗原供应商 | Species + protein 物种 + 蛋白质 | Website 网站 |
|---|---|---|
| University of Queensland Protein Expression Facility UQ PEF | Pf (LDH), PvLDH, HuLDH, PmLDH, PoLDH (*curtisi*) PoLDH (*wallikeri*) and PkLDH coming soon. | https://pef.facility.uq.edu.au/research-services/malaria-proteins-pef-and-path |
| Span Diagnostics S.A.R.L | Pf (HRP2 type B), A, C PfLDH, PvLDH, PmLDH, PoLDH (w), PoLDH (c), PkLDH, aldolase | https://span-diagnostics.com/products/antigens/ |
| CTK Biotech | Pf (LDH), PvLDH, HRP2, aldolase | https://ctkbiotech.com/ |
| MyBioSource | PfLDH, PvLDH, HRP2 | https://www.mybiosource.com/ |
| Fapon Biotech | pLDH and Pf HRP2 | https://en.faponbiotech.com/ |

*Many suppliers have additional antigens in development or available – ask about new part numbers available*
*许多供应商还有更多处于研发阶段或可提供的抗原 —— 可咨询最新可用的产品编号。*

| Supplier 供应商 | Part Number 编号 | Description 描述 | Website 网站 |
|---|---|---|---|
| National Institute for Biological Standards and Control (NIBSC) 英国国家生物标准与控制研究所 | **16/376** | *Plasmodium falciparum* antigens (1st International Standard) 16/376 | https://nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=16%2f376 |
| National Institute for Biological Standards and Control (NIBSC) | **19/116** | 1st WHO *Plasmodium vivax* antigen (LDH) 19/116 | https://nibsc.org/products/brm_product_catalogue/detail_page.aspx?CatId=19/116 |

# Culture strains and clinical specimens 培养菌株与临床标本

| Culture Parasite 培养的疟原虫 | Source 来源 | Part number 编号 |
|---|---|---|
| ITG, *P. falciparum* | BEI Resources | MRA-326 |
| 3D7, *P. falciparum* | BEI Resources | MRA-102 |
| *W2, P. falciparum* | BEI Resources | MRA-157 |
| Dd2 (*hrp2-/hrp3+*) *P. falciparum* | BEI Resources | MRA-150 |
| HB3 (*hrp2+/hrp3-) P. falciparum* | BEI Resources | MRA-155 |
| LA476-1 (*hrp2-/hrp3-*) *P. falciparum* | BEI Resources | MRA-1332 |

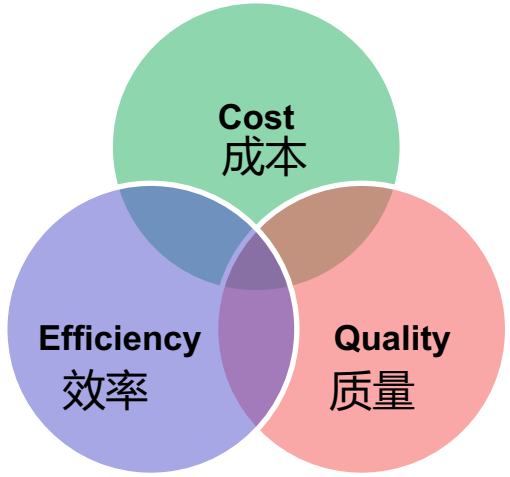
Other strains available 其他可获取的菌株
**BEI Resources :BEI 资源库**
https://www.beiresources.org/Home.aspx

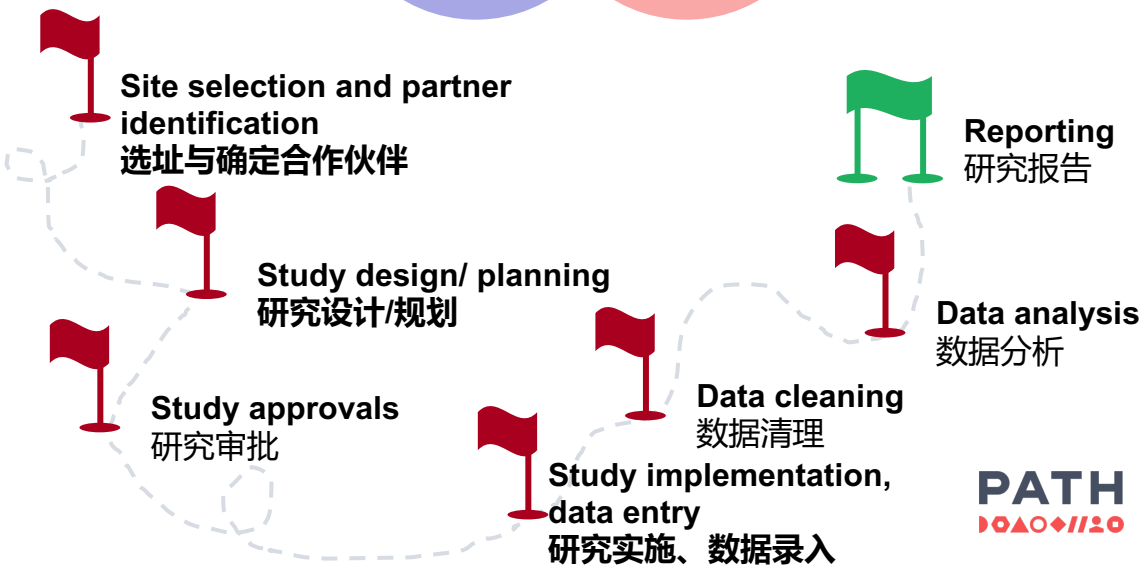
| Sample types样本类型 | Source来源 | notes说明 |
|---|---|---|
| Pf- and Pv-positive clinical samples (febrile).<br>Pf和Pv阳性临床样本（发热病例） | Discovery Life Sciences:探索生命科学公司<br>https://dls.com/biospecimens/ | May require additional confirmation by PCR.<br>可能需要通过PCR进行额外确认。 |
| Pf- and Pv-positive clinical samples<br>Pf和Pv阳性临床样本 | PATH Biorepository, in collaboration with clinical partners<br>PATH 生物样本库（与临床合作伙伴协作） | Planning for availability in 2026<br>计划于 2026 年实现供应 |

# High-quality clinical performance evidence is critical for market access高质量的临床性能证据对于市场准入至关重要


- Inform product performance claims为产品性能声明提供依据
- Required for regulatory submissions监管申报所需材料
- Demonstrate value to buyer向采购方证明产品价值
- Inform product marketing and positioning为产品营销与定位提供参考

# But, clinical research can be time and resource intensive但是，临床研究可能会耗费大量时间和资源



# Clinical strategy planning is essential
# 临床策略规划至关重要

WHO PQ has clear guidelines for malaria RDT verification and validation data: the *TSS-3 Malaria Rapid Diagnostic Tests, Second Edition,* (issued in October 2025).
WHO PQ对疟疾快检试剂的验证和确认数据有明确指南。指南可在此获取（第二版，2025 年 10 月发布）。

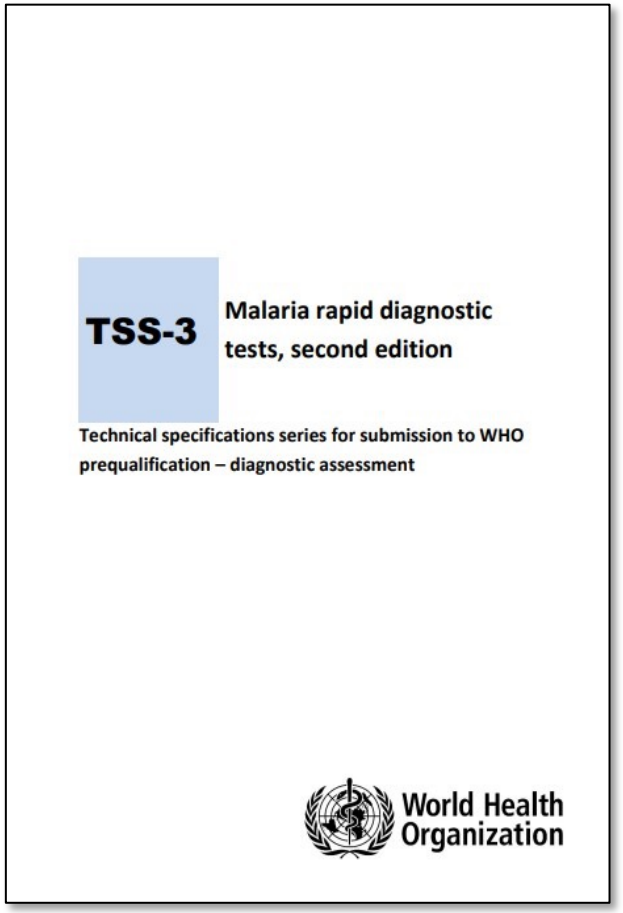
**For clinical sensitivity: 临床灵敏度:**

- At least **400 confirmed *P. falciparum*-positive** specimens from a symptomatic population
  至少 400 份来自有症状人群的Pf阳性确诊标本。
- At least **100 confirmed *P. vivax*-positive** specimens from a symptomatic population.
  至少 100 份来自有症状人群的Pv阳性确诊标本。
- For products with “pan-specific” claims: performance determined for each species for which specimens are available (at minimum *P. falciparum* and *P. vivax)*.
  针对声称具备 “泛特异性” 的产品：需针对可获取标本的每种疟原虫物种测定其性能（至少包含Pf和Pv）。
- Products detecting Pf by pLDH antigen: prospective sampling of **30 specimens with *hrp2/hrp3* gene deletions**, with **at least 20 being double deletions of both *hrp2* and *hrp3*.**
  **通过pLDH抗原检测Pf的产品：需前瞻性采集 30 份含hrp2/hrp3基因缺失的标本，其中至少 20 份为 hrp2 和 hrp3 双基因缺失标本。**

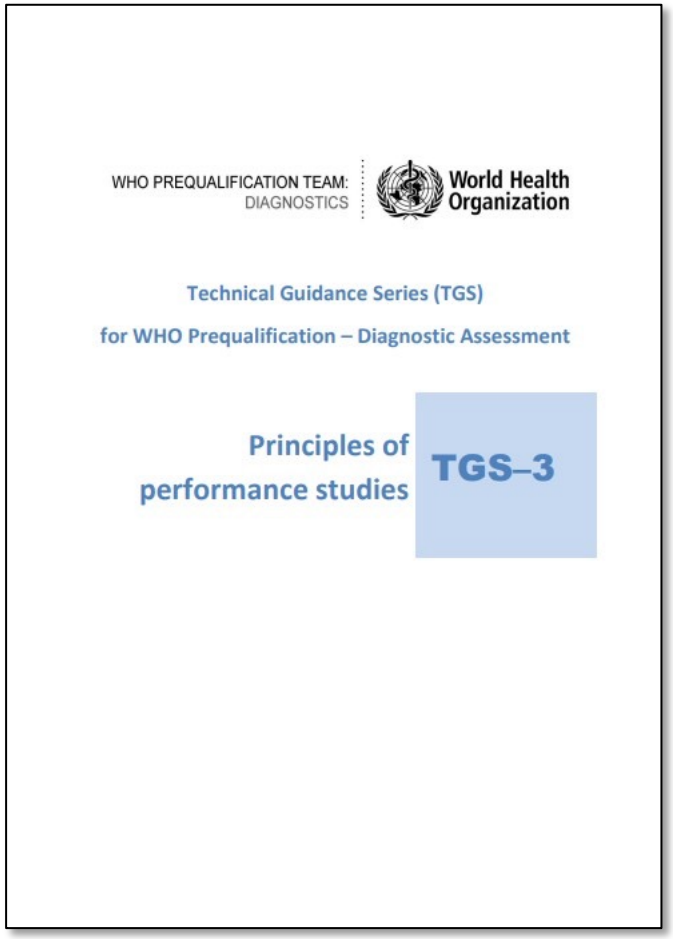
**For clinical specificity:临床特异性**

- At least **1000 *Plasmodium* negative** specimens from a symptomatic population.
  至少 1000 份来自有症状人群的疟原虫阴性标本。

**Clinical studies can also be an opportunity to embed other elements of regulatory data collection that require specimens be collected in intended use settings or require access to intended users (e.g., specimen equivalence, qualification of usability). 临床研究也可以成为一个契机，纳入监管数据收集中的其他要素 —— 这些要素需要在目标使用场景下采集标本，或需要接触到目标使用者（例如，标本等效性验证、可用性确认）。**



# Key IVD clinical research resources
# 关键的体外诊断临床研究资源

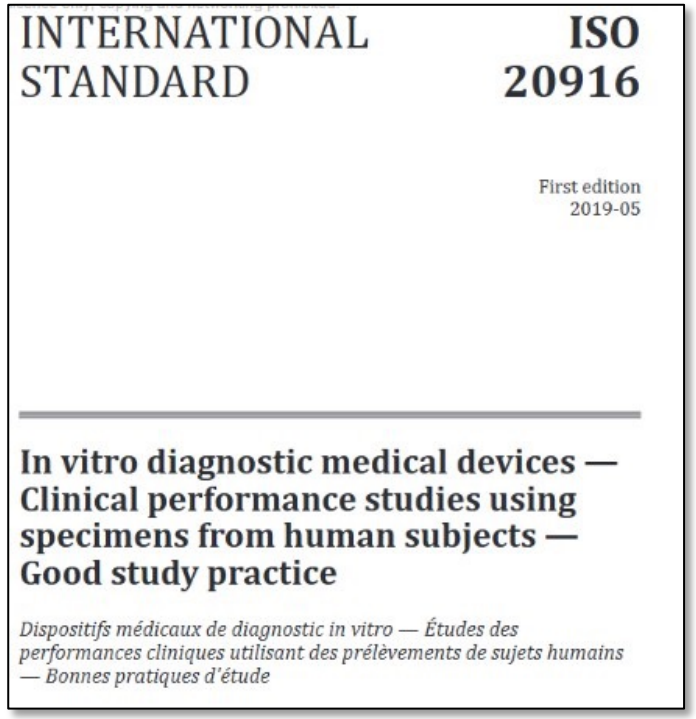



**TGS-3**

specifies the key principles for conducting and reporting performance studies for IVDs that are seeking WHO Prequalification.

**TGS-3** 规定了为寻求WHO PQ的体外诊断试剂开展和报告性能研究的关键原则。

LINK




**ISO 20916**

Defines good study practice for the planning, design, conduct, recording and reporting of clinical performance studies carried out to assess the clinical performance and safety of IVDs for regulatory purposes

**ISO 20916**定义了为监管目的而开展临床性能研究（旨在评估体外诊断试剂的临床性能与安全性）时，该类研究在规划、设计、实施、记录及报告方面的良好研究规范。

LINK (for purchase)

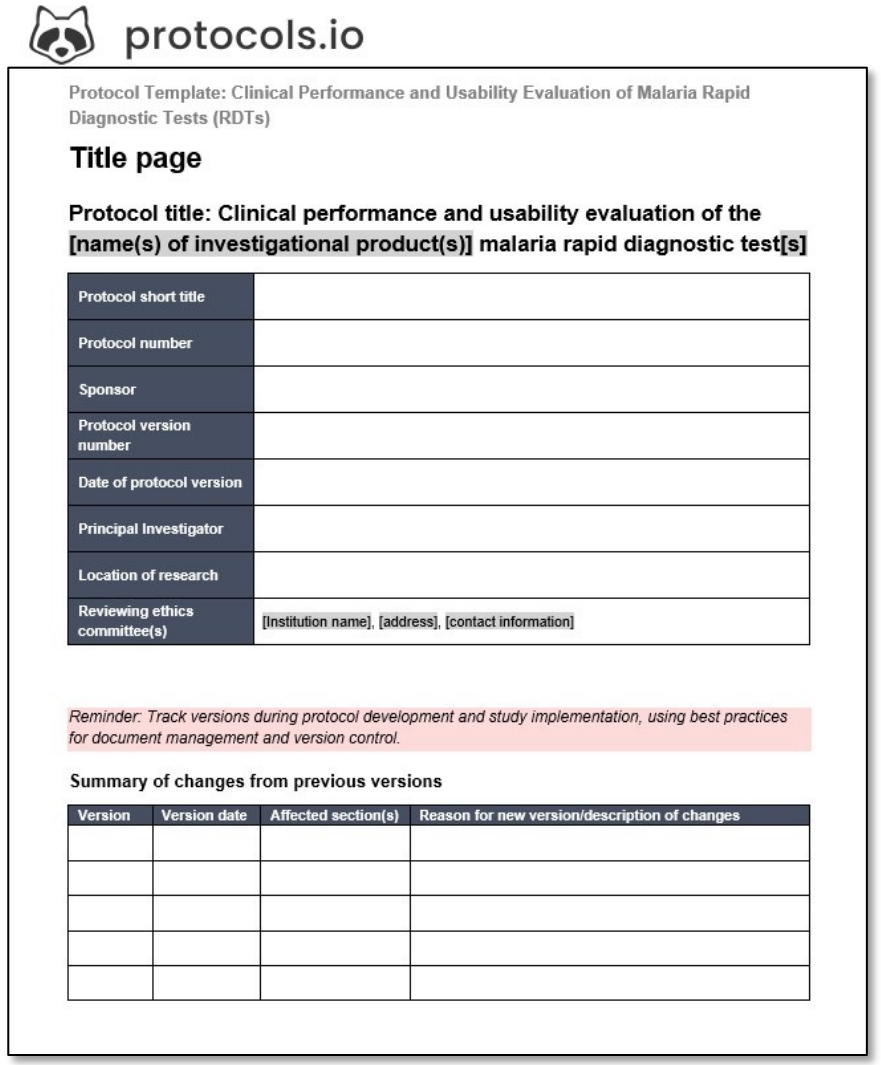
# Resources from PATH to support malaria RDT clinical study design and implementation

## PATH提供的支持疟疾快检试剂临床研究设计与实施的资源

**Available from可从该网站获取:**
dx.doi.org/10.17504/protocols.io.261gekpxdg47/v1

**Includes包括:**

- **Template protocol** for a clinical performance and usability evaluation of one or more malaria rapid diagnostic tests (RDTs). 一种或多种疟疾快检试剂的临床性能与可用性**评价方案模板。**
- Assistance in developing a comprehensive clinical study protocol and in considering key assumptions and elements of study design, planning, and execution.协助制定全面的临床研究方案，并协助考量研究设计、规划与执行过程中的关键假设及核心要素。
- **Additional supportive resources 其他的支持性资源**
  - Template Case Report Forms (CRFs) 病例报告表模板
  - Site selection checklist 研究中心筛选清单
  - Job aides 工作辅助工具
  - Assay resources 检测相关资源
  - Quality control procedures 质量控制程序




*Template is not intended to replace regulatory guidance or formal clinical development planning. Protocols intended to generate data for regulatory submissions must be developed within a comprehensive clinical plan that is aligned with applicable regulatory requirements.*
*本模板并非旨在替代监管指南或正式的临床开发规划。拟用于生成监管申报数据的研究方案，必须在符合适用监管要求的全面临床计划框架内制定。*

# Site selection and partner identification

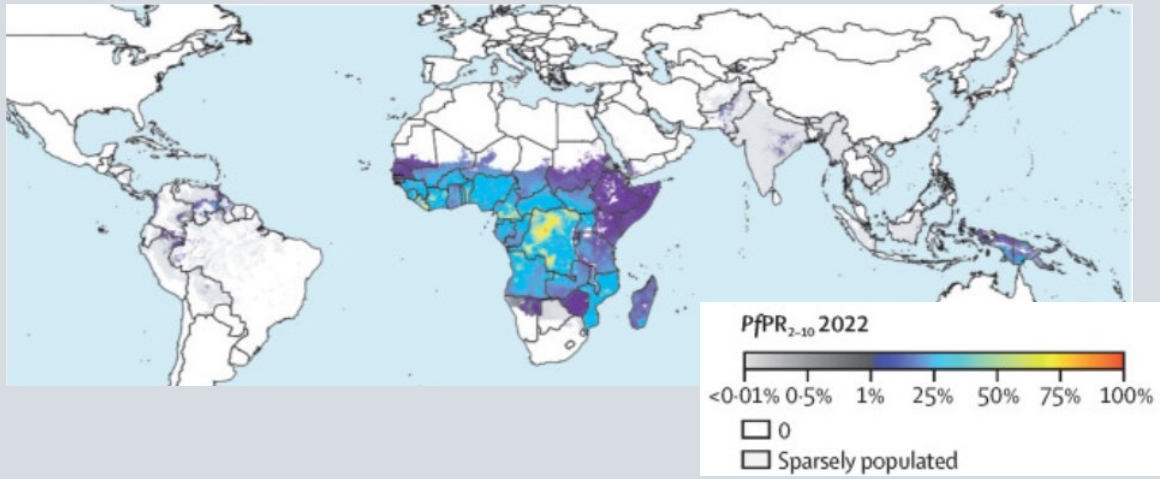
## 研究中心筛选与合作伙伴确定

**Key considerations** 关键考量因素

- At least 2 regions 至少2个地区
- Burden and prevalence 疾病负担与患病率
  - By species 按物种（划分/分类）
  - *pfhrp2/3* deletions *pfhrp2/3*基因缺失
- Site capacity, including: 研究中心能力，包括：
  - Prior experience with IVD and malaria RDT evaluations
    体外诊断试剂及疟疾快检试剂评价的既往经验
  - Laboratory capacity for reference testing
    用于参考检测的实验室能力
  - Experience with Good Clinical Practice compliance and regulatory studies
    具备良好临床实践合规性和监管研究相关经验
- National and ethics and regulatory review requirements and timelines
  国家层面的伦理与监管审查要求及时间安排
- Budget 预算

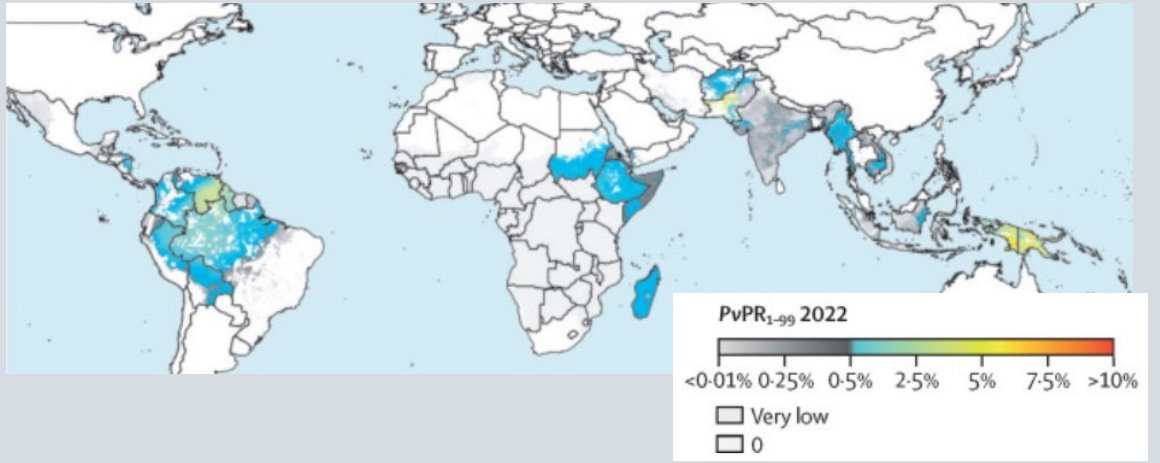
**Estimated prevalence of *P. falciparum* (ages 2-10) Pf感染估计流行率（2-10 岁人群)**

Source: Weiss et al. 2025



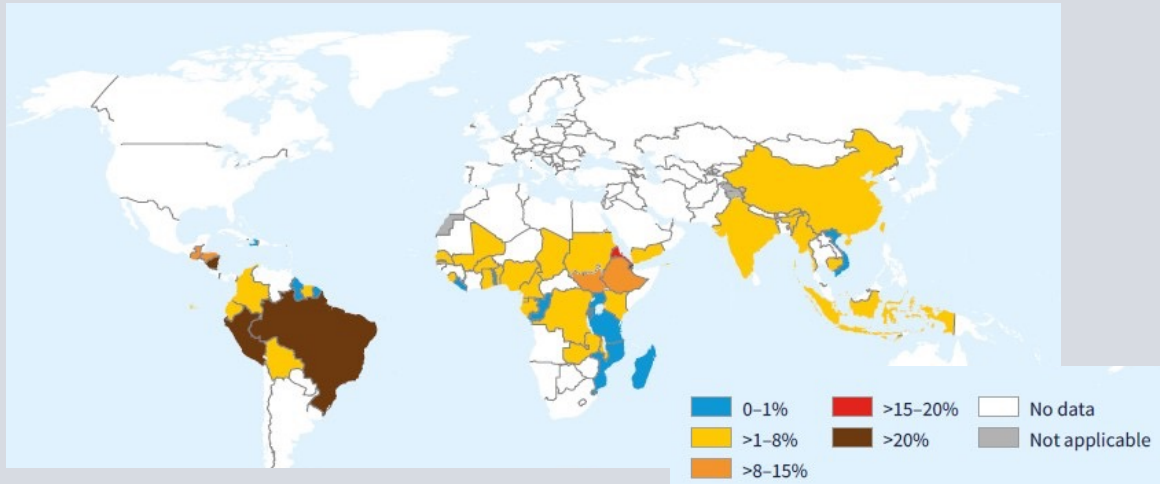

**Estimated prevalence of *P. vivax* (all ages) Pv感染估计流行率（全年龄段)**

Source: Weiss et al. 2025




**Estimated prevalence of *pfhrp2/3* gene deletions (1996-2023) pfhrp2/3 基因缺失估计流行率（1996-2023 年)**

Source: World Malaria Report 2024



# Study design considerations
# 研究设计考虑因素

## Specimen types for RDT performance 快速诊断检测性能评价用样本类型

- Principal sample type is capillary whole blood, secondary is venous.
  主要样本类型为毛细血管全血，次要样本类型为静脉血。
- Venous blood is collected to establish the reference result.
  采集静脉血用于确定参考结果。

## Testing workflow 测试流程

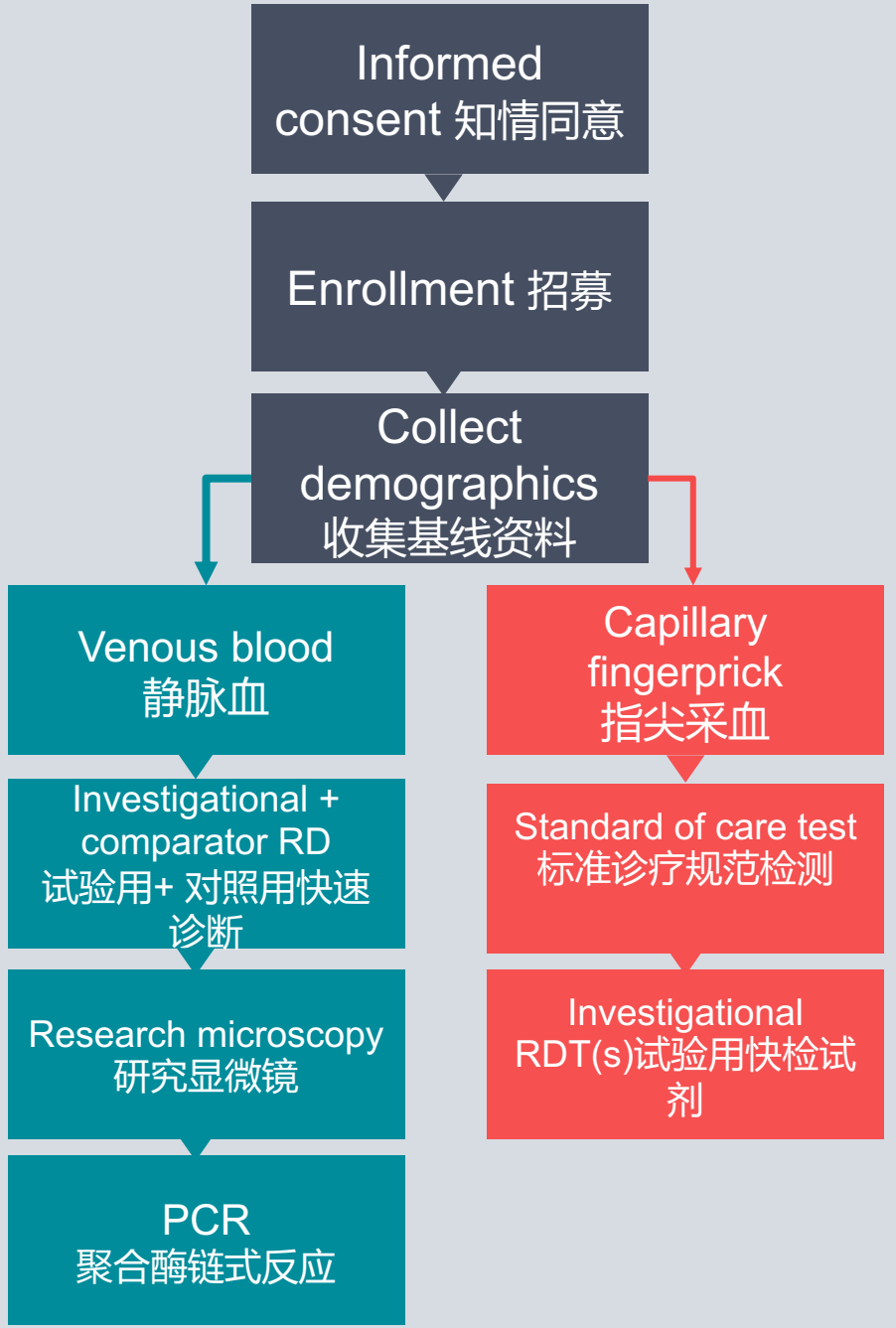
- **Order of procedures**. The study should not interfere with routine care (standard of care test first). **操作顺序**：研究不得干扰常规诊疗（需优先进行标准诊疗检测）
- **Number of tests on capillary.** This should be reasonable, feasible within normal limits, and appropriately justified to minimize discomfort and withdrawals.
  毛细血管血**检测次数**：检测次数应合理、在正常范围内可行，且需提供充分依据以最大限度减少受试者不适及脱落。

## Sampling strategy 抽样策略

- Cross-sectional? 采用横断面抽样?
- Or enriching for a specific type of specimens? (e.g., *pfhrp2/3* deleted)
  或针对特定类型样本进行富集抽样？（例如，针对pfhrp2/3基因缺失型样本）

## Reference method 参考方法

- Per WHO TSS-3: "*The testing algorithm used to determine the reference results shall include microscopy and PCR (for identification/differentiation of species). Justification for the use of the testing algorithm and PCR test chosen shall be provided.*"根据WHOTSS-3 规定：*"用于确定参考结果的检测流程应包括显微镜镜检和聚合酶链式反应（PCR，用于物种鉴定 / 区分）。需提供采用该检测流程及所选 PCR 检测方法的依据。"*



# Test considerations检测考量因素

## RDTs 快速诊断检测

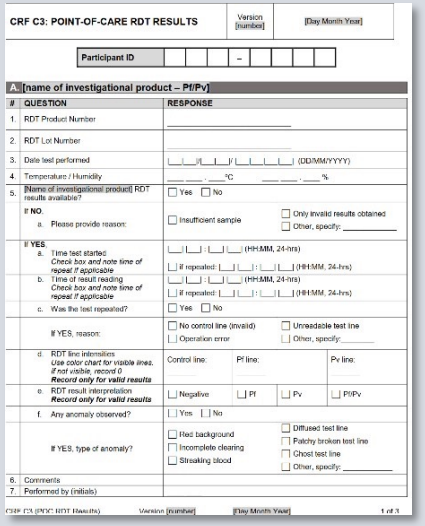
- WHO International Standards can be used for quality control checks at defined time points. These materials can also support user training and proficiency assessment.
  WHO国际标准品可用于在规定时间点进行质控检测。此类物质还可支持用户培训及能力验证评估。

- Record any invalids, environmental conditions during use (temp/humidity), line intensity and, information about anomalies.
  记录所有无效结果、使用过程中的环境条件（温度/湿度）、条带强度，以及异常情况相关信息。

- Comparator tests are important to include. 纳入对照检测十分重要。
  - The rationale for selection of the comparator should be described in the protocol. 应在方案中说明选择对照检测的依据。
  - Recommendations: 推荐选择以下两类对照检测：
    - Current standard of care RDT at site.
      研究中心当前使用的标准诊疗用快速诊断检测
    - WHO Prequalified RDT with a test line for HRP2.
      经WHO PQ且含HRP2检测线的快速诊断检测
      (List available here)

# Resources 资源

## Template Case Report Forms
病例报告表模板



CRF C3: POINT-OF-CARE RDT RESULTS

Version [number] | [Day Month Year]

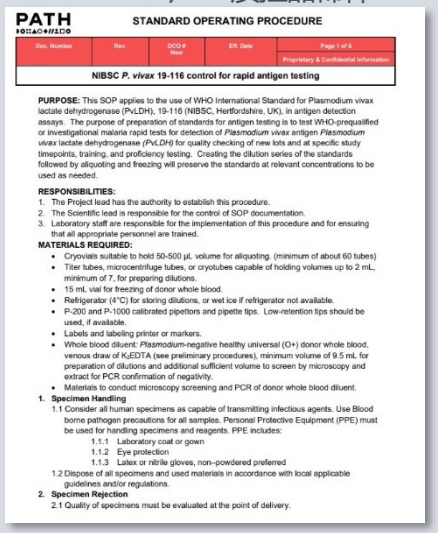
Participant ID

A. [name of investigational product – Pf/Pv]

| # | QUESTION | RESPONSE |
|---|---|---|
| 1. | RDT Product Number | |
| 2. | RDT Lot Number | |
| 3. | Date test performed | (DD/MM/YYYY) |
| 4. | Temperature / Humidity | °C ; % |
| 5. | [Name of investigational product] RDT results available? | Yes / No |
| | If NO, a. Please provide reason: | Insufficient sample; Only invalid results obtained; Other, specify: |
| | If YES, a. Time test started (Check box and note time of repeat if applicable | (HH:MM, 24-hrs) |
| | b. Time of result reading (Check box and note time of repeat if applicable | (HH:MM, 24-hrs) |
| | c. Was the test repeated? | Yes / No |
| | If YES, reason: | No control line (invalid); Unreadable test line; Operation error; Other, specify: |
| | d. RDT line intensities (Use color chart for visible lines, if not visible, record 0. Record only for valid results | Control line: ; Pf line: ; Pv line: |
| | e. RDT result interpretation (Record only for valid results | Negative / Pf / Pv / Pf/Pv |
| | f. Any anomaly observed? | Yes / No |
| | If YES, type of anomaly? | Red background; Incomplete clearing; Streaking blood; Diffused test line; Patchy broken test line; Ghost test line; Other, specify: |
| 6. | Comments | |
| 7. | Performed by (initials) | |

CRF C3 (POC RDT Results) Version [number] [Day Month Year] 1 of 3

## NIBSC *Pv* 19/116 control dilutions SOP
NIBSC Pv 19/116质控品稀释SOP



PATH STANDARD OPERATING PROCEDURE

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NIBSC *P. vivax* 19-116 control for rapid antigen testing

**PURPOSE:** This SOP applies to the use of WHO International Standard for Plasmodium vivax lactate dehydrogenase (PvLDH), 19-116 (NIBSC, Hertfordshire, UK), in antigen detection assays. The purpose of preparation of standards for antigen testing is to test WHO-prequalified or investigational malaria rapid tests for detection of *Plasmodium vivax* antigen *Plasmodium vivax* lactate dehydrogenase *(PvLDH)* for quality checking of new lots and at specific study timepoints, training, and proficiency testing. Creating the dilution series of the standards followed by aliquoting and freezing will preserve the standards at relevant concentrations to be used as needed.

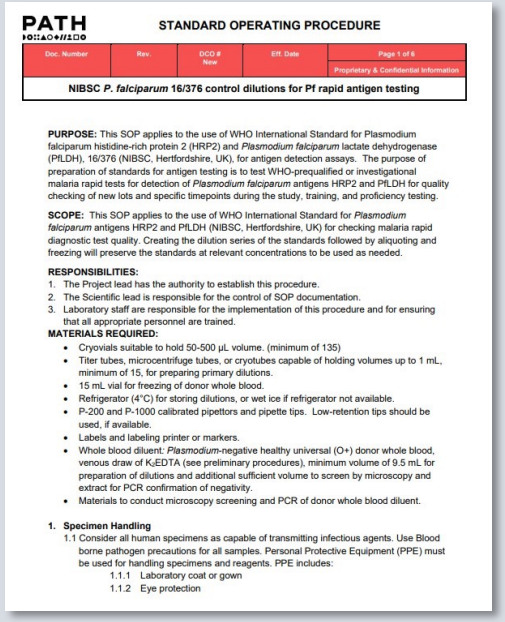
**RESPONSIBILITIES:**
1. The Project lead has the authority to establish this procedure.
2. The Scientific lead is responsible for the control of SOP documentation.
3. Laboratory staff are responsible for the implementation of this procedure and for ensuring that all appropriate personnel are trained.

**MATERIALS REQUIRED:**
- Cryovials suitable to hold 50-500 µL volume for aliquoting. (minimum of about 60 tubes)
- Titer tubes, microcentrifuge tubes, or cryotubes capable of holding volumes up to 2 mL, minimum of 7, for preparing dilutions.
- 15 mL vial for freezing of donor whole blood.
- Refrigerator (4°C) for storing dilutions, or wet ice if refrigerator not available.
- P-200 and P-1000 calibrated pipettors and pipette tips. Low-retention tips should be used, if available.
- Labels and labeling printer or markers.
- Whole blood diluent: *Plasmodium*-negative healthy universal (O+) donor whole blood, venous draw of $K_2$EDTA (see preliminary procedures), minimum volume of 9.5 mL for preparation of dilutions and additional sufficient volume to screen by microscopy and extract for PCR confirmation of negativity.
- Materials to conduct microscopy screening and PCR of donor whole blood diluent.

**1. Specimen Handling**
1.1 Consider all human specimens as capable of transmitting infectious agents. Use Blood borne pathogen precautions for all samples. Personal Protective Equipment (PPE) must be used for handling specimens and reagents. PPE includes:
1.1.1 Laboratory coat or gown
1.1.2 Eye protection
1.1.3 Latex or nitrile gloves, non-powdered preferred
1.2 Dispose of all specimens and used materials in accordance with local applicable guidelines and/or regulations.

**2. Specimen Rejection**
2.1 Quality of specimens must be evaluated at the point of delivery.

## NIBSC *Pf* 16/376 control dilutions SOP
NIBSC Pf16/376 质控品稀释SOP



PATH STANDARD OPERATING PROCEDURE

Doc. Number | Rev. | DCO # New | Eff. Date | Page 1 of 6 | Proprietary & Confidential Information

NIBSC *P. falciparum* 16/376 control dilutions for Pf rapid antigen testing

**PURPOSE:** This SOP applies to the use of WHO International Standard for Plasmodium falciparum histidine-rich protein 2 (HRP2) and *Plasmodium falciparum* lactate dehydrogenase (PfLDH), 16/376 (NIBSC, Hertfordshire, UK), for antigen detection assays. The purpose of preparation of standards for antigen testing is to test WHO-prequalified or investigational malaria rapid tests for detection of *Plasmodium falciparum* antigens HRP2 and PfLDH for quality checking of new lots and specific timepoints during the study, training, and proficiency testing.

**SCOPE:** This SOP applies to the use of WHO International Standard for *Plasmodium falciparum* antigens HRP2 and PfLDH (NIBSC, Hertfordshire, UK) for checking malaria rapid diagnostic test quality. Creating the dilution series of the standards followed by aliquoting and freezing will preserve the standards at relevant concentrations to be used as needed.

**RESPONSIBILITIES:**
1. The Project lead has the authority to establish this procedure.
2. The Scientific lead is responsible for the control of SOP documentation.
3. Laboratory staff are responsible for the implementation of this procedure and for ensuring that all appropriate personnel are trained.

**MATERIALS REQUIRED:**
- Cryovials suitable to hold 50-500 µL volume. (minimum of 135)
- Titer tubes, microcentrifuge tubes, or cryotubes capable of holding volumes up to 1 mL, minimum of 15, for preparing primary dilutions.
- 15 mL vial for freezing of donor whole blood.
- Refrigerator (4°C) for storing dilutions, or wet ice if refrigerator not available.
- P-200 and P-1000 calibrated pipettors and pipette tips. Low-retention tips should be used, if available.
- Labels and labeling printer or markers.
- Whole blood diluent: *Plasmodium*-negative healthy universal (O+) donor whole blood, venous draw of $K_2$EDTA (see preliminary procedures), minimum volume of 9.5 mL for preparation of dilutions and additional sufficient volume to screen by microscopy and extract for PCR confirmation of negativity.
- Materials to conduct microscopy screening and PCR of donor whole blood diluent.

**1. Specimen Handling**
1.1 Consider all human specimens as capable of transmitting infectious agents. Use Blood borne pathogen precautions for all samples. Personal Protective Equipment (PPE) must be used for handling specimens and reagents. PPE includes:
1.1.1 Laboratory coat or gown
1.1.2 Eye protection

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# Test considerations检测考量因素

## Microscopy 显微镜镜检

- WHO TSS-3 recommends microscopy be conducted using venous blood.
  WHO技术规范系列 3（TSS-3）建议采用静脉血进行显微镜镜检。

- There is wide variability in microscopy practices globally.[1] Because of this, even if microscopy is routinely conducted at the study site, plan for **study-specific research-grade** microscopy with defined quality.
  全球范围内，显微镜镜检操作存在较大差异 [1]。因此，即使研究中心常规开展显微镜镜检，也需为研究专属的、具有明确质量标准的研究级显微镜镜检制定方案。

- Research-specific light microscopy for malaria should follow recommended best practices and include:
  疟疾研究专用光学显微镜镜检应遵循推荐的最佳操作规范，具体包括：
  - High quality stain, slides, and microscopes 高质量的染色剂、载玻片及显微镜
  - Trained microscopists (study staff) 经过培训的镜检人员（研究成员）。
  - Multiple independent readers (two, and a third in the case of a discrepancy) 多名独立阅片人员（通常为 2 名；若出现结果不一致，需增加第 3 名阅片人员）。

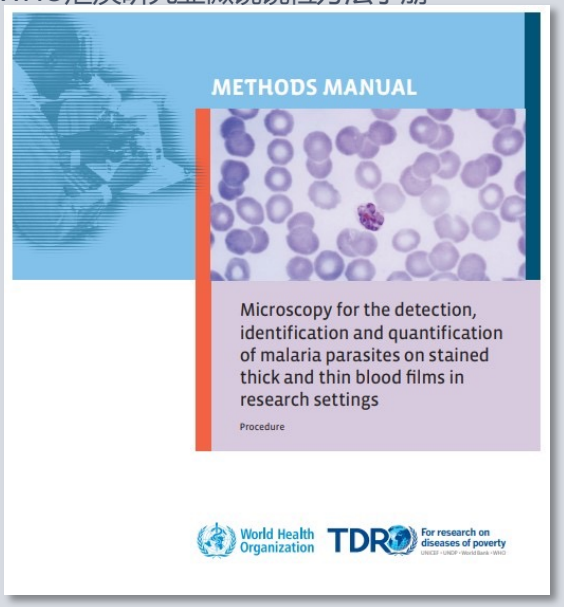
- The Obare Method Calculator (an Excel tool) can also support calculating mean parasite density and assessing concordance.奥巴尔法计算器（一款 Excel 工具）还可支持计算平均寄生虫密度并评估一致性。

[1] Dhorda M, Ba EH, Baird JK, et al. Towards harmonization of microscopy methods for malaria clinical research studies. Malaria Journal. 2020;19(1):324. doi:10.1186/s12936-020-03352-z



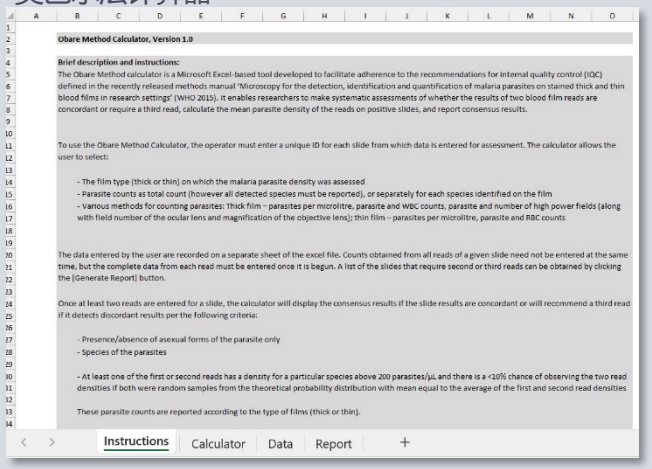
# Resources 资源

### WHO methods manual for research microscopy for malaria
WHO疟疾研究显微镜镜检方法手册



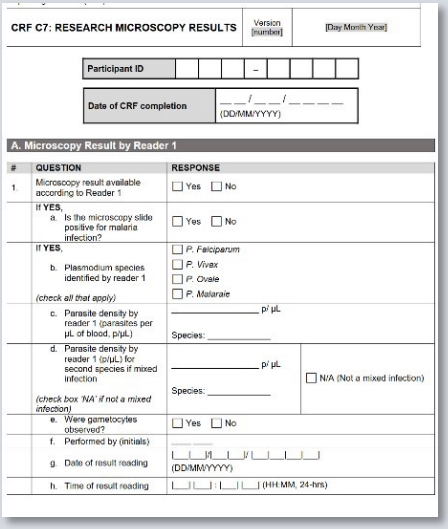

*Source: WHO, 2015*

### Obare Method Calculator
奥巴尔法计算器




*Source: WWARN*

### Template Case Report Forms
病例报告表模板

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*可从 PATH 获取*

# Test considerations检测考量因素

## PCR 聚合酶链式反应

- PCR is recommended as the reference assay (superior performance to microscopy): minimizes classification bias due to species misdiagnosis. 建议将PCR作为参照检测方法（其性能优于显微镜镜检）：该方法可最大限度减少因物种误诊导致的分类偏倚。

- Numerous PCR methods and protocols exist. **Consider a site's capacity and established protocols for PCR in selection.** 目前存在多种PCR方法及试验方案。**选择时，需考虑研究中心开展 PCR 检测的能力以及已有的 PCR 相关试验方案。**

- Real-time, quantitative polymerase chain reaction (qPCR) for quantification and speciation is preferred over qualitative PCR given its potential for greater sensitivity and specificity, reproducibility, lowered risk for contamination, and quantitative output, which can be correlated to parasite density. 用于定量分析和物种鉴定的实时定量qPCR，因其具有更高的灵敏度与特异性、更好的可重复性、更低的污染风险，且能提供可与寄生虫密度关联的定量结果，故比定性 PCR更受青睐。

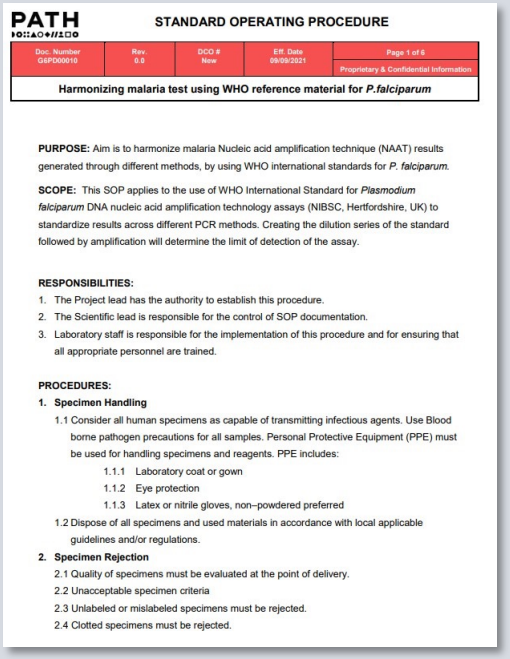
- WHO International Standards can be used to harmonize qPCR results across different methods and sites, and to establish the assay's limit of detection. WHO国际标准品可用于统一不同方法、不同研究中心的实时定量qPCR检测结果，并确定该检测方法的检出限。



## Resources 资源

### NIBSC *Pf* 04/176 control dilutions SOP for molecular and antigen testing

NIBSC Pf04/176 分子检测和抗原检测用质控品稀释SOP



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STANDARD OPERATING PROCEDURE

| Doc. Number | Rev. | DCO # | Eff. Date | Page 1 of 6 |
|---|---|---|---|---|
| G6PD00010 | 0.0 | New | 09/09/2021 | Proprietary & Confidential Information |

**Harmonizing malaria test using WHO reference material for *P.falciparum***

**PURPOSE:** Aim is to harmonize malaria Nucleic acid amplification technique (NAAT) results generated through different methods, by using WHO international standards for *P. falciparum*.

**SCOPE:** This SOP applies to the use of WHO International Standard for *Plasmodium falciparum* DNA nucleic acid amplification technology assays (NIBSC, Hertfordshire, UK) to standardize results across different PCR methods. Creating the dilution series of the standard followed by amplification will determine the limit of detection of the assay.

**RESPONSIBILITIES:**

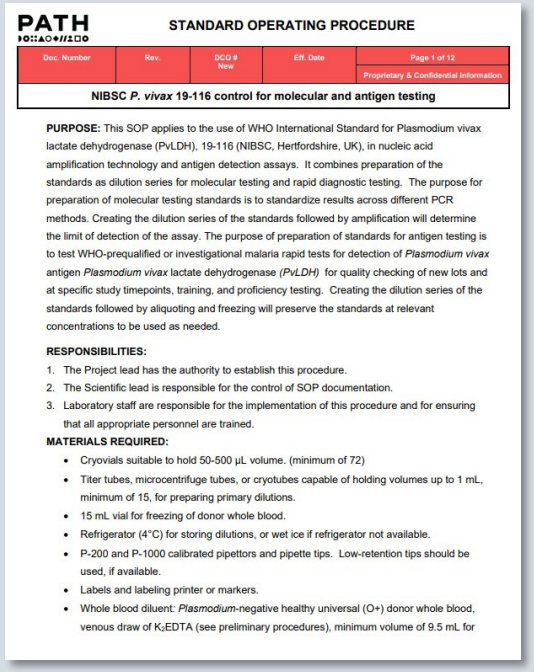
1. The Project lead has the authority to establish this procedure.
2. The Scientific lead is responsible for the control of SOP documentation.
3. Laboratory staff is responsible for the implementation of this procedure and for ensuring that all appropriate personnel are trained.

**PROCEDURES:**

1. **Specimen Handling**
   - 1.1 Consider all human specimens as capable of transmitting infectious agents. Use Blood borne pathogen precautions for all samples. Personal Protective Equipment (PPE) must be used for handling specimens and reagents. PPE includes:
     - 1.1.1 Laboratory coat or gown
     - 1.1.2 Eye protection
     - 1.1.3 Latex or nitrile gloves, non–powdered preferred
   - 1.2 Dispose of all specimens and used materials in accordance with local applicable guidelines and/or regulations.
2. **Specimen Rejection**
   - 2.1 Quality of specimens must be evaluated at the point of delivery.
   - 2.2 Unacceptable specimen criteria
   - 2.3 Unlabeled or mislabeled specimens must be rejected.
   - 2.4 Clotted specimens must be rejected.

### NIBSC *Pv* 19/116 control dilutions SOP for molecular and antigen testing

NIBSC Pv19/116 分子检测和抗原检测用质控品稀释SOP



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| | | New | | Proprietary & Confidential Information |

**NIBSC *P. vivax* 19-116 control for molecular and antigen testing**

**PURPOSE:** This SOP applies to the use of WHO International Standard for Plasmodium vivax lactate dehydrogenase (PvLDH), 19-116 (NIBSC, Hertfordshire, UK), in nucleic acid amplification technology and antigen detection assays. It combines preparation of the standards as dilution series for molecular testing and rapid diagnostic testing. The purpose for preparation of molecular testing standards is to standardize results across different PCR methods. Creating the dilution series of the standards followed by amplification will determine the limit of detection of the assay. The purpose of preparation of standards for antigen testing is to test WHO-prequalified or investigational malaria rapid tests for detection of *Plasmodium vivax* antigen *Plasmodium vivax* lactate dehydrogenase *(PvLDH)* for quality checking of new lots and at specific study timepoints, training, and proficiency testing. Creating the dilution series of the standards followed by aliquoting and freezing will preserve the standards at relevant concentrations to be used as needed.

**RESPONSIBILITIES:**

1. The Project lead has the authority to establish this procedure.
2. The Scientific lead is responsible for the control of SOP documentation.
3. Laboratory staff are responsible for the implementation of this procedure and for ensuring that all appropriate personnel are trained.

**MATERIALS REQUIRED:**

- Cryovials suitable to hold 50-500 µL volume. (minimum of 72)
- Titer tubes, microcentrifuge tubes, or cryotubes capable of holding volumes up to 1 mL, minimum of 15, for preparing primary dilutions.
- 15 mL vial for freezing of donor whole blood.
- Refrigerator (4°C) for storing dilutions, or wet ice if refrigerator not available.
- P-200 and P-1000 calibrated pipettors and pipette tips. Low-retention tips should be used, if available.
- Labels and labeling printer or markers.
- Whole blood diluent: *Plasmodium*-negative healthy universal (O+) donor whole blood, venous draw of $K_2$EDTA (see preliminary procedures), minimum volume of 9.5 mL for

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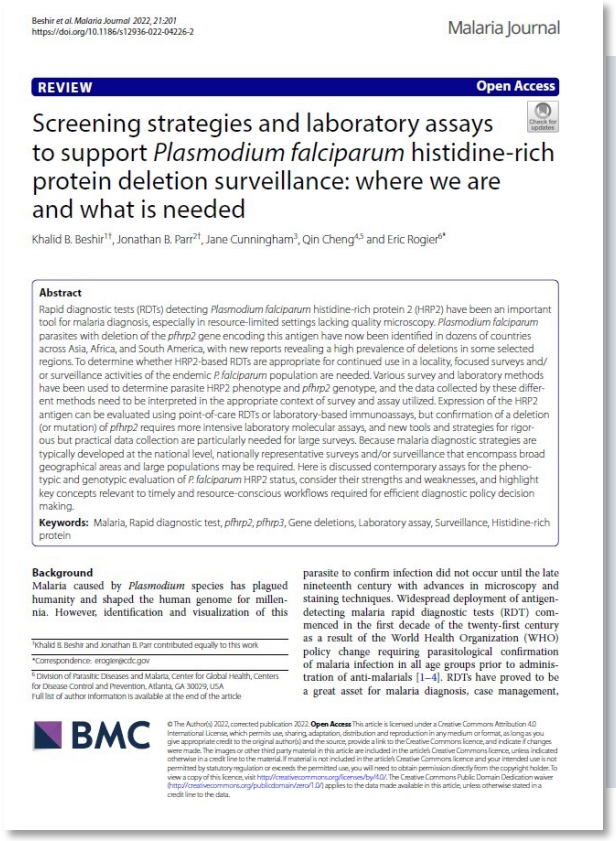
# Test considerations检测考量因素

## *pfhrp2/3* gene deletion assay
## pfhrp2/3 基因缺失检测

- Depending on the goals/objectives of the study, product claims, and the epidemiology at the site, confirmatory testing for *hrp2/hrp3* gene deletion status of *P. falciparum* infections can be conducted. 根据研究目标/目的、产品宣传及研究中心的流行病学情况，可对Pf感染样本的hrp2/ hrp3基因缺失进行确认检测。
- Ideally, all *P. falciparum* positives should be tested. Specimens with discordant profiles (e.g., confirmed positive for *P. falciparum* on PCR but negative on an HRP2-based *P. falciparum* RDT) may be suggestive of potential deletions. 理想情况下，所有Pf阳性样本均应接受检测。有不一致检测结果的样本（例如，PCR检测确认Pf阳性，但基于HRP2的Pf快检结果为阴性），可能提示存在（hrp2/hrp3）基因缺失的可能性。
- Numerous testing methods exist. These include: 存在多种检测方法，包括：
  - Conventional PCR 常规PCR
  - Multi-plex real-time PCR 多重实时PCR
  - Digital PCR 数字PCR
  - Next-generation sequencing (**optimal)下一代测序技术（**最佳方法）
- If PCR is used: employ a validated protocol that has been verified in the performing laboratory, with an established LOD, clear cycle threshold cutoff values, employment of human housekeeping genes to evaluate specimen integrity, and appropriate quality controls. 若使用PCR，应采用经执行实验室验证的标准化实验方案，该方案需满足以下要求：具备已确定的检测限、明确的循环阈值（Ct 值）截断值、使用人类管家基因评估样本完整性，以及配备适当的质量控制措施。

## Resources 资源



Beshir et al. Malaria Journal 2022, 21:201
https://doi.org/10.1186/s12936-022-04226-2

Malaria Journal

REVIEW Open Access

Screening strategies and laboratory assays to support *Plasmodium falciparum* histidine-rich protein deletion surveillance: where we are and what is needed

Khalid B. Beshir[†1], Jonathan B. Parr[†2], Jane Cunningham[3], Qin Cheng[4,5] and Eric Rogier[6*]

**Abstract**

Rapid diagnostic tests (RDTs) detecting *Plasmodium falciparum* histidine-rich protein 2 (HRP2) have been an important tool for malaria diagnosis, especially in resource-limited settings lacking quality microscopy. *Plasmodium falciparum* parasites with deletion of the *pfhrp2* gene encoding this antigen have now been identified in dozens of countries across Asia, Africa, and South America, with new reports revealing a high prevalence of deletions in some selected regions. To determine whether HRP2-based RDTs are appropriate for continued use in a locality, focused surveys and/or surveillance activities of the endemic *P. falciparum* population are needed. Various survey and laboratory methods have been used to determine parasite HRP2 phenotype and *pfhrp2* genotype, and the data collected by these different methods need to be interpreted in the appropriate context of survey and assay utilized. Expression of the HRP2 antigen can be evaluated using point-of-care RDTs or laboratory-based immunoassays, but confirmation of a deletion (or mutation) of *pfhrp2* requires more intensive laboratory molecular assays, and new tools and strategies for rigorous but practical data collection are particularly needed for large surveys. Because malaria diagnostic strategies are typically developed at the national level, nationally representative surveys and/or surveillance that encompass broad geographical areas and large populations may be required. Here is discussed contemporary assays for the phenotypic and genotypic evaluation of *P. falciparum* HRP2 status, consider their strengths and weaknesses, and highlight key concepts relevant to timely and resource-conscious workflows required for efficient diagnostic policy decision making.

**Keywords:** Malaria, Rapid diagnostic test, *pfhrp2*, *pfhrp3*, Gene deletions, Laboratory assay, Surveillance, Histidine-rich protein

**Background**

Malaria caused by *Plasmodium* species has plagued humanity and shaped the human genome for millennia. However, identification and visualization of this parasite to confirm infection did not occur until the late nineteenth century with advances in microscopy and staining techniques. Widespread deployment of antigen-detecting malaria rapid diagnostic tests (RDT) commenced in the first decade of the twenty-first century as a result of the World Health Organization (WHO) policy change requiring parasitological confirmation of malaria infection in all age groups prior to administration of anti-malarials [1–4]. RDTs have proved to be a great asset for malaria diagnosis, case management,

[†]Khalid B. Beshir and Jonathan B. Parr contributed equally to this work

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Full list of author information is available at the end of the article

BMC



支持PfHRP缺失监测的筛查策略与实验室检测方法：现状与需求

Beshir KB, Parr JB, Cunningham J, Cheng Q, Rogier E. Screening strategies and laboratory assays to support *Plasmodium falciparum* histidine-rich protein deletion surveillance: where we are and what is needed. *Malaria Journal*. 2022;21:201. doi:10.1186/s12936-022-04226-2



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# Test considerations 检测考量因素

## Antigen quantification抗原定量

- Optional test, but can allow for comparison of the antigen-based RDT results against a quantitative assay that detects the **cognate analyte**.
  该检测为可选项目，但其能将基于抗原的快检结果与可检测同源分析物的定量检测结果进行对比。

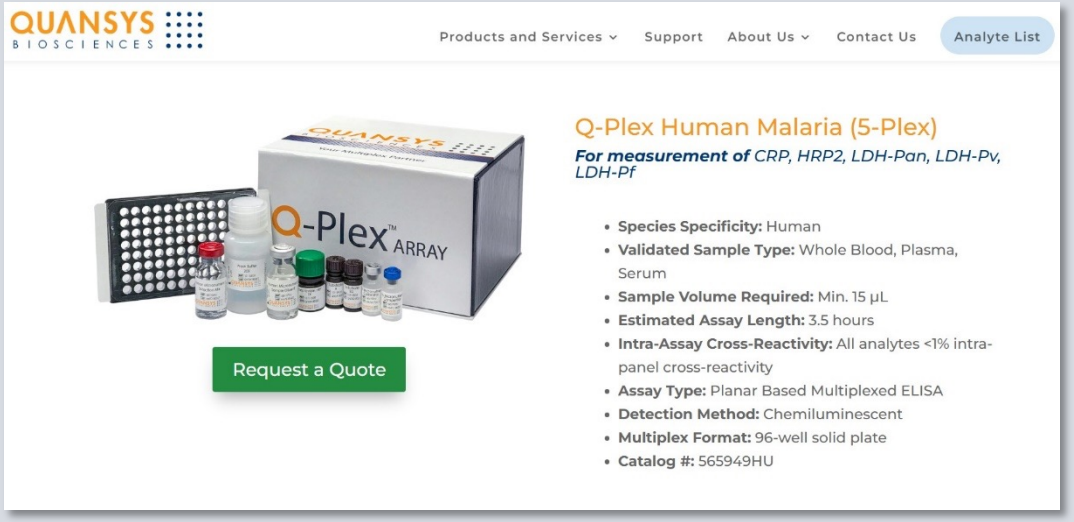
- Reasons to include: 纳入原因
  - Secondary reference test 二级参考检测
  - Confirmatory test to understand discordant results from the primary evaluation 确认性检测以理解主要评估中出现的不一致结果

- Several methods are available. 可用几种方法
  - Commercial assays: 商品化检测试剂 / 检测方法
    - Q-Plex Human Malaria Array (Quansys Biosciences企业名称)
      Q-Plex 人类疟疾检测芯片
    - Quantimal CELISA (Cellabs企业名称) 竞争性酶联免疫法
  - Assays using the Luminex platform have been reported in literature or are under development.
    采用 Luminex 平台的检测方法已有文献报道，或正处于研发阶段。



## Resources 资源

### Q-Plex Human Malaria Array Q-Plex人类疟疾芯片




*Source: Quansys Biosciences*

### Quantimal CELISA for HRP2, pLDH
### Quantimal HRP2、pLDH化学发光酶联免疫吸附测定试剂盒


*Source: Cellabs*

# Visit our website for more information

# 访问我们的网站以获取更多信息

https://www.path.org/who-we-are/programs/diagnostics/partnership-for-acceleration-of-innovative-diagnostics-for-malaria-paradigm/

# Reagent resources available to support manufacturers

# 可用于支持生产商的试剂资源

PATH

# Confronting Diagnostic Challenges: Core Reagent Solutions for Malaria RDTs that Overcome hrp2/3 Deletion and Sensitivity Limitations

# 面对诊断挑战：克服HRP2/3缺失和灵敏度限制的疟疾RDTs核心试剂解决方案

# CONTENTS

01

# About Fapon Biotech
# 关于菲鹏生物

# The world's leading Life sciences organization
# 世界领先的生命科学组织

FAPON BIOTECH

## No.1 in China, global leader

Raw material industry and reagent services

## 中国首选，全球领先

的原料工业和试剂服务

**24**

Years of experience

Over

**1,300**

Patent applications

**50%**

Employees in R&D

## A top player

In the infectious disease segment

## 传染病原料顶级玩家

**70+**

Countries and regions

Over

**2,500**

Global partners

# Driving growth through innovation
# 创新驱动成长




## 2001–2008

Focused on key technologies for three types of IVD raw materials
聚焦三大体外诊断原料

Became China's leading supplier of raw materials for diagnosing infectious diseases
成为中国领先的传染病诊断原材料供应商

- Antibodies抗体
- Diagnostic enzymes诊断酶
- Antigens抗原

## 2009–2015

Expanded to provide reagent services
扩展提供试剂服务

Became a highly recognized Chinese brand in the global IVD raw material market
在全球IVD原料市场成为备受认可的中国品牌

- Core raw materials核心原材料
- Reagent services试剂服务

## 2016–2019

Provided total solutions
提供整体解决方案

Ventured into the pharmaceuticals field
冒险进入制药领域

- Core raw materials核心原材料
- Reagent services试剂服务
- Open-system instruments开放系统仪器
- Pharma制药

## 2020–present2020年至今

Building an ecosystem focusing on three segments
围绕三个细分领域构建生态系统

Began to use AI-powered diagnostic & pharmaceutical solutions
开始使用人工智能驱动的诊断和制药解决方案

- Diagnostics诊断学
- Pharma制药
- AI-powered diagnostics & pharma solutions
- 人工智能驱动的诊断和制药解决方案

We established ourselves as a leader in providing IVD raw materials for infectious diseases
确立了自己在为传染病提供体外诊断原料方面的领先地位。

Our IVD raw materials have been well received in the global market, and we entered the United States and Europe markets.
IVD原材料在全球市场广受欢迎，并已进入美国和欧洲市场。

We have been collaborating with partners to build an integrated ecosystem that encompasses diagnostics and therapeutics.
一直在与合作伙伴合作，建立一个涵盖诊断和治疗的综合生态系统。

# Fapon, as the only Chinese enterprise, joined the external advisory committee of the Pandemic Fund

Fapon作为**唯一一家中**国企业加入**大流行病基金**外部顾问委员会。

## Pandemic Fund:大流行病基金:

- The Pandemic Fund was initiated by the G20 and led by the World Bank. It was established in 2022 with extensive international support from the World Health Organization (WHO), multiple sovereign donors from various countries, and the private sector.
- 流行病基金由二十国集团发起，世界银行牵头。它于2022年成立，得到了世界卫生组织（WHO）、多个国家的主权捐助者和私营部门的广泛国际支持。
- It is the world's first multilateral financing mechanism dedicated to **building the capacity for pandemic prevention, preparedness and response (PPR) in low- and middle-income countries and regions**, filling the gap in dedicated PPR funds and ensuring the sustainability of the global health system by mobilizing more resources.
- 该基金会是世界上第一个致力于在低收入和中等收入国家和地区建设流行病预防、准备和应对能力的多边融资机制，填补了专门用于流行病预防、准备和应对的资金缺口，并通过调动更多资源确保全球卫生系统的可持续性。

The Pandemic Fund
FOR A RESILIENT WORLD

- **Fapon will work together with the Pandemic Fund to enhance disease control capabilities by injecting diagnostic knowledge and technology into countries and regions with underdeveloped medical infrastructure.**
  **Fapon将与大流行病基金合作，通过向医疗基础设施不发达的国家和地区注入诊断知识和技术，增强疾病控制能力。**
- **Fapon is committed to achieving medical equality on a global scale.**
  **Fapon致力于在全球范围内实现医疗平等。**

# Corporate Social responsibilities我们的社会责任

## Serious infectious diseases
## 重大传染病

- We are a leading Chinese provider of raw materials for HIV blood screening tests and we have been collaborating with several WHO-prequalified manufacturers. Additionally, we are a top-tier supplier of raw materials for hepatitis C and syphilis tests.
- Fapon是中国领先的HIV血液筛查检测原材料供应商，我们一直在与几家通过世卫组织资格预审的制造商合作。此外，我们是丙型肝炎和梅毒检测原材料的顶级供应商。

## Tropical infectious diseases
## 热带传染病

- We are the key raw materials supplier for tropical disease tests worldwide.

  菲鹏是全球热带疾病测试的主要原材料供应商。
- We have been exploring co-development opportunities with NGOs in new diagnostic products for tropical diseases, particularly malaria.
- 我们一直在探索与非政府组织共同开发热带疾病，特别是疟疾的创新诊断产品。

## COVID-19
## 新冠肺炎

- We have supplied raw materials for 15 billion COVID-19 tests
- 菲鹏为150亿次新冠肺炎测试提供了原材料
- We have assisted India and Brazil in building their capacity to manufacture their own COVID-19 tests, ensuring a stable supply of reagents during periods of shortage.
- 帮助印度和巴西建立了自己生产新冠肺炎测试的能力，确保在短缺时期稳定供应试剂。
- Donate free PCR test components，during COVID-19 period
- 在新冠肺炎期间，免费捐赠聚合酶链式反应测试组件

02

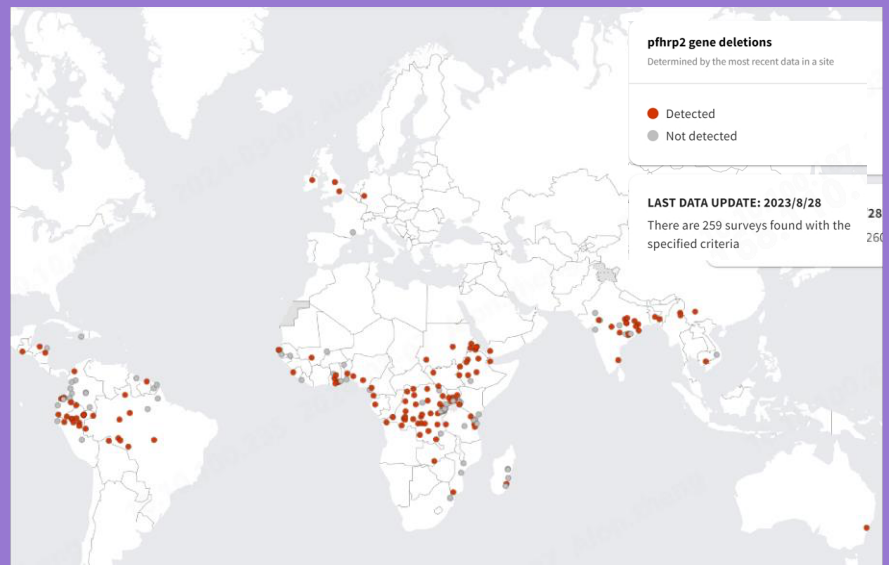
# Core Reagent Solutions for Malaria RDTs

## 疟疾快速诊断测试的核心试剂解决方案

# New Challenges for Malaria Rapid Test 疟疾快速检测面临的新挑战

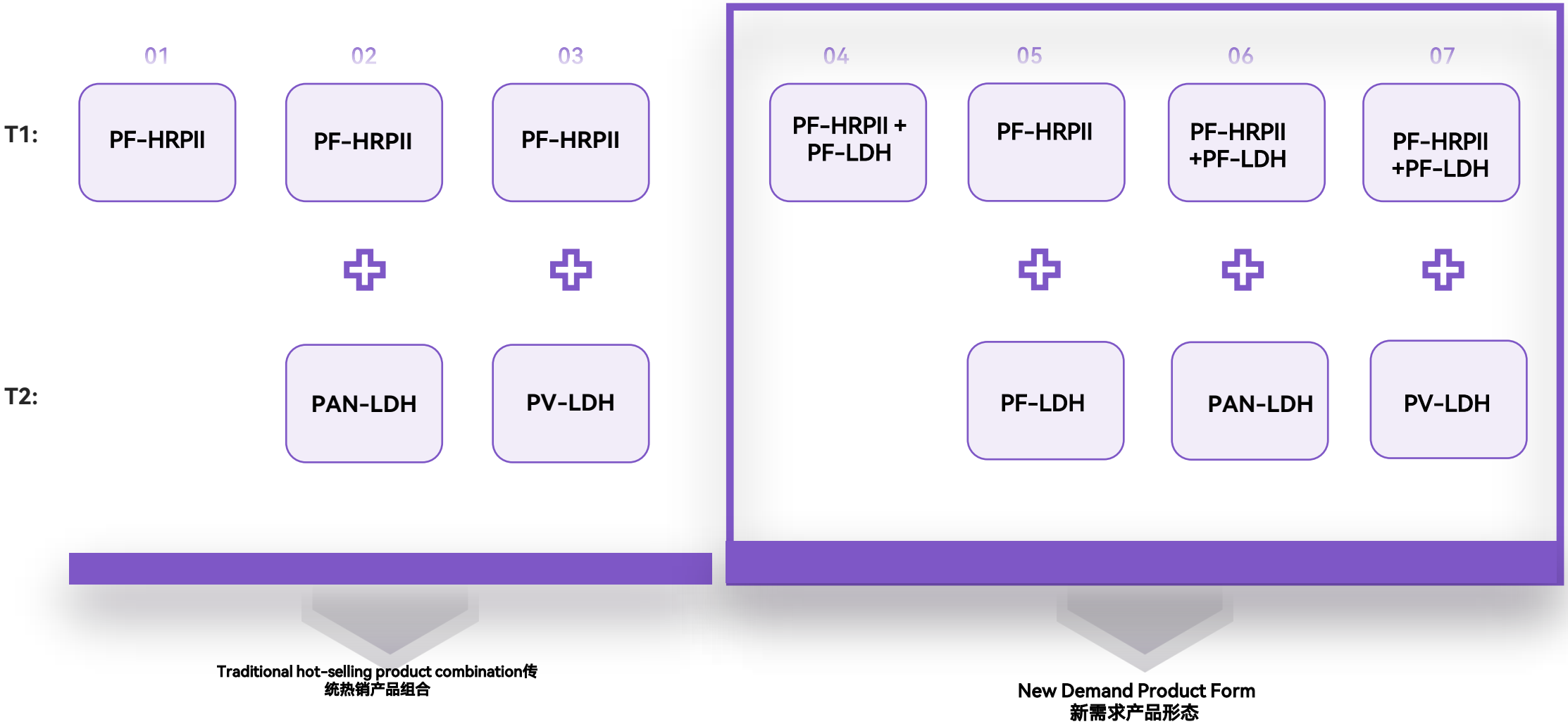
Traditional malaria rapid test products mainly rely on HRP2 as the detection marker, which currently addresses the majority of P. falciparum malaria detection needs. However, an increasing number of countries and regions have reported the presence of Plasmodium parasites with HRP2 gene deletions, leading to missed detection in traditional HRP2-based RDTs. 传统的疟疾快速检测产品主要依靠HRP2作为检测标记，目前解决了大部分恶性疟原虫疟疾的检测需求。然而，越来越多的国家和地区报道了存在HRP2基因缺失的疟原虫，导致传统的基于HRP2的RDTs的漏检。


If the prevalence of Pf-HRP2 deletions causing HRP2 RDT-negative results in symptomatic individuals is found to be common (lower limit of the 95% confidence interval > 5%), countries will have to switch to RDTs that are not solely dependent on HRP2 for the detection of P. falciparum. This issue necessitates the use of highly sensitive Pf-LDH raw materials to improve detection accuracy.如果在有症状的个体中，PF-HRP2缺失导致HRP2 RDT阴性结果的发生率被发现是常见的（95%置信区间的下限>5%），那么各国将不得不改用不完全依赖于HRP2的RDT来检测恶性疟原虫。这个问题需要使用高灵敏度的PF-LDH原料来提高检测精度。




**HRP2 gene deletion means traditional HRP2 marker-based detection methods can no longer meet current testing needs.**
**HRP2基因缺失意味着传统的基于HRP2标记的检测方法已经不能满足当前的检测需求。**

# Diverse Options for Fapon Malaria Diagnostic Raw MaterialsFapon 疟疾诊断原料的多种选择

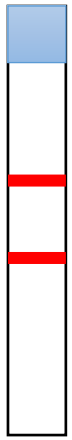



Fapon can provide relevant raw materials for all product combinations.Fapon可为所有产品组合提供相关原材料。

# Performance of Fapon HRPII &HRPII+Pf-LDH　Fapon HRPII&HRPII+PF-LDH的性能

菲鹏生物 FAPON BIOTECH

## HRPII single line　HRPII单线



C-line

T-HRPII

10 IU/mL (NIBSC 16/376)

| Cat# | Blocker | Target | Application |
|---|---|---|---|
| MA-Ab38# | HIER-R-001 | HRPII | Coating |
| MA-Ab36# | | HRPII | Conjugate |

## HRPII+Pf-LDH combine line
## HRPII+PF-LDH 混线

C-lineC线

T-HRPII+ pf-LDH

2 IU/mL (NIBSC 16/376)

## HRPII+LDH double line
## HRPII+LDH双线

C-line

T-pf-LDH 2 IU/mL (NIBSC 16/376)

T-HRPII 10 IU/mL (NIBSC 16/376)

| Cat# | Bocker | Target | Application |
|---|---|---|---|
| MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Conjugate |
| MA-Ab38# | | HRPII | Coating |
| MA-REAB-G2-017 | | Pf-LDH | Coating |
| MA-Ab36# | | HRPII | Conjugate |

**Specificity**: **100%(0/200)**
**特异性:100%（0/200）**

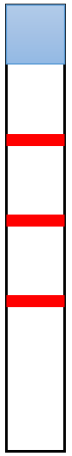
**Cross-reactivity: able to detect HRP3, no cross-reactive with human-LDH ,no cross react with ≤ 1 ug/mL recombinant pv/pm/po-LDH**
**交叉反应：能检测到HRP3，与人LDH无交叉反应，与≤1 ug/mL重组PV/PM/Po-LDH无交叉反应**

# Performance of Fapon HRPII+Pv-LDH & HRPII+Pf-LDH+Pv-LDH

## Fapon HRPII+PV-LDH和HRPII+PF-LDH+PV-LDH的性能

菲鹏生物 FAPON BIOTECH

### HRPII+Pv-LDH combo test
### HRPII+PV-LDH混合检测



C-lineC线

T-pv-LDH 2 IU/mL (NIBSC 19/116)

T-HRPII 10 IU/mL (NIBSC 16/376)

| Cat# | Blocker | Target | Application |
|---|---|---|---|
| MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Coating |
| MA-Ab38# | | HRPII | Coating |
| MA-REAB-G3-016 | | Pv-LDH | Conjugate |
| MA-Ab36# | | HRPII | Conjugate |

**Specificity：100%(0/200)**
**特异性:100%（0/200）**

**Cross-reactivity: able to detect HRP3, no cross-reactive with human-LDH， no cross react with ≤ 1 ug/mL recombinant pf/pm/po-LDH,**
**交叉反应性：能检测到HRP3，与人LDH无交叉反应，与≤1μg/ml重组PF/PM/Po-LDH无交叉反应**

### HRPII+Pf-LDH +Pv-LDH combo test
### HRPII+PF-LDH+PV-LDH混合检测

C-lineC线

T-pv-LDH 2 IU/mL (NIBSC 19/116)

T-HRPII + pf-LDH 2 IU/mL (NIBSC 16/376)

| Cat# | Blocker | Target | Application |
|---|---|---|---|
| MA-REAB-G3-016 | HIER-R-040 | Pv-LDH | Coating |
| MA-REAB-G2-017 | | Pf-LDH | Coating |
| MA-Ab38# | | HRPII | Coating |
| MA-REAB-G4-007 | | Pan-LDH | Conjugate |
| MA-Ab36# | | HRPII | Conjugate |

**Specificity：100%(0/200)**
**特异性:100%（0/200）**

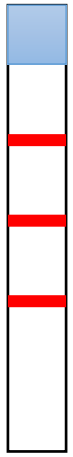
**Cross-reactivity: able to detect HRP3, no cross-reactive with human-LDH， For pf-LDH antibody: no cross react with ≤ 1 ug/mL recombinant pv/pm/po-LDH. For pv-LDH antibody: no cross react with ≤ 1 ug/mL recombinant pf/pm/po-LDH,**

**交叉反应性：能检测到HRP3，与人LDH无交叉反应，pf-LDH抗体与≤1μg/ml重组pv/pm/Po-LDH无交叉反应. Pv-LDH与≤1μg/ml重组pf/pm/Po-LDH无交叉反应**

# Performance of Fapon HRPII+Pan-LDH &HRPII+Pf-LDH+Pan-LDH
## Fapon HRPII+PAn-LDH和HRPII+PF-LDH+Pan-LDH的性能

菲鹏生物 FAPON BIOTECH

### HRPII+Pan-LDH combo testHRPII+PAN-LDH联合试验



C-lineC线

T-pan-LDH 5 IU/ml (NIBSC 16/376) 2 IU/mL (NIBSC 19/116)

T-HRPII 10 IU/ml (NIBSC 16/376)

| Cat# | Blocker | Target | Application |
|---|---|---|---|
| MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Coating |
| MA-Ab38# | | HRPII | Coating |
| MA-REAB-G4-013 | | Pan-LDH | Conjugate |
| MA-Ab36# | | HRPII | Conjugate |

### HRPII+Pf-LDH +Pan-LDH combo test HRPII+PF-LDH+PAN-LDH联合试验

C-lineC线

T-pan-LDH 5 IU/ml (NIBSC 16/376) 2 IU/mL (NIBSC 19/116)

T-HRPII+pf-LDH 2 IU/ml (NIBSC 16/376)

| Cat# | Blocker | Target | Application |
|---|---|---|---|
| MA-REAB-G4-013 | HIER-R-040 | Pan-LDH | Coating |
| MA-REAB-G2-017 | | Pf-LDH | Coating |
| MA-Ab38# | | HRPII | Coating |
| MA-REAB-G4-007 | | Pan-LDH | Conjugate |
| MA-Ab36# | | HRPII | Conjugate |

**Specificity：100%(0/200)**
**特异性:100%（0/200）**

**Cross-reactivity: able to detect HRP3, able to detect recombinant pf/pv/pm/po-LDH ,no cross-reactive with human-LDH ，**
**交叉反应性：能检测HRP3，能检测重组pf/pv/pm/po-LDH，与人LDH无交叉反应**

# Product List

菲鹏生物 FAPON BIOTECH

| Items | Cat# | Blocker | Target | Application | Uncut sheet for Verification |
|---|---|---|---|---|---|
| HRPII single line | MA-Ab38# | HIER-R-001 | HRPII | Coating | MA-PF-HRPII抗原检测胶体金大板-3 |
| | MA-Ab36# | | HRPII | Conjugate | |
| HRPII+Pf-LDH | MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Conjugate | MA PF-HRP II+PF-PLDH抗原混合检测胶体金大板-1 |
| | MA-Ab38# | | HRPII | Coating | |
| | MA-REAB-G2-017 | | Pf-LDH | Coating | |
| | MA-Ab36# | | HRPII | Conjugate | |
| HRPII+Pv-LDH | MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Coating | MA-HRPII+PV联检胶体金大板-2 |
| | MA-Ab38# | | HRPII | Coating | |
| | MA-REAB-G3-016 | | Pv-LDH | Conjugate | |
| | MA-Ab36# | | HRPII | Conjugate | |
| HRPII+Pf-LDH +Pv-LDH | MA-REAB-G3-016 | HIER-R-040 | Pv-LDH | Coating | MA PF-HRP II+PF-PLDH/Pv-PLDH抗原联合检测胶体金大板-1 |
| | MA-REAB-G2-017 | | Pf-LDH | Coating | |
| | MA-Ab38# | | HRPII | Coating | |
| | MA-REAB-G4-007 | | Pan-LDH | Conjugate | |
| | MA-Ab36# | | HRPII | Conjugate | |
| HRPII+Pan-LDH | MA-REAB-G4-007 | HIER-R-040 | Pan-LDH | Coating | MA-HRPII+PAN联检胶体金大板-2 |
| | MA-Ab38# | | HRPII | Coating | |
| | MA-REAB-G4-013 | | Pan-LDH | Conjugate | |
| | MA-Ab36# | | HRPII | Conjugate | |
| HRPII+Pf-LDH +Pan-LDH | MA-REAB-G4-013 | HIER-R-040 | Pan-LDH | Coating | MA PF-HRP II+PF-PLDH/Pan-PLDH抗原联合检测胶体金大板-1 |
| | MA-REAB-G2-017 | | Pf-LDH | Coating | |
| | MA-Ab38# | | HRPII | Coating | |
| | MA-REAB-G4-007 | | Pan-LDH | Conjugate | |
| | MA-Ab36# | | HRPII | Conjugate | |
| Quality control | MA-AG-G1-001 | \ | MA-HRPII-PF | \ | \ |
| | MA-AG-G2-001 | | MA-PLDH-PF | | |
| | MA-AG-G3-001 | | MA-PLDH-PV | | |
| | MA-AG-G7-003 | | MA-PLDH-PM | | |
| | MA-AG-G8-004 | | MA-PLDH-PO | | |
| | MA-AG-G9-005 | | MA-PLDH-PK | | |

## Supporting materials are available in a range of product formats.

**各种产品形式的其他支持材料:**

**Uncut sheet for research or comparison 比对用大卡**

**Technical support service 技术支持服务**

# Fapon Malaria raw material advantages　Fapon疟疾原料优势

菲鹏生物 FAPON BIOTECH

Offers diversified product portfolio formats提供多样化的产品组合形式

Supports clients in obtaining WHO-PQ certification支持客户获得WHO-PQ认证

Delivers excellent product performance
提供卓越的产品性能


Recognized by top domestic and international manufacturers
获得国内外顶级厂商的认可

Accounts for a major share in upstream raw material supply volume
上游核心原材料主要供应商

03

菲鹏生物
FAPON BIOTECH

# Production Capacity and Quality Management System
# 生产能力和质量管理体系

# High-standard
# R&D and production
## 高标准研发和生产

**100,000+** $m^2$
facilities
十万平米生产场地

R&D and manufacture equipment that meets customer needs
满足客户需求的研发和制造设备

High-standard equipment for stringent quality control
高标准设备只为严格质量控制


Antibody discovery 抗体发现


Stable cell line development 开发稳定的细胞株


High cell density culture 高细胞密度培养


Protein purification 蛋白纯化


Physicochemical analysis 物理化学分析


Chemiluminescence immunoassay 化学发光免疫分析

# Well-developed quality management system, SOPs and standards ensure superior quality and steady supply
# 完善的质量管理体系、标准作业程序和标准确保了卓越的品质和稳定的供应

**Fermentation**
**发酵**

More than 100 imported bioreactors with large capacity at our disposable, avoiding cross contamination of products

100多台进口大容量生物反应器可供使用，避免产品交叉污染

Industry-leading production capacity of a single batch of 2,000 L and high consistency in process control, meeting the requirements of various customers for large-scale production

行业领先的单批2000L生产能力，工艺控制一致性高，满足客户各类规模化生产要求

**Purification**
**纯化**

Dozens of ÄKTA fully automatic purifiers, achieving automatic control and operation of key parameters

数十台ÄKTA全自动净化仪，实现关键参数的自动控制和操作；

World-leading production capacity

生产能力处于世界领先水平

**Physicochemical analysis物**
**理化学分析**

The analysis and control methods with pharmaceutical standards, such as SEC-HPLC, CE, CIEF, ensure the consistency of key parameters such as protein purity, structure, and charge heterogeneity in the production process

SEC-HPLC、CE、CIEF等制药级别的分析控制方法，确保了生产过程中蛋白质纯度、结构、电荷异质性等关键参数的一致性。

**Performance evaluation**
**性能评估**

A comprehensive and mainstream screening and quality control platform for chemiluminescence immunodiagnostics, biochemistry, molecular diagnostics and POCT

为化学发光免疫诊断、生化、分子诊断和POCT提供全面和主流的筛选和质量控制平台

Same analyzers as partners to ensure consistency in product quality and compatibility

与合作伙伴相同的仪器，以确保产品质量和兼容性的一致性

# Quality Management System
# 质量管理体系

| Standardization<br>标准化 | Systematization<br>系统化 | Compliance<br>合规 |
|---|---|---|
| • Design and development 设计和开发<br>• Manufacturing processes 制造工艺<br>• QC standards 质量控制标准 | • Dual certifications 双重认证<br>• Full process quality management 全过程质量管理 | • China NMPA compliance 中国NMPA合规<br>• International compliance 国际合规 |

ISO 9001:2015 certified ISO 9001:2015认证


2020 ISO 13485:2016 certified 2020 ISO 13485:2016认证


The well-developed quality management system has also been widely recognized and appraised by customers.
完善的质量管理体系也得到了客户的广泛认可和好评。

# Joining Forces to Meet New Challenges
## 合力应对新挑战

## The WHO's 2030 Goals for Malaria Control and Elimination
### 世卫组织2030年控制和消除疟疾的目标

TABLE 1.GOALS,MILESTONESAND TARGETS FOR *THE GLOBAL TECHNICAL STRATEGY FOR MALARIA 2016-2030*

| GOALS | MILESTONES | | TARGETS |
|---|---|---|---|
| | 2020 | 2025 | |
| 1. Reduce malaria mortality rates globally compared with 2015 | At least 40% | At least 75% | At least 90% |
| 2. Reduce malaria case incidence globally compared with 2015 | At least 40% | At least 75% | At least 90% |
| 3.Eliminate malaria from countries in which malariawas transmitted in 2015 | At least 10 countries | At least 20 countries | At least 35 countries |
| 4. Prevent re-establishment of malaria in all countriesthat are malaria-free | Re-establishment prevented | Re-establishment prevented | Re-establishment prevented |

### Our Collective Efforts 我们共同努力

- Fapon will assist more diagnostic manufacturers in entering the supply chain and help domestic companies expand into overseas markets, making diagnostic reagents more accessible.
- Fapon将协助更多的诊断试剂制造商进入供应链，并帮助国内公司拓展海外市场，使诊断试剂更容易获得。
- Fapon will work closely with partners to keep up with the WHO's new requirements, continuously improve product performance, and enhance diagnostic accuracy.
- Fapon将与合作伙伴密切合作，遵循世卫组织的新要求，不断改进产品性能，提高诊断准确性。
- Together with our partners, we will strive to achieve the WHO's 2030 malaria control and elimination goals.
- 我们将与合作伙伴一起，努力实现世卫组织2030年控制和消除疟疾的目标。

## The Supply Chain for Malaria Diagnostic Product 疟疾诊断产品供应链

**Raw Material Suppliers**
Fapon, etc.

**Reagent Manufacturers**
Mostly Asian manufacturers

**Reviewing Party**
WHO Prequalification (WHO-PQ)

**Payers**
WHO, The Global Fund, and other NGOs

**End-users**
Local clinics, health centers

04

菲鹏生物
FAPON BIOTECH

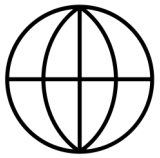
# Discussion讨论

# THANK YOU谢谢你们

菲鹏生物
FAPON BIOTECH

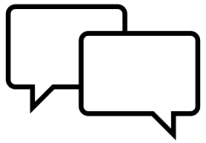
# Break
# 茶歇

# Webinar Information 会议须知



**Language & Interpretation 语言与同声传译**

- This webinar offers simultaneous interpretation in Chinese and English
  本次研讨会提供**中文与英文**的同声传译。
- To access, click the globe “Interpretation” icon on your Zoom toolbar 请点击工具栏上的“口译”功能，
- Select your preferred language and adjust audio settings as needed 并选择你希望听到的语言频道

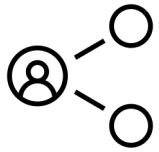


**Question & Feedback 提问与反馈**

- Use the Zoom Chat to submit comments, feedback, or questions throughout the webinar
  (Note your name, organization, and who your question is posed to (if specific) for any questions raised)
  请通过聊天提交评论或问题，注明姓名、机构和提问对象。
- Questions will be monitored and shared during the Q&A sessions 问题将在问答环节汇总分享。

**Interactive Participation 互动参与**

- Mentimeter will be used for polls and reflections during the webinar. More information to follow
  研讨会将使用投票工具收集意见，详情稍后说明。



**Recording & Materials 录制与资料**

- Recording of the webinar and material presented will be shared with participants after the webinar
  会议将录制，会后分享录音和资料。

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# Regulatory pathways and strategy

# 监管途径与策略

# Regulatory considerations监管考量因素

The *in vitro diagnostics (IVD)* market is becoming increasingly regulated, favoring market share for quality products.
体外诊断（IVD）市场的监管正日益严格，这一趋势更有利于优质产品占据市场份额。

Obtaining a stringent regulatory authority review of your product can accelerate registration into other countries through mechanisms such as expedited reviews, and reliance.
通过严格的监管机构对产品进行审查，可借助快速审查、互认等机制，加快产品在其他国家的注册进程。

Malaria RDTs have been successfully reviewed by the Australian TGA and the European CE IVDR mechanisms
疟疾快检试剂已通过澳大利亚治疗用品管理局（TGA）及欧洲《体外诊断医疗器械法规》（CE IVDR）相关机制的审查，并获得认可。

WHO PQ is not a regulatory authority but it seeks to ensure products meet global standards for quality, safety, and performance, particularly for use in low- and middle-income countries
WHO PQ并非监管机构，但其致力于确保产品符合质量、安全性和性能方面的全球标准，尤其针对中低收入国家的使用场景。

- It is essential for manufacturers who want their IVDs to be procured by international agencies like UNICEF, the Global Fund, and WHO procurement programs.
  对于希望其体外诊断试剂被联合国儿基会（UNICEF）、全球基金（the Global Fund）以及WHO采购项目等国际机构采购的生产商而言，获得WHO PQ至关重要。

For malaria RDTs WHO PQ evidence requirements exceed those of most regulatory agencies.
在疟疾快检试剂方面，WHO PQ的证据要求超出了大多数监管机构的要求。

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# Typical Intended Use statements for malaria RDTs

# 疟疾快检试剂的典型预期用途说明

Information available in the WHO PQ Public Assessment Reports (WHO Public Reports for In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control))
WHO PQ公开评估报告中的可用信息（WHO体外诊断器械公开报告 |WHO - 医疗产品预认证（体外诊断器械、药品、疫苗及免疫接种器械、病媒控制产品））

1. ""the Bioline Malaria Ag P.f (HRP2/pLDH) test is a rapid, **qualitative test for the detection of histidine rich protein II (HRP2) antigen and lactate dehydrogenase from Malaria Plasmodium falciparum in human whole blood.** Bioline Malaria Ag P.f (HRP2/pLDH) test is intended for professional use as an initial screening test only. Reactive specimens should be confirmed by a supplemental assay such as microscopic examination of thin blood smear"
   "Bioline 【恶性疟原虫抗原检测试剂盒（HRP2/pLDH）】是一种快速**定性检测试剂盒，用于检测人全血中Pf的HRP2抗原和pLDH**。该试剂盒仅适用于专业人员操作，且仅作为初步筛查检测使用。检测结果呈阳性的样本，需通过补充检测（如薄血涂片显微镜检查）进行确认。"

2. "FalciVax [- Rapid test for Malaria Pv/Pf] is a rapid, qualitative, two site sandwich immunoassay utilizing capillary and venous whole blood specimens of symptomatic patients for the detection of P.falciparum specific histidine rich protein-2 (Pf. HRP-2) and P.vivax specific plasmodium Lactate Dehydrogenase (pLDH) antigens and it is used in aiding the diagnosis and differentiation of malaria infections caused by P.falciparum and P.vivax. It is intended to be used by trained healthcare or laboratory professionals or other health care workers who have received appropriate training. This product can be used by trained lay providers operating at point-of-care in resource-limited settings. This product is not intended for self-testing and it is not for blood donor screening. The test is not automated; it needs to be performed and interpreted manually by the user"
   "FalciVax【恶性疟原虫 / 间日疟原虫疟疾快速检测试剂盒】是一种快速、定性的双位点夹心免疫检测试剂盒，可采用有症状患者的毛细血管全血和静脉全血样本，检测Pf特异性Pf. HRP-2和Pv特异性疟pLDH抗原，用于辅助诊断和区分由Pf与Pv引起的疟疾感染。本产品适用于经过培训的医疗保健人员、实验室专业人员或接受过相应培训的其他卫生保健工作者使用。在资源有限的情况下，经过培训的非专业医疗服务提供者也可在医疗点使用本产品。本产品不适用于自我检测，也不用于献血者筛查。该检测为非自动化检测，需由使用者手动操作并判读结果。"

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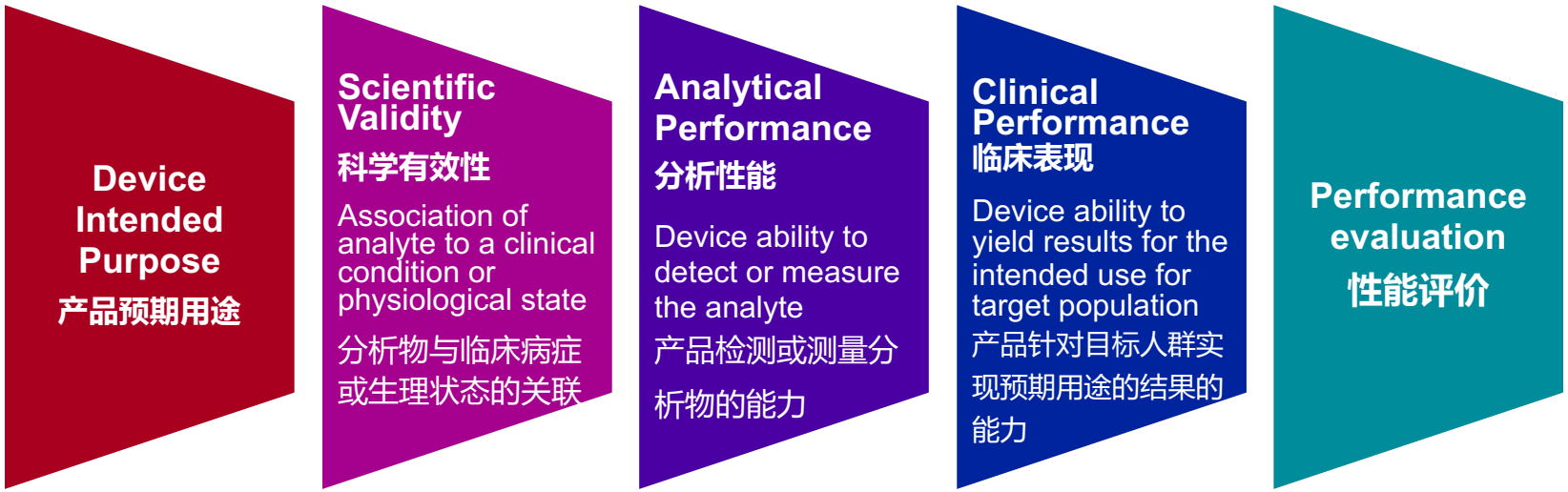
# Define your product claims, intended purpose and most stringent target regulatory requirements early in product development. 产品开发初期就要明确产品宣称、预期用途以及最严格的目标监管要求

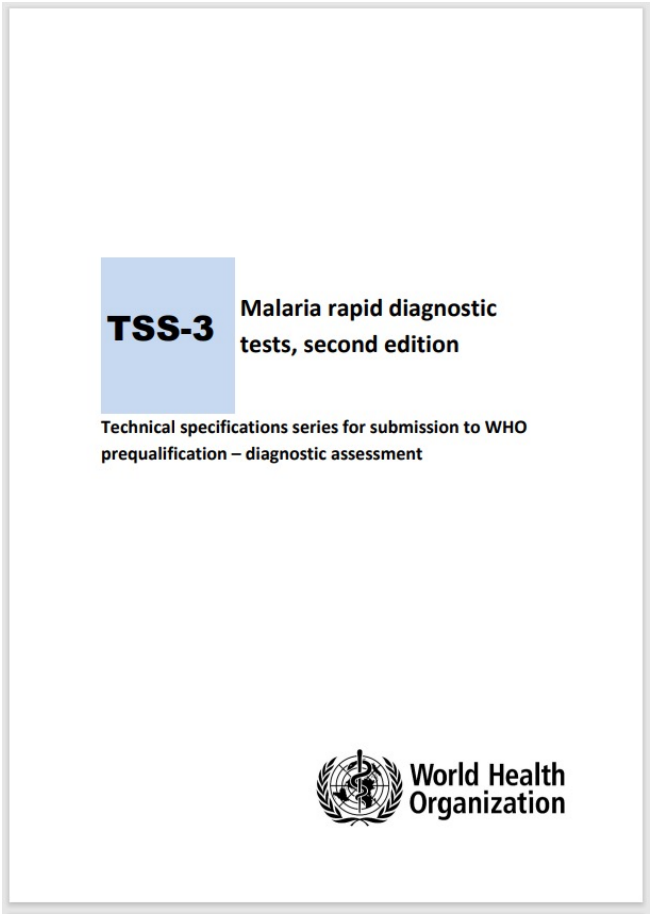
Given the intended use for a malaria RDT and target population, your evidence package for regulatory authorities will require a clinical performance evaluation.
基于疟疾快检试剂的预期用途及目标人群，向监管机构提交的证明材料需包含一项临床性能评价报告。

Meeting the requirements for WHO PQ will meet most of the requirements for for most regulatory authorities.
满足WHO PQ的要求将能符合大多数监管机构的大部分要求。

- For malaria RDTs, these are described in the Technical Specifications Series TSS-3 document
  对于疟疾快检试剂，相关要求在《技术规范丛书 TSS-3 文件》中有详细说明。

Define your verification and validation strategy accordingly. For claims of performance against hrp2/hrp3 deletion samples you will need to demonstrate this analytically and clinically
制定相应的验证与确认策略。对于针对 hrp2/hrp3 缺失样本的性能宣称，需从分析层面和临床层面对此进行证明。




TSS-3 content

Adapted from Meditrial (CLINICAL EVIDENCE FOR IVDs: THE NEW GOOD CLINICAL PRACTICES | Meditrial)

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# Regulatory levels overview 监管层级概述

There are generally four levels of regulatory review – unregulated, national regulators, Global Harmonization Taskforce (GHTF) founding members (soon to be WHO Listed Authority (WLA)), and WHO PQ/ERPD – that involve increasing levels of scrutiny but result in increasingly large potential markets
监管审查通常分为四个层级，分别是无监管、国家监管机构、全球协调工作组（GHTF）创始成员（即将更名为WHO列名机构（WLA））以及 WHO PQ/ERPD。这四个层级的审查严格程度逐级提高，对应的潜在市场规模也随之逐步扩大。

1

**Unregulated markets无监管市场::**

- Not all countries require the registration of diagnostics that will be sold in private sector markets.
  并非所有国家都要求在私营部门市场销售的诊断试剂必须进行注册。
- While these may be the fastest markets to enter, selling diagnostics without submitting products to regulatory scrutiny could backfire if users believe they aren't working, potentially resulting in major reputational harm to the manufacturer
  尽管这类市场或许最易快速进入，但如果在未将诊断试剂提交监管机构审查的情况下就进行销售，一旦用户认为产品无效，这种做法可能会适得其反，进而可能对生产商造成严重的声誉损害。

2

**National regulatory authorities (NRAs)**国家监管机构

- Most countries require registration with NRAs for RDTs to be sold in the private or public sector.
  多数国家要求，快检试剂若要在私营或公立部门销售，需先在国家监管机构完成注册。
- Every country will have their own specific regulations, timelines, and fees. Working with a local distributor is often the best way to understand local NRA requirements.
  每个国家都有其特定的法规、时间周期和费用标准。与当地经销商合作通常是了解当地国家监管机构要求的最佳方式。

3

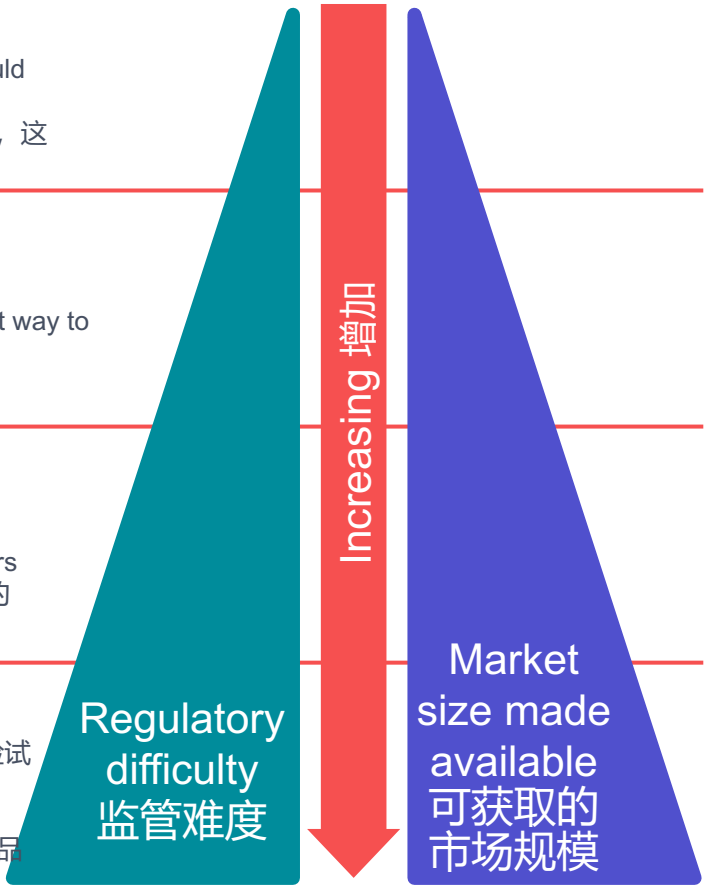
**GHTF founding members (soon to be WLA) GHTF 创始成员 (即将更名为WHO列名机构 - WLA)**

- This includes Australia, Canada, European Union, Japan and the United States, commonly called Stringent Regulatory Authorities (SRAs) 其中包括澳大利亚、加拿大、欧盟、日本和美国，这些地区 / 国家通常被称为 "严格监管机构"（SRAs）
- Eventually, SRAs will be replaced with WHO-Listed Authorities (WLA), although work on this is ongoing and will take years to finalize for diagnostics. 最终，SRAs将被WHO列名机构（WLA）取代，不过相关工作仍在推进中，且要完成试剂领域的这一过渡还需数年时间。

4

**WHO PQ and Expert Review Panel on Diagnostics (ERPD) WHO PQ及诊断产品专家审查小组**

- While SRA approval can make a diagnostic eligible for Global Fund procurement, nearly all RDTs currently procured by Global Fund have WHO PQ. 尽管获得SRA的批准可使某个试剂具备参与全球基金采购的资格，但目前全球基金采购的快检试剂中，几乎所有都已通过WHO PQ。
- Many country malaria programs also either explicitly cite the need for WHO PQ or place significant weight on having WHO PQ when selecting RDTs via national tenders. 许多国家的疟疾防控项目在通过国家招标采购快检试剂时，要么明确要求产品须具备WHO PQ资质，要么会对拥有该资质的产品给予重点考量。

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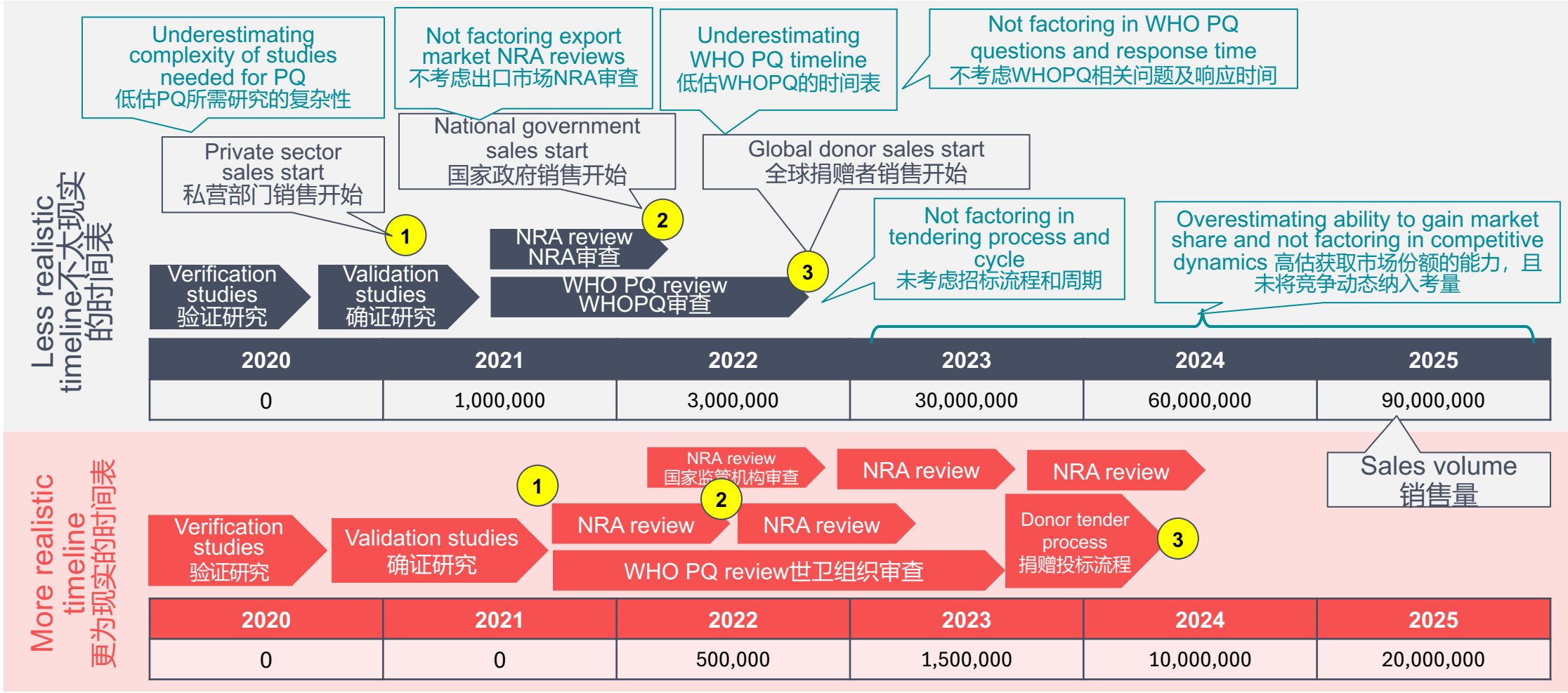
# Regulatory strategy and sales forecasts监管策略与销售预测

Sales forecasts include estimates of future sales **volumes** and the **timing** of those sales, both volume and timing depend in passing regulatory hurdles. Many forecasts make unrealistic assumptions about timelines and uptake
销售预测包含对未来销量及销售时机的估算，而销量与销售时机均取决于能否通过各项监管障碍。许多预测在时间周期和市场接受度方面做出了不切实际的假设。



# WHO prequalification timelines　WHO PQ时间表

The timeline below illustrates the time needed for a malaria RDT to go through the full PQ process and factors before dossier submission and after WHO PQ that can impact timelines
下图时间线展示了快检试剂完成整个WHO PQ流程所需时间，以及在提交文件前和WHO PQ后可能影响时间线的因素

Maximum time allowed: 873 days, 2.4 years
允许的最长时间为873天，即2.4年

Analytical & clinical studies, ethics review, CRO contracting
分析和临床研究、伦理审查、CRO签约

Pre-submission stage
**90 days**
预提交阶段
90 天

Dossier screening (for completeness)
**180 days**
**档案筛选（以确保完整性）**
**180天**

Dossier review **270 days**
**档案审核 270 天**

Performance evaluation
**240 days试剂性能评估**
**240天**

Manufacturing site inspection**423 days**
生产场地检查423天

Labelling review
**90 days**
**标签审核 90 天**

Prequalification decision
**90 days**
**预认证决定 90 天**

Tendering process, additional NRA submissions
招标流程、国家监管机构补充申报材料

VERY optimistic scenario: 523 days, 1.4 years
非常乐观的情况：523天，1.4年

Assumes WHO is 33% faster, and manufacturer is 50% faster 假设WHO的流程速度快 33%，且生产商的流程速度快 50%

Analytical & clinical studies, ethics review, CRO contracting

Pre-submission stage
**55 days**
预提交阶段
55天

Dossier screening (for completeness)
**105 days**
**档案筛选（以确保完整性）**
**105天**

Dossier review**170 days**
**档案审核 170 天**

Performance evaluation
**155 days**
**试剂性能评估155天**

Manufacturing site inspection
**256 days**生产场地检查256天

Labelling review
**55 days**
**标签审核**
**55 天**

Prequalification decision
**55 days**
**预认证决定**
**55 天**

Tendering process, additional NRA submissions
招标流程、国家监管机构补充申报材料

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# WHO PQ Overview

# 世卫组织预认证审查

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# Overview of WHO Prequalification for IVD Program (PQDX)

# 体外诊断世界卫生组织预认证概述

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# WHO Prequalification Programs 世界卫生组织预认证

- A **comprehensive quality assessment** of IVD products through a standardized procedure aimed at determining whether a product meets WHO prequalification requirements.
  通过标准化程序对体外诊断产品进行全面质量评估，旨在确定该产品是否符合世界卫生组织的预认证要求。
- In the **WHO list of prequalified IVDs** which guides interested United Nations (UN) agencies and WHO Member States in their procurement decisions.
  在世界卫生组织（WHO）的体外诊断试剂（IVDs）预认证清单，为感兴趣的联合国机构和世卫组织成员国的采购决策提供指导。
- Benefit underserved populations in low-and middle-income countries that have little or no domestic regulatory frameworks for IVDs, and whose need for diagnosis, initiation and monitoring of treatment for high-burden diseases is considerable.
  这有利于中低收入国家的弱势群体，这些国家体外诊断试剂监管框架薄弱乃至根本没有，而它们在高负担疾病的诊断、治疗启动和治疗监测方面有相当大的需求。

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# WHO Prequalification Programs 世界卫生组织预认证

- Promotes and facilitates access to safe, appropriate and affordable IVDs of good quality in an equitable manner, thus improving public health outcomes and value for money;
  以公平的方式促进并推动获取安全、适宜、可负担且质量良好的 IVD 产品，从而改善公共卫生结果，实现更高的资金使用效益。
- Increases visibility and eligibility of IVD products for donor- and government-sponsored tenders;
  提升 IVD 产品在捐助方及政府资助采购项目中的可见度及参与资格。
- Supports manufacturers develop a deeper understanding of how to meet international standards for quality-assured production of IVDs;
  帮助制造商更深入地理解如何符合质量保证的国际标准进行 IVD 产品的生产。
- Generates and makes publicly available independent technical information on the safety, quality and performance of IVDs.
  生成并公开提供有关体外诊断器械（IVDs）安全性、质量和性能的独立技术信息。

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# Overview WHO Prequalification 世界卫生组织预认证概况

- The World Health Organization (WHO) Prequalification is conducted through the Department of Essential Medicines and Health Products.
  世界卫生组织（WHO）资格预审由基本药物和卫生产品司负责实施
- Focus on priority diseases and their suitability for use in resource-limited settings.
  重点关注重点疾病及其在资源有限环境中的适用性
- Products can be WHO Prequalified: 可通过WHO资格预审的产品包括：
  - Drugs 药品API or FPP原料药（AP I）或成品药（FPP）
  - Generic or Innovative 仿制药或创新药
- Vaccine 疫苗
- IVD (HIV, Malaria, HPV, Cholera, Syphilis, HCV, HBV, TB, Haemoglobin, Blood Glucose, SARC-Cov-2, Mycobacterial lipoarabinomannan (LAM), Neisseria gonorrhoeae (NG), Chlamydia trachomatis, and Trichomonas vaginalis (TV)
  体外诊断试剂（包括用于检测HIV、疟疾、人乳头瘤病毒（HPV）、霍乱、梅毒、丙型肝炎病毒（HCV）、乙型肝炎病毒（HBV）、结核病（TB）、血红蛋白、血糖、严重急性呼吸综SARC-Cov-2）、分枝杆菌脂阿拉伯甘露聚糖（LAM）、淋病奈瑟菌（合征冠状病毒2型（NG）、沙眼衣原体和阴道毛滴虫（TV）的试剂）
- Emergency Use Listing 紧急使用清单

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# Overview of the WHO PQ for IVDs 世卫诊断试剂预认证概况

- Four principal types of documents can be consulted by manufacturers seeking WHO prequalification: guidance documents, Technical Specifications Series (TSS), Technical Guidance Series (TGS), and sample product dossiers.
  寻求世界卫生组织（WHO）资格预审的制造商可查阅四类主要文件：指导文件、技术规范系列（TSS）、技术指南系列（TGS）和产品档案样本。

- It is strongly recommended that manufacturers consult these guidance documents before submitting an IVD product dossier.
  强烈建议制造商在提交体外诊断（IVD）产品档案前查阅这些指导文件。

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# Overview of the WHO Prequalification Procedure for IVDs
# PQDX的程序

Dossier Preparation and Submission 申请资料的准备和递交

- Pre-submission meeting 提交前会议
- Completed pre-submission form 填写完整的提交前表格
- WHO review of pre-submission form 世卫审阅提交前表格

Full/Abridged Assessments 世卫组织对提交前表格的审核

- Full product dossier submission or Abridged assessment 全面评估/简要评估
- Performance evaluation 完整产品档案提交或简要评估，生产现场检查
- Manufacturing site inspection by WHO assigned QC site or manufacturer commissioned site 性能评估性能评估, WHO 指定实验室或厂商自己找的WHO PQ的实验室
- Post-Prequalification Commitments 预认证后承诺

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# Submitting a Full Product Dossier

- A product dossier is a selection of technical records and documents that a manufacturer holds for a product
  产品档案是厂商为某一产品保存的一系列技术记录和文件。
- Manufacturers compile a product dossier from their existing technical documentation to provide evidence that an IVD product conforms to internationally-recognized quality, safety, and performance principles for IVD products
  厂商从其现有的技术文档中汇编产品档案，以提供证据证明体外诊断产品符合国际公认的体外诊断产品质量、安全和性能原则
  - Product information 产品信息
  - Design & manufacturing 设计与制造
  - Labelling 标签
  - Commercial history 商业历史
  - Performance specification & associated studies 性能规格及相关研究

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# Submitting a Full Product Dossier - Product Information
# 申报资料产品信息

The dossier should include product descriptive information that allows the dossier assessor to understand the product and how it functions.
申报资料应包含产品描述信息，以便审评员了解该产品及其工作原理。

- Intended use and users of the diagnostic 诊断产品的预期用途和使用者
- What the product detects and intended testing population 产品的检测内容及预期检测人群
- Function of the product and setting of use 产品的功能和使用场景
- A general description of the principle assay method or instrument principles of operation 检测方法原理或仪器操作原理的概述
- A description of the components of the assay and reactive ingredients of relevant components where appropriate 检测组件的描述以及相关组件的活性成分（如适用）
- A description of the accessories and other products that are intended to be used in combination with the product 拟与该产品联合使用的附件及其他产品的描述

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# Submitting a Full Product Dossier - Design & Manufacturing

Information on the design and manufacturing processes for the product under assessment, including 关于受评估产品的设计和制造流程信息，包括

- Product design 产品设计
  - Formulation and composition 配方和成分
  - Biological safety 生物安全性

- Manufacturing process制造流程
  - Overview and sites of manufacture制造概况和地点
  - Key suppliers主要供应商

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# Submitting a Full Product Dossier – Labelling 申报资料-标签

A complete set of labelling associated with the product 与产品相关的一整套标签

Product labels, including packaging labels 产品标签，包括包装标签

- Package inserts 产品说明书
- Instructions for use 使用说明
- Quick Instructions 快速指南
- Technical and operator manuals, including instrument manual 技术手册和操作手册，包括仪器手册

Minimal requirements for the information provided on labels
标签上所提供信息的最低要求

- Expiry dates 有效期
- Lot/batch and/or serial numbers 批号/批次号和/或序列号
- Product conditions 产品状态
- Names of all included reagents 所有包含的试剂名称

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# Submitting a Full Product Dossier - Commercial History
# 申报资料 –商业化历史

- A list of countries in which the product under assessment is currently supplied, and the year when supply started
  一份当前供应受评估产品的国家清单及供应开始年份
- A list of all adverse events and global incident reports from the last five years that required field safety corrective actions
  过去五年内所有需要采取现场安全纠正措施的不良事件和全球事故报告清单
- Evaluation and inspection reports 评估和检查报告
- The minimum and maximum price of supply for this product for the last financial year 该产品上个财政年度的最低和最高供应价格
- Detailed information about the training and support network that is available in each country of supply 关于每个供应国可获得的培训与支持网络的详细信息

PATH

# Submitting a Full Product Dossier - Performance Specification & Associated Studies 申报资料 – 产品性能和相关研究

- Relevant investigations to support the intended use of a product支持产品预期用途的相关调查
- Assess the potential effects of interfering factors评估干扰因素的潜在影响
- Results from testing in performance panels and other TSS-specific evidence 来自性能检测组的测试结果和其他特定于TSS的证据
- Analytical studies 非临床研究
  - Specimen types样本类型
  - Accuracy of measurement 测量准确性
  - Analytical sensitivity and specificity分析灵敏度和特异性
- Stability of specimen(s) 样本稳定性
  - Storage and transport conditions 储存和运输条件
- Robustness studies 稳健性研究
  Impact of human behavior and environmental factors 人因行为和环境的影响
- Clinical evidence临床证据
  - Clinical evaluations and independent studies 临床评价和独立研究
- Risk management 风险管理
  - Foreseeable hazards 可预见的危害

PATH

# IVD Performance Evaluations -- Commissioned by the Manufacturer IVD 性能评估 – 由厂商委托及协调

- A manufacturer can commission a performance evaluation from an independent laboratory selected from WHO's List of Prequalification Evaluating Laboratories 厂商可以委托从世卫资格预审评估实验室名单中选定的独立实验室进行性能评估
- Manufacturer will be responsible for paying the full cost of the performance evaluation and for coordinating the performance evaluation directly with the evaluating site 厂商将负责支付性能评估的全部费用，并直接与评估机构协调性能评估事宜
- The laboratory will conduct the performance evaluation and share the resultant data directly with WHO and with the manufacturer 实验室将开展性能评估，并将所得数据直接分享给世界卫生组织和厂商
- To ensure the independence of the performance evaluation, data analysis will be performed by the laboratory and reviewed by WHO 为确保性能评估的独立性，数据分析将由实验室进行，并由世界卫生组织审核

PATH

# IVD Performance Evaluations -- Commissioned by the Manufacturer IVD 性能评估 – 由厂商委托及协调

- The evaluation site(s) will submit a draft evaluation report to the manufacturer and to WHO. WHO will review the data analysis and report and, if necessary, request clarification from the evaluating site(s) 评估机构将向厂商和世界卫生组织提交评估报告草案。世界卫生组织将审查数据分析和报告，必要时会要求评估机构做出澄清。
- The manufacturer will be in copy of the exchanges between WHO and the evaluation site(s) on data analysis and report 厂商将收到世界卫生组织与评估机构之间关于数据分析和报告的往来函件副本
- The manufacturer will have an opportunity to review and comment on the performance evaluating laboratory draft report and results 制造商将有机会对执行评估的实验室的报告草案和结果进行审查并发表意见

PATH

# IVD Performance Evaluations IVD性能评估

- A manufacturer must send to the evaluating site(s) the requisite quantities and lots of the product (test kits and/or instruments). The products need to be delivered “free domicile”, free-of-charge, and with all customs declarations, customs duties, transportation and other charges paid for by the manufacturer 厂商必须向评估实验室发送所需数量和批次的产品（检测试剂盒和/或仪器）。这些产品需要以“工厂交货价”条件交付，且费用全免，所有报关、关税、运输及其他费用均由厂商承担
- WHO has absolute, exclusive, unfettered control over how the prequalification assessment is carried out, including the performance evaluation and/or the publication of results of the prequalification assessment, irrespective of the outcome.世卫对资格预审评估的执行方式拥有绝对、专属且不受限制的控制权，包括性能评估以及/或者资格预审评估结果的公布，无论结果如何
- A manufacturer may decide or be required to visit the specified evaluating site(s) to observe the operator performing the test procedure on the manufacturer‘s product(s) before starting performance evaluation. 厂商可自行决定或按要求访问指定的评估实验室，以便在性能评估开始前，观察操作人员对其产品执行检测程序的过程

PATH

# Clinical Performance Characteristics 临床性能特征

- Clinical performance studies should be conducted using the specimen types most likely to be used in resource-limited WHO Member States (i.e., capillary whole blood) and are claimed in the instructions for use. 临床性能研究应使用世界卫生组织资源有限的成员国最可能使用的标本类型（即毛细血管全血）进行，且使用说明书中应对此有所说明。
- Performance studies shall also be designed to consider the diversity of knowledge and skills across the population of rapid diagnostic test (RDT) users, but also the likely operational settings in which testing will occur. 性能研究的设计还应考虑到快速诊断检测（RDT）用户群体在知识和技能方面的多样性，同时也要考虑到检测可能进行的实际操作环境。
- Diagnostic sensitivity and specificity 诊断灵敏度和特异性
- Qualification of usability 可用性的认定

PATH

# Clinical Performance Characteristics - Diagnostic Sensitivity and Specificity 临床性能特征 – 诊断灵敏度和特异性

## TSS 3. 2.1.1 Diagnostic Sensitivity TSS 3. 2.1.1 诊断灵敏度

- For IVD intended for detection of p falciparum: 对于用于检测恶性疟原虫的体外诊断试剂：

At least 400 confirmed P. falciparum-positive specimens from symptomatic population
至少需要400份来自有症状人群的确诊恶性疟原虫阳性标本

- For IVDs intended for detection of P. vivax:对于用于检测间日疟原虫的体外诊断试剂：

At least 100 confirmed P. vivax-positive specimens 至少需要100份确诊间日疟原虫阳性标本

Where a claim is made for “pan-specific” detection of Plasmodium species, performance characteristics shall be determined in each species for which specimens are available. At a minimum this shall include detection in specimens positive for P. falciparum and P. vivax (Note that specimens characterized as “non-P. falciparum” are not sufficient). Where testing in these specimens has not been undertaken, this limitation of IVD performance should be reported to the user as a warning in the inspections for use.
当宣称可“泛特异性”检测疟原虫种类时，需针对每种可获得标本的疟原虫种类确定其性能特征。至少应包括对恶性疟原虫和间日疟原虫阳性标本的检测（请注意，仅标注为“非恶性疟原虫”的标本是不够的）。如果未对这些标本进行检测，应在使用说明中以警告形式向用户告知该体外诊断试剂性能的这一局限性。

## TSS 3， 2.3.2 Diagnostic Specificity TSS 3， 2.3.2 诊断特异性

Testing of at least 1000 Plasmodium negative specimens from a symptomatic population
检测至少1000份来自有症状人群的疟原虫阴性标本。

PATH

# Clinical Performance Characteristics - Qualification of Usability
# 临床性能特征 – 可用性确认

TSS 3， 2.2.1 Label Comprehension Study TSS 3， 2.2.1 标签理解研究

- Questionnaire-based testing of subjects shall be undertaken to assess ability of intended users to correctly comprehend key messages from packaging and labelling
  应通过基于问卷的受试者测试，评估目标用户正确理解包装和标签上关键信息的能力。
- Understanding key warnings, limitations and /or restrictions 理解关键警告、局限性和/或限制条件
- Proper test procedure 适当的测试程序
- Test result interpretation 测试结果解读
- Questionnaire shall be administrated to at least 10 intended users, in order to demonstrate comprehension of key messages in each population described in comment 2.
  应向至少10名目标用户发放问卷，以证明其对评论2中所述每个群体的关键信息的理解程度。

# Clinical Performance Characteristics - Qualification of Usability
# 临床性能特征 – 可用性确认

TSS3， 2.2.2 Results interpretation Study TSS 3， 2.2.2 结果解读研究

- Subjects shall interpret the results of contrived IVDs (e.g. static/pre-made tests) to assess their ability to correctly interpretate predetermined test results.
  受试者应解读人为设计的体外诊断试剂（如静态/预制测试）的结果，以评估他们正确解读预定测试结果的能力。
- Contrived tests should be made to demonstrate the following potential test results:
  人为设计的测试应能展示以下潜在的测试结果：
  - Non-reactive consist 无反应性一致
  - Range of invalid results 一系列无效结果
  - Reactive 有反应性
  - Weak reactive 弱阳性反应
  - Testing subjects shall consist of at least 10 intended users from two geographically diverse populations 测试受试者应包括来自两个地理上不同群体的至少10名目标用户

# Submitting a Full Product Dossier -- Regulatory History
# 申报资料 – 监管历史

- A list of national regulatory authorities (NRAs) that have provided current regulatory approvals for the supply of the product in their country/region of authority
  一份已提供其管辖国家/地区内该产品供应的现行监管批准的国家监管机构（NRA）名单
- Details of the type of regulatory approval obtained from each NRA and certified copies of obtained certificates
  从每个国家监管机构获得的监管批准类型的详细信息以及所获证书的认证副本
- Details regarding any situations in which the product was rejected by an NRA
  关于该产品被国家监管机构拒绝的任何情况的详细信息
- Information relating to export-only regulatory approvals
  与仅供出口的监管批准相关的信息

PATH

# Submitting a Full Product Dossier -- Quality Management System 申报资料 – 质量管理体系

An IVD product should be manufactured under an appropriate and effective quality management system (QMS)

体外诊断产品的生产应在适当且有效的质量管理体系（QMS）下进行

- A current version of the manufacturer's quality manual 厂商质量管理手册的现行版本
- A complete list of all valid QMS documents and procedures, including risk management planning and supplier controls

  所有有效的质量管理体系文件和程序的完整清单，包括风险管理计划和供应商控制措施
- A certified copy of the QMS certification held by the manufacturer

  厂商所持有的质量管理体系认证的经认证副本

PATH

# Submitting a Full Product Dossier - Essential Principles
# 申报资料 – 基本原理

- An essential principles (EP) checklist can be used by a manufacturer to readily understand how they demonstrate compliance with the EP for a particular IVD 基本原理（EP）检查表可供制造商使用，以便其轻松理解自己是如何证明符合特定体外诊断试剂（IVD）的基本原理的
- The EP checklist also facilitates easy identification of relevant documents and data for conformity assessment purposes 该基本原理检查表还有助于为符合性评估目的轻松识别相关文件和数据

PATH

# Post-prequalification Commitments 预认证后的承诺

- Commitments to prequalification must be fulfilled by the manufacturer within the agreed deadlines in order to keep the prequalification status of the product.
  生产商必须在约定的截止日期前履行对资格预审的承诺，以维持产品的资格预审状态
- Failure to meet prequalification commitments within the agreed deadlines will lead to delisting of the product(s) from the WHO List of Prequalified IVDs.
  若未能在约定截止日期前履行资格预审承诺，相关产品将从《世卫组织资格预审体外诊断产品清单》中除名。

- Annual Report 年度报告
- Variations 变更
- TSS Compliance 技术规范符合性
- Annual fee 年度费用
- Post-market Surveillance 上市后监测

PATH

# The WHO Coordinated Scientific Advice Procedure
# 世卫合作科学指导机制

- Advise product developers on the most appropriate way to generate robust evidence on a product's benefits and risks for future product prequalification evaluations
  为产品开发者提供建议，指导他们以最合适的方式收集关于产品益处和风险的充分证据，以便用于未来的产品资格预审评估
- Represents a novel platform for interaction between product developers and the relevant technical department(s) and the Prequalification team within WHO
  它是产品开发者与相关技术部门以及世界卫生组织（WHO）内部资格预审团队之间进行互动的一个全新平台。
- Provide on product development strategies; it is **NOT** a pre-evaluation of the product and will not itself award any WHO endorsement.
  提供有关产品开发策略的建议；它不是对产品的预评估，本身也不会授予任何世界卫生组织的认可
- Not be binding on product developers and will not guarantee positive PQ outcomes, as those assessments will always be based on data not yet available at the time of the scientific advice.
  不对产品开发者具有约束力，也不保证能获得积极的资格预审结果，因为这些评估将始终基于科学咨询时尚未获得的数据

PATH

# What is ERPD 什么是ERPD

- A mechanism to review the risks and benefits associated with procurement and use of in vitro diagnostics (IVDs) 一种用于审查与体外诊断试剂（IVDs）采购和使用相关的风险及益处的机制
  - Have a high public health impact 具有较高的公共卫生影响
  - Not WHO prequalified 未通过世界卫生组织资格预审
  - Not undergone stringent regulatory assessment by a founding member of the International Medical Device Regulators Forum (IMDRF).
    未经过国际医疗器械监管机构论坛（IMDRF）创始成员的严格监管评估。
- The principal users are the Global Fund to Fight AIDS, Tuberculosis and Malaria and Unitaid.
主要用户是全球抗击艾滋病、结核病和疟疾基金以及国际药品采购机制。
- The Global Fund is responsible for overseeing ERPD.
全球基金负责监督体外诊断试剂紧急使用评估（ERPD）
- Any procurer can request ERPD evaluation of IVDs.
任何采购方都可以申请对体外诊断试剂进行体外诊断试剂紧急使用评估（ERPD）

PATH

# Verification and Validation Requirements Specific to Malaria RDTs

WHO Pre-Qualification team has established clear guidelines for verification and validation data they would like to see specifically for malaria RDTs.

世界卫生组织预认证团队已针对疟疾快速诊断检测试剂（RDTs）制定了明确的验证和确认数据指南

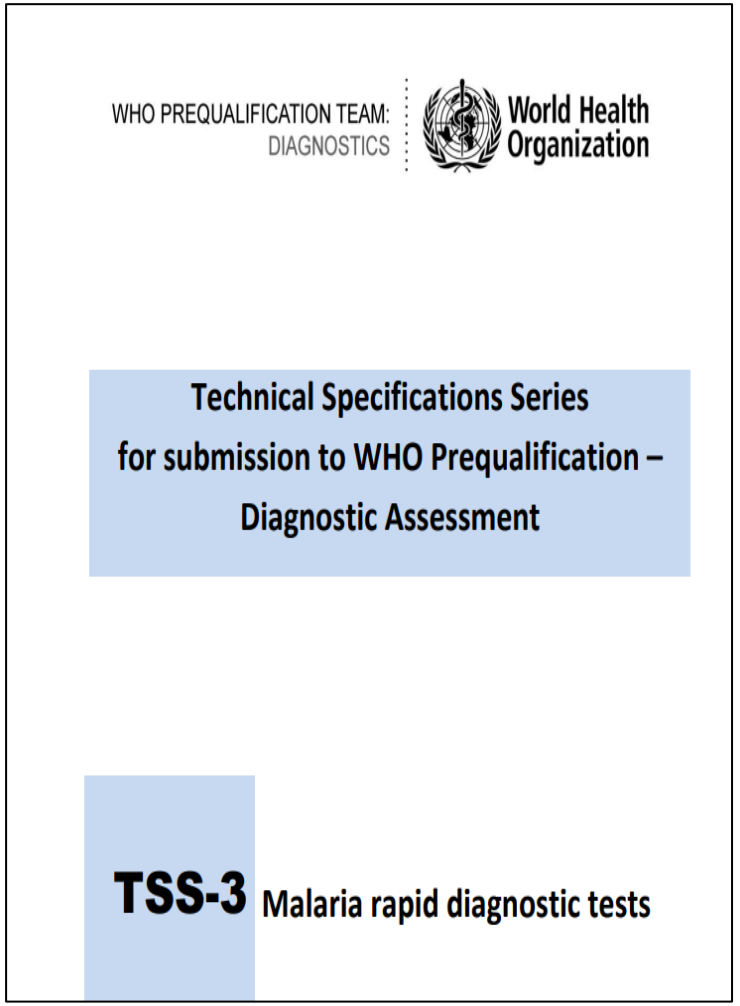
https://apps.who.int/iris/bitstream/handle/10665/255038/9789241512275-eng.pdf

For example for **Diagnostic Sensitivity and Specificity**:

例如，关于诊断灵敏度和特异性

Clinical studies should be conducted in **two regions with 9-12 users and more than 1 lot**.

临床研究应在两个地区开展，涉及9-12名使用者，且使用超过1个批次的产品。




PATH

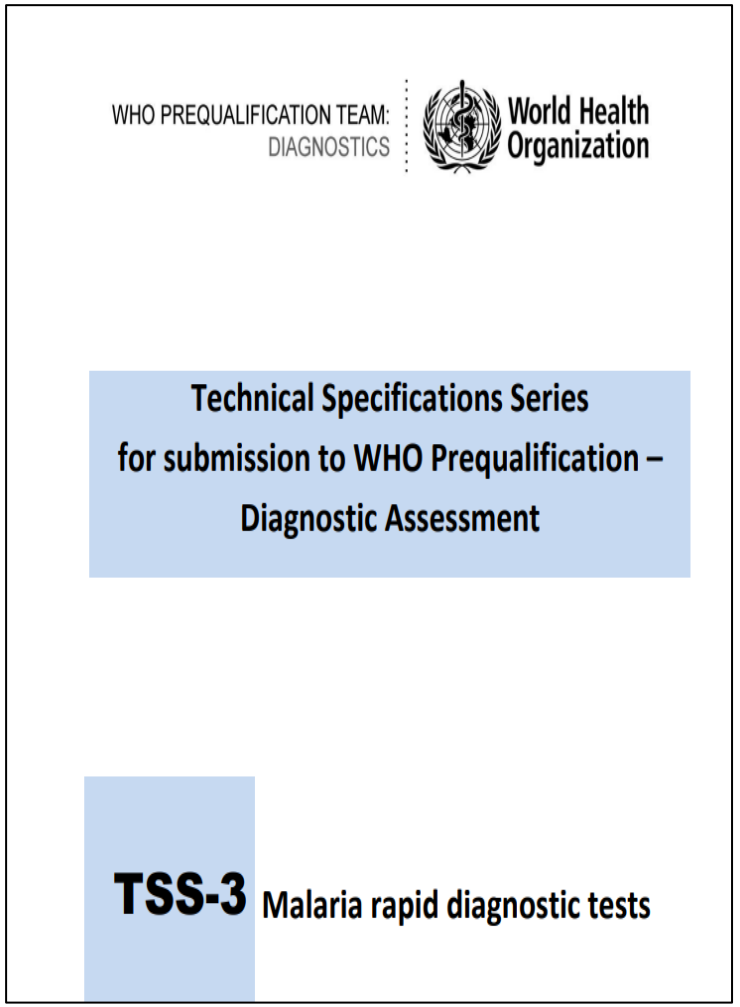
# Verification and Validation Requirements Specific to Malaria RDTs

**Diagnostic Sensitivity:** 诊断灵敏度：

- For IVDs intended for detection of *P. falciparum*: at least **400 confirmed *P. falciparum*-positive specimens** from a symptomatic population.
  对于用于检测恶性疟原虫的体外诊断试剂：需至少400份来自有症状人群的经确认的恶性疟原虫阳性标本。
- For IVDs intended for detection of P. vivax: at least **100 confirmed *P. vivax*-positive specimens**.
  对于用于检测间日疟原虫的体外诊断试剂：需至少100份经确认的间日疟原虫阳性标本。

**Diagnostic Specificity: 诊断特异性**

- at least **1000 Plasmodium negative** specimens from a symptomatic population
  至少1000份来自有症状人群的疟原虫阴性标本。

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# Increasing Importance for RDTs with Highly Sensitive Lines for LDH
# 具有高灵敏度乳酸脱氢酶（LDH）检测线的快速诊断试纸（RDTs）的重要性日益提升

**RDT for *P.falciparum:*** 恶性疟原虫的快速诊断检测（RDT）

- Current test for Pf LDH are not very sensitive 目前针对恶性疟原虫乳酸脱氢酶（Pf LDH）的检测灵敏度不高
- More sensitive tests for LDH: with a lower limit of detection are needed to reliably diagnose *P.falciparum* infections with hrp2/hrp3 deletions 需要更灵敏的乳酸脱氢酶检测方法：其检测下限更低，以便可靠诊断存在组氨酸-rich蛋白2/3（hrp2/hrp3）缺失的恶性疟原虫感染

**RDT for *P.vivax*** 间日疟原虫的快速诊断检测

- Current test for  Pv LDH are not very sensitive 当前针对间日疟原虫乳酸脱氢酶的检测灵敏度不高
- More sensitive tests for Pv LDH will improve diagnosis of *P.vivax*. 更敏感的间日疟原虫乳酸脱氢酶检测将改善间日疟原虫的诊断。

**New competitive tests have 5 to 10 x lower limit of detection for LDH for both *P.vivax* and *P.falciparum***

***Should target < 1 ng/ mL LDH.***

新的竞争性检测对间日疟原虫（P.vivax）和恶性疟原虫（P.falciparum）的乳酸脱氢酶（LDH）检测下限降低了5到10倍。

目标应设定为 < 1纳克/毫升乳酸脱氢酶（LDH）。

PATH

# Recommendations for Malaria RDT Manufacturers
# 给疟疾快速诊断检测试剂盒厂商的建议

Countries with *P.falciparum* will need to transition to more sensitive Pf-LDH based assays as *hrp2/hrp3* deletions arise
存在恶性疟原虫（P.falciparum）的国家，在出现hrp2/hrp3基因缺失时，将需要过渡到更灵敏的基于Pf-LDH的检测方法

Countries with *P.vivax* will prefer tests with more sensitive Pv-LDH lines 存在间日疟原虫（P.vivax）的国家会更倾向于使用具有更灵敏Pv-LDH检测线的检测试剂

If a company is looking to enter the malaria RDT market: 如果一家公司希望进入疟疾快速诊断检测（RDT）市场

1. Plan on meeting the WHO PQ TSS-3 data requirements 计划满足世界卫生组织（WHO）预认证（PQ）TSS-3的数据要求
2. Plan with enough time to conduct the clinical and usability studies 预留足够的时间来开展临床研究和可用性研究
3. Invest in developing reagents for LDH which target less than 1 ng/mL limit of detection for LDH, or < 5 U/mL NIBSC antigen standard limit of detection. 投资研发针对乳酸脱氢酶（LDH）的试剂，使其对乳酸脱氢酶的检测限低于1纳克/毫升，或对国家生物标准与控制研究所（NIBSC）抗原标准的检测限低于5单位/毫升
4. Manufacturers should pay attention to the combination of HRP2 and LDH they use on their RDTs 厂商应关注其快速诊断检测（RDT）上使用的HRP2和LDH的组合

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# Manufacturer experience with WHO PQ (InTec)

# 生产商在WHO PQ方面的经验（英科新创公司）

# 英科新创在WHO PQ方面的实践与经验分享
# The Path to WHO Pre-qualification: InTec's Malaria RDTs Case

许跃龙 Allen Xu
注册总监 RA Director
2025.10.23

Part 01 公司介绍
Company Overview

Part 02 申请WHO PQ的初衷
Why Pursue WHO PQ?

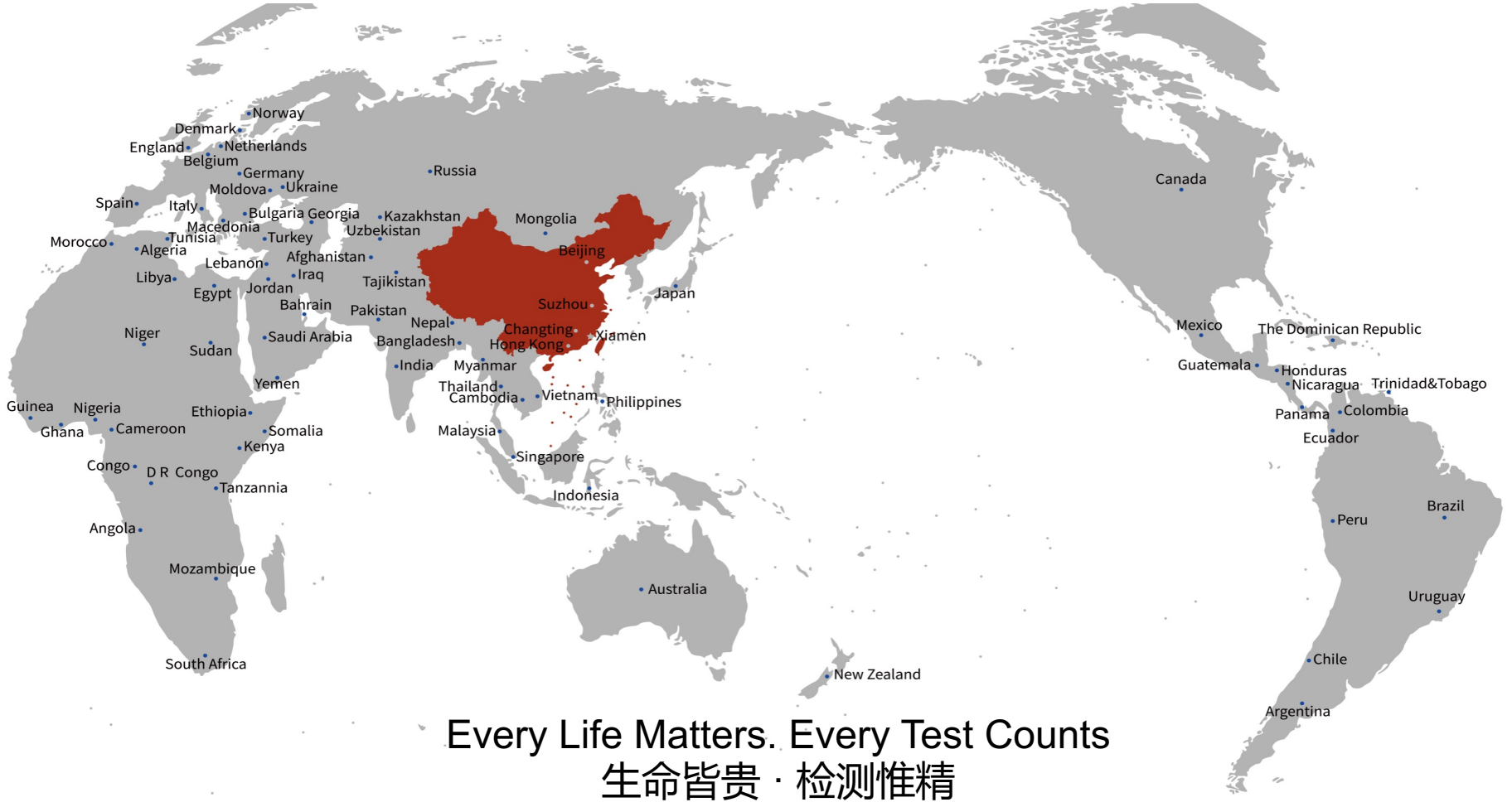
Part 03 Malaria PQ案例分享
Malaria RDTs Case

Part 04 PQ申请周期
WHO PQ Timeline

Part 01

# 公司介绍
# Company Overview

# 公司简介Company Overview




Every Life Matters. Every Test Counts

生命皆贵 · 检测惟精

**35+年** IVD研产销历史,为实现疾病预防筛查在全球范围内的可及性和可负担性做出企业贡献

**Over 35 years** of IVD research, production and sales history. Committed to advancing the accessibility and affordability of disease prevention and screening worldwide.

**100+个**国家

**More than 100** countries

**5亿人份**年供应量

Annual supply of **500 million tests**

# 公司简介Company Overview

英科新创从中国首个实现商业批量的乙肝表面抗原ELISA试剂盒，到获得世卫组织预认证(WHO-PQ)数量最多的中国企业，英科新创始终秉持推动全球公共卫生进步的坚定使命，不断创造新的里程碑。

InTec has been dedicated to advancing global public health and continuously setting new milestones, from being the first Chinese company to achieve commercial-scale production of HBsAg ELISA kits to holding the highest number of pre-qualification from the World Health Organization (WHO PQ).

**诞生于中国/厦门Born in Xiamen, China**

**筑基之本 Solid Foundation**

**1989**

**中国首个**乙肝表面抗原ELISA试剂
China's first HBsAg ELISA reagent

**1998**

**中国首个通过** ISO 9001 认证的 IVD企业
The first IVD enterprise in China to obtain ISO 9001 certification

**2002**

通过中国 GMP 质量体系
Obtained China GMP Quality System Certification

**稳健发展 Stable Development**

**2003**

第三代HIV抗体检测快速检测试剂获证
The HIV-3th antibody RDT NMPA certified

**2006**

通过ISO 13485认证
ISO13485 certified

**2007**

**中国首个获批HCV抗体快速检测试剂**
China's first approved HCV antibody RDT

**2017**

HIV和HCV胶体金检测试剂获得**CE认证**
HIV and HCV colloidal gold detection reagents CE certified

**深耕致远 Deep Cultivation**

**2019**

**同时取得 HIV ， HCV** 胶体金检测产品WHO PQ认证
Obtain WHO PQ certification for both HIV and HCV RDT products simultaneously

**2024**

**中国首个获得疟疾快检产品** (pf, pf/pv) PQ认证的企业
China's first enterprise to obtain WHO PQ certification for malaria RDT products (pf, pf/pv)

**2025**

**HIV自测快检产品获WHO PQ 认证，获得最多WHO PQ认证的中国企业**
HIV self-test RDT product has obtained WHO PQ certification, and also the Chinese enterprise with the most WHO PQ listed products.

# 已获PQ认证的产品 InTec PQ listed products

| No. | 品名<br>Product name | 获证时间<br>PQ time |
|---|---|---|
| 1 | ONE STEP Anti-HIV (1&2) Test<br>人类免疫缺陷病毒抗体检测试剂盒（胶体金法） | 2019/05 |
| 2 | Rapid Anti-HCV Test<br>丙型肝炎病毒抗体检测试剂盒（胶体金法） | 2019/05 |
| 3 | ONE STEP Malaria (Pf) Test<br>恶性疟原虫抗原检测试剂盒（胶体金法） | 2024/05 |
| 4 | ONE STEP Malaria (Pf/Pv) Tri-line Test<br>恶性疟原虫/间日疟原虫抗原检测试剂盒（胶体金法） | 2024/05 |
| 5 | Advanced Quality HIV Self Test<br>人类免疫缺陷病毒抗体检自测测试剂盒（胶体金法） | 2025/08 |

# 公司简介Company Overview

## 其余产品认证与市场准入
## Other Certifications and Market Access


获中国NMPA认证的产品数量达 147个
The number of products that have obtained CHINA NMPA certification reaches 147


获 CE 认证的产品数量达 127 个
The number of products that have obtained CE certification reaches 127


获 UKCA 认证的产品数量达 54 个
The number of products that have obtained UKCA certification reaches 54


产品已在全球 50 余个国家和地区获得准入资质，累计获批证书达 634 个
More than 50 countries and regions worldwide, with a number of approved items 634

Part 02

# 申请WHO PQ的初衷
# Why Pursue WHO PQ?

# 申请WHO PQ的初衷 Why Pursue WHO PQ?

英科新创申请 WHO PQ，不仅是商业决策，更体现了对全球健康公平的长期承诺。这一行动契合了世卫组织《2022–2025 全球健康战略》和"诊断可及性倡议（Access to Diagnostics Initiative）"的核心目标——确保全球各地人人都能公平获得高质量、可负担、可靠的体外诊断产品。英科新创的 PQ 工作与世卫组织"全民健康覆盖（UHC）"和"卫生产品政策与标准（HPPS）"框架保持一致。这些努力有助于强化卫生体系，加速在中低收入国家实现艾滋病、肝炎、疟疾等传染病的消除目标。
作为全球健康的长期合作伙伴，英科深知 WHO PQ 在帮助质量有保障的诊断产品进入国家项目、捐助机制及最需要的社区方面发挥着关键作用。PQ 过程虽严格，但正是这种严格确保了列名产品的安全性、质量和性能达到世卫组织国际标准。产品列名后，可通过全球基金、联合国儿童基金会、泛美卫生组织等国际机制实现采购，从而扩大在资源有限地区的可及性。

InTec's pursuit of WHO Prequalification (PQ) is not merely a business choice — it reflects a long-term commitment to global health equity. It supports WHO's 2022–2025 Global Health Strategy and the Access to Diagnostics Initiative, aiming to ensure equitable access to high-quality, affordable, and reliable in vitro diagnostics (IVDs) for everyone, everywhere. InTec's PQ efforts are aligned with WHO's principles of Universal Health Coverage (UHC) and the Health Products Policy and Standards (HPPS) framework. These efforts contribute to strengthening health systems and accelerating the elimination of infectious diseases such as HIV, hepatitis, and malaria in low- and middle-income countries.
As a global health partner, InTec recognizes the critical role of WHO PQ in ensuring that quality-assured diagnostics reach national programs, donor-funded initiatives, and communities most in need. The PQ process, though rigorous, guarantees that listed products meet WHO's international standards for safety, quality, and performance. Once listed, products can be procured through mechanisms such as the Global Fund, UNICEF, and PAHO, expanding access in resource-limited settings.

Part 03

# Malaria PQ案例分享
# Malaria RDTs Case

# 产品开发历史 Product Development History

设计输入
Design Input
(2016)

设计输出
Design output
(2019.09)

设计转换和设计锁定
Design Transfer & Design Lockdown
(2020.02~2020.07)

资料输出和注册申报
PQ Dossier Preparation and PQ application
(2021)

01 02 03 04 05 06 07

(2016.09-2019.09)
原料、质控材料和工艺的筛选、验证和确认
The selection, verfication and validation of raw materials, control materials and process

(2019.10~2021.03)
设计验证
Design Verification

(2020.07~2021.01)
设计确认(主要为临床)
Design Validation

# 设计输入时考虑PQ要求
# Consider PQ requirements when designing inputs

## 1 研读TSS Guideline和技术标准
## Study TSS Guidelines and Technical Standards

**在产品设计的初始阶段，深入研读WHO发布的TSS和TGS Guideline以及相关技术标准是关键。TSS Guideline对疟疾产品的性能、质量、安全性等多方面提出了严格要求，涵盖了检测灵敏度、特异性、稳定性等关键指标。英科新创专业团队对这些要求和标准进行细致分析，将其融入产品设计理念中，确保产品从根源上符合PQ认证的基础要求 。**

In the initial stage of product design, it is crucial to thoroughly study the TSS and TGS Guidelines and related technical standards published by WHO. The TSS Guideline sets strict requirements for the performance, quality, safety, and other aspects of malaria products, covering key indicators such as detection sensitivity, specificity, and stability. The professional team of InTec conducts a detailed analysis of these requirements and standards, integrates them into the product design concept, and ensures that the product meets the basic requirements of PQ certification from the root.

# Malaria PQ案例分享 Malaria RDTs Case

## Considerations for WHO PQ
## 针对PQ的产品设计需要考虑的因素

**操作环境：**要充分考虑预期的操作场景，常为高温且高湿。
Operating Environment: The intended operating scenarios, which are often in a state of high temperature and high humidity.

**目标用户：**该测试旨在供实验室专业人员、受过培训的医护人员或受过培训的非专业人员在实验室和非实验室环境中使用。
Intended Users: This test is intended for professional use by laboratory professionals, trained healthcare workers or trained lay providers in laboratory and non-laboratory settings.

**产品设计验证：**鉴于上述考虑，产品的可靠性（保证在复杂环境下仍能精准检测）、稳定性（长期维持性能稳定）、可用性等关键属性，需在产品设计阶段就进行全面考量与验证。
Product Design and R&D Verification: Key attributes of the product such as reliability (ensuring accurate detection in complex environments), stability (maintaining stable performance for a long time), and usability (having the characteristic of being easy to operate, convenient for different users to use) need to be comprehensively considered in the product design stage, and strict verification should be carried out in the R&D stage.

**Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment**

***From TSS-3:***

D.2 Diversity of specimen types, users and testing environments and impact on required studies

For WHO purposes, clinical performance studies should be conducted using the specimen types that are both claimed in the instructions for use and most likely to be used in resource-limited WHO Member States (e.g. capillary whole blood and oral fluid). If this is not possible, substantial data should be presented to show the equivalence between specimen types used in performance studies.

Prequalified RDTs in low- and middle-income countries are likely to be used by laboratory professionals[1] and at point-of-care by healthcare workers, trained lay providers[2] or by individuals who self-test. Depending on the intended use of an RDT, performance studies must be designed to take into account not only the diversity of knowledge and skills across the population of RDT users, but also the likely operational settings in which testing will occur. For example, studies that comprise the testing of left-over/repository specimens by research and development staff at a manufacturer's facility would, on their own, be considered insufficient to meet many of the performance requirement summarised in this document.

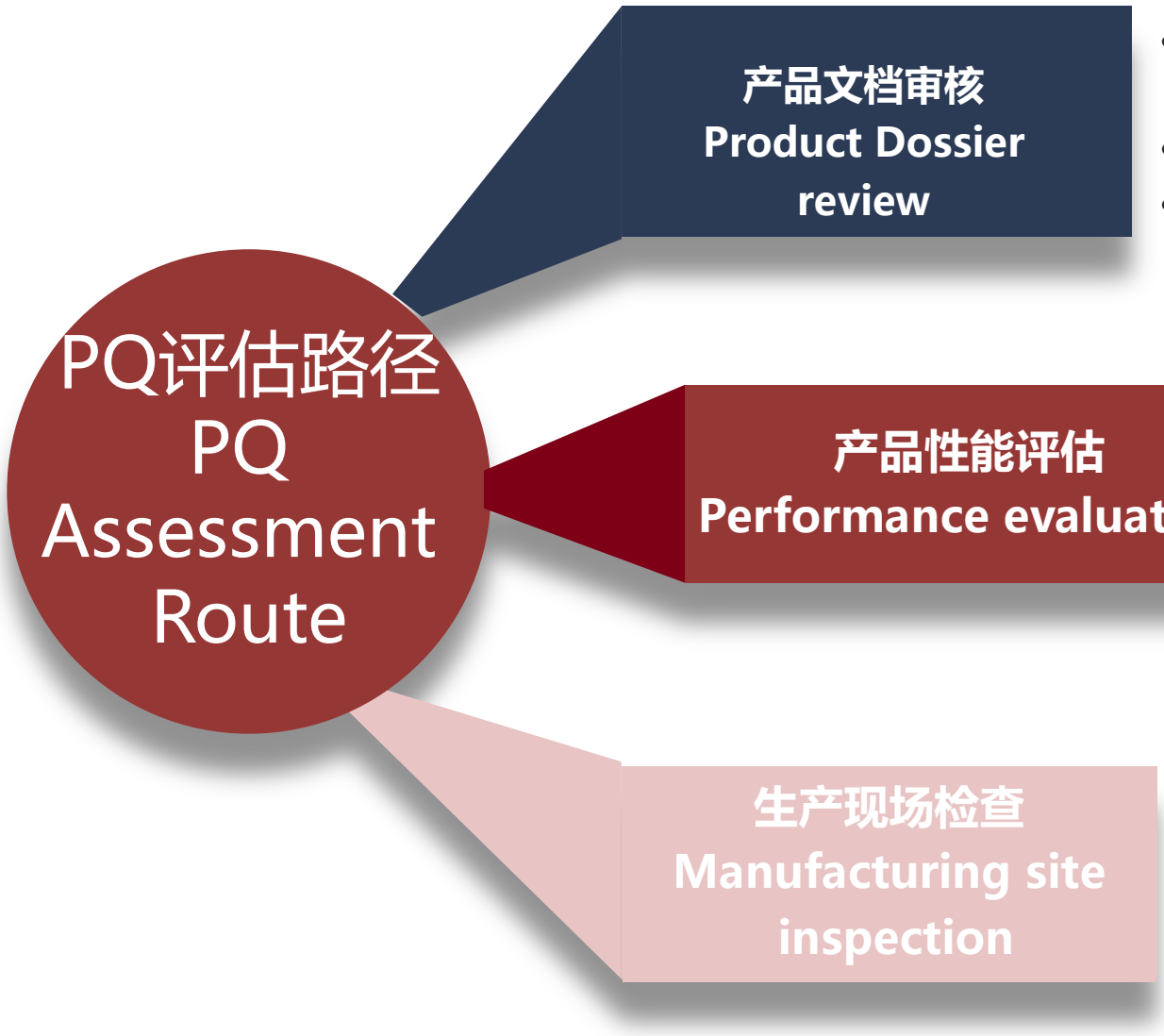
# 设计输入时考虑PQ要求
# Consider PQ requirements when designing inputs

## 2 调研产品未来上市的适应性

**全面调研未来产品上市后的应用环境至关重要。英科新创分析市场上已有的疟疾RDT产品，从技术原理、检测性能、成本价格、使用便捷性等维度进行对比。研究已上市PQ产品的应用场景，如某些产品可能在检测速度上具有优势；同时找出其不足，例如部分产品可能对特殊疟原虫亚型检测能力不足，或在高温高湿环境下稳定性欠佳。基于这些调研结果，并结合PATH，盖茨基金等相关机构的意见，明确自身产品的设计方向。**

It is crucial to conduct comprehensive research on the application environment of future products after they are launched. InTec analyzes existing malaria RDT products in the market and compares them from dimensions such as technical principles, detection performance, cost price, and ease of use. Research the application scenarios of PQ products already on the market, such as certain products that may have advantages in testing speed; At the same time, identify its shortcomings, such as some products may have insufficient detection ability for specific malaria parasite subtypes, or poor stability in high temperature and high humidity environments. Based on these research results and combined with opinions from relevant institutions such as PATH and the Gates Foundation, clarify the design direction of our own product.

# WHO PQ审查流程 PQ Assessment Route




- IVD产品WHO PQ认证的综述
- Overview of WHO prequalification of in vitro diagnostics assessment
- 产品文档编制说明
- Instructions for compilation of a product dossier

- 世界卫生组织实验室性能评估及相关方案
- WHO Laboratory performance evaluation and related protocol

- 质量管理体系评估
- Assessment of the quality management system

# 疟疾RDT PQ申请的关键节点
# Key milestones for InTec Malaria RDT PQ application

**6.最终获批 Finally approved**
2024年5月正式获得PQ list资格，6月发布Public Report
Formally obtain PQ list qualification in May 2024 and release Public Report in June

**5.包材和说明书审核 Packaging and IFU review**
2024.05 完成两轮标签审核发布
Complete two rounds of label review and release by May 2024

**4.现场审核 On-Site Audit**
2023.10 完成两产品联合现场检查
2023.12 关闭所有不符合项
Complete joint on-site inspection of two products by October 2023
Close all non conformities on December 2023

**3.文档审核 Document Review**
2022 Q1-2024 Q1：经由全面文档审核，共有两次整改发补充
2022 Q1-2024 Q1: After comprehensive document review, there were two rounds of rectification and supplementation

**2.2.文档筛查 Document screening**
2021.08 完成Completed on August 2021

**2.1.由WHO实验室进行性能评估**
**Performance Evaluation by WHO laboratories**
2021.06-2021.12:根据WHO PQ的疟疾评估方案送样评估，确定产品的性能符合WHO 要求
June 2021 to December 2021: According to the malaria assessment protocol of WHO PQ, sample evaluation was conducted to determine that the product's performance meets WHO requirements

**1. 预提交 & 接收申请**
**Pre submission & Acceptance of Application**
**2021 Q1**收到WHO全面评估通知，标志着公司正式开启Malaria产品的PQ申请之路，迈出了关键的第一步。
Received notification of WHO Full Assessment in 2021 Q1 , marking the official start of the company's PQ application process and taking a crucial first step.

# 临床研究介绍
# InTec Malaria RDT Clinical Performance Studies

01 分别在四个地点（坦桑尼亚、孟加拉、中国、埃塞俄比亚）进行临床试验。
Conduct clinical trials in four sites (Tanzania, Bangladesh, China, Ethiopia). This experiment is compared with the results of microscopy and PCR to evaluate the consistency between the investigational reagent and the control test results.

02 本次试验与镜检&PCR结果进行比较，以评价考核试剂与对照检测结果的一致性。
The confirmation method used was Microscopy & qPCR

## 针对Pf产品 (for Malaria Pf RDT):

- 疟疾Pf静脉全血样本（≥200个虫体/μL）和指尖全血样本（ ≥200个虫体/μL）的灵敏度分别为98.67%（95%CI:95.27-99.63%）和98.01%（95%CI:95.94-99.03%）。
  总特异性为98.43%（95%置信区间：97.22-99.12%）。
- The sensitivity of malaria Pf venous whole blood samples (≥200 parasites/μL) and fingerstick whole blood samples (≥200 parasites/μL) were 98.67% (95% CI: 95.27-99.63%) and 98.01% (95% CI: 95.94-99.03%), respectively. The total specificity was 98.43% (95% CI: 97.22-99.12%).

## 针对Pf/Pv产品(for Malaria Pf/Pv RDT):

- 疟疾Pf静脉全血样本（≥200个虫体/μL）和指尖全血样本（ ≥200个虫体/μL）的灵敏度分别为98.08%（95%CI:95.16-99.25%）和98.29%（95%CI:96.32-99.21%）。
  疟疾Pv静脉全血样本（≥200个虫体/μL）的灵敏度为97.52%（95%CI:93.79-99.03%）。
  总特异性为98.89%（95%置信区间：98.10-99.35%）。
- The sensitivity of malaria Pf venous whole blood samples (≥200 parasites/μL) and fingerstick whole blood samples (≥200 parasites/μL) were 98.08% (95% CI: 95.16-99.25%) and 98.29% (95% CI: 96.32-99.21%), respectively. The sensitivity was 97.52% (95% CI: 93.79-99.03%) for malaria Pv venous whole blood samples (≥200 parasites/μL). The total specificity was 98.89% (95% CI: 98.10-99.35%).

Part 04

# PQ申请周期
# WHO PQ Timeline

# PQ申请周期
# WHO PQ Timeline

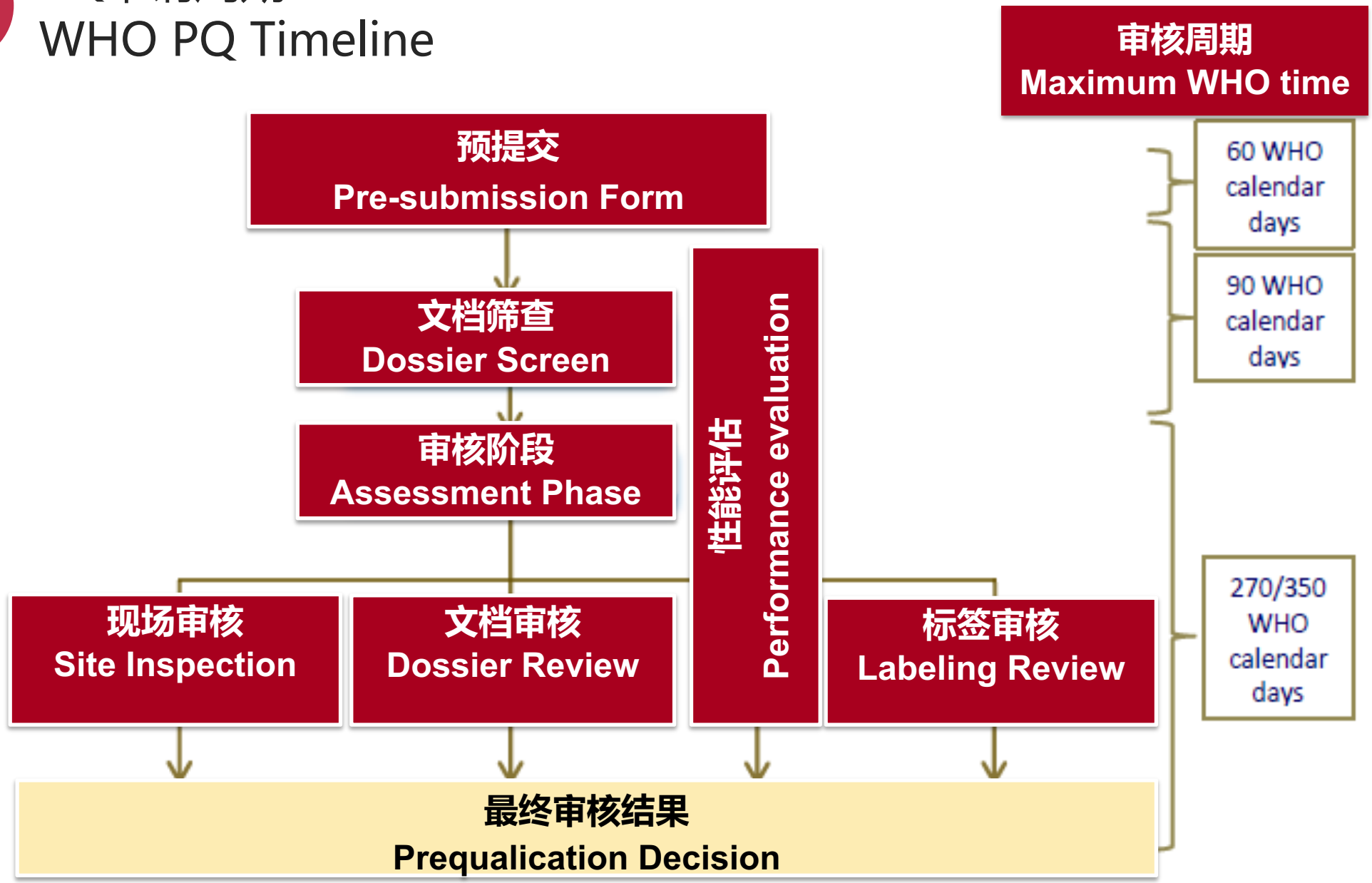



*Figure 1 Full prequalification assessment deadlines*

*From*:
Prequalification assessment and change assessment target deadlines, PQDx_300 v1 21 July 2017

# Thank You ！


📧: intecproducts@asintec.com
☎️: +86-592-6807188
🌐: www.intecasi.com

# Research resources to support manufacturers (HKJCGHI)

# 支持生产商的研究资源

（香港赛马会环球衞生研究院）

PATH

The Hong Kong Jockey Club Global Health Institute 香港賽馬會環球衞生研究院

Gates Foundation

LKS Faculty of Medicine School of Public Health 香港大學公共衞生學院

# Introduction to Research Support Resources at The University of Hong Kong

Leo Poon
Daniel C K Yu Professor in Virology
School of Public Health
The University of Hong Kong
Hong Kong
llmpoon@hku.hk

HKU Med
LKS Faculty of Medicine
School of Public Health
香港大學公共衞生學院

# Key Milestones

**1950** — The Dept of Social Medicine was established.

**1974** — The name was changed to the Dept of Community Medicine.

**2013** — The School of Public Health incorporated the Dept of Community Medicine and the Behavioural Sciences Unit.

**2016** — The academic and research arms of the Institute of Human Performance were incorporated into the School.

**2019** — The BASc in Global Health and Development Programme was established

**2022** — The MPH Programme was CEPH accredited. (accreditation date back to 2020)

HKU Med
LKS Faculty of Medicine
School of Public Health
香港大學公共衞生學院

# Academic divisions & research clusters

## Six Academic divisions

- Behavioural Sciences
- Community Medicine and Public Health Practice
- Epidemiology and Biostatistics
- Health Economics, Policy and Management
- Public Health Laboratory Sciences
- Kinesiology

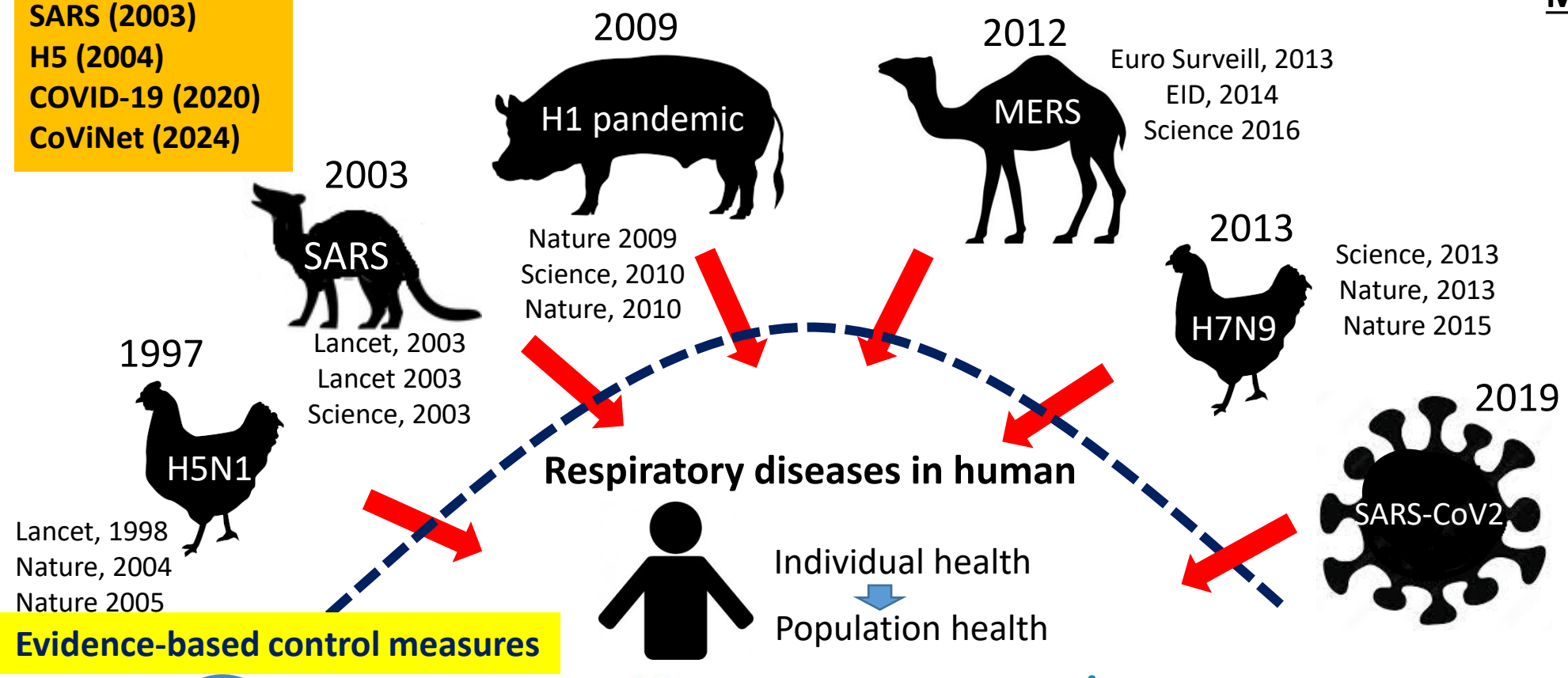
## Two Research clusters

- Influenza and other infections of public health significance
- Non-communicable diseases in global health

HKU Med
LKS Faculty of Medicine
School of Public Health
香港大學公共衞生學院

# Over 2 decades of EID research using the One Health approach

**WHO Ref Lab for:**
**SARS (2003)**
**H5 (2004)**
**COVID-19 (2020)**
**CoViNet (2024)**




**Evidence-based control measures**

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
Founded as OIE

World Health Organization

**Multidisciplinary approach**

- **Animal models**
- **Antivirals**
- **Basic virology**
- **Clinical studies**
- **Molecular Diagnosis**
- **Evolution**
- **Ex vivo models**
- **Immunology**
- **Pathogenesis**
- **Transmission**
- **Surveillance**
- **Stem cell research**
- **Vaccines**
- **BSL3 laboratory studies**

## Industrial Partners

cordlife

Crucell

Johnson & Johnson

HealthBaby 生寶臍帶血庫

Genentech
A Member of the Roche Group

BD

InvVax
Next Generation Vaccines

applied biosystems
by life technologies

ARBOR VITA

## Health institutions

Food and Agriculture Organization of the United Nations

OIE WORLD ORGANISATION FOR ANIMAL HEALTH

World Health Organization

Diagnostic guidelines:

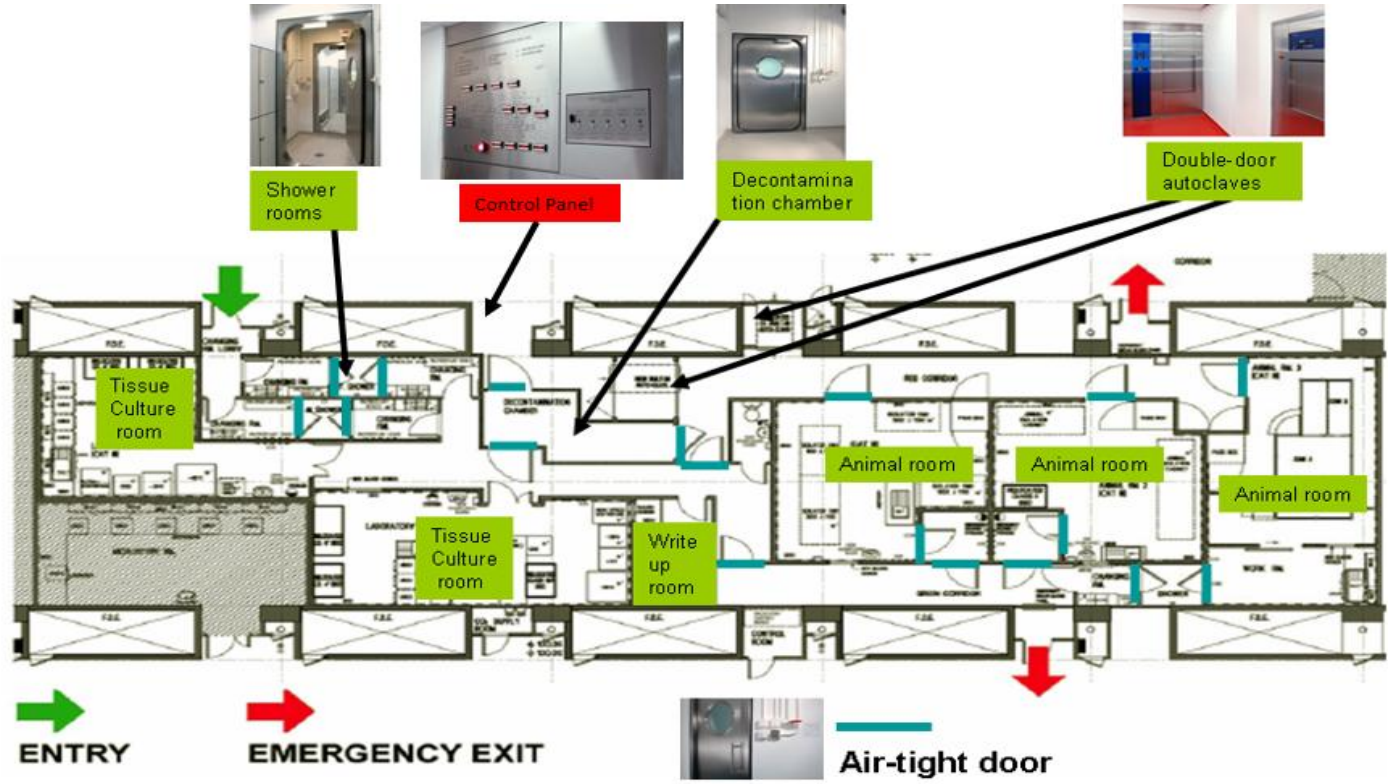
- Molecular test
- Antigen test
- Serology test

HKU Med LKS Faculty of Medicine School of Public Health 香港大學公共衞生學院

# Reference laboratory for EID

- **State Key Laboratory for Emerging Infectious Diseases**
- **World Health Organization (WHO) Reference Laboratory (H5 and CoViNet)**
- **WHO Collaborating Centre for Infectious Disease Epidemiology and Control**

**World-class BSL3 laboratory:**




**Studied pathogens:**

Influenza virus (HP H5 and H7)

Coronavirus (SARS, MERS and COVID19)

**Animal models:**

Poultry Mouse Ferret

# Multidisciplinary

- Basic virology
- Clinical virology
- Clinical diagnosis
- Clinical treatment
- Epidemiology
- Molecular epidemiology
- Sero-epidmiology
- Surveillance
- T cell Immunology
- Pathogenesis
- Virus transmission
- Virus evolution

nature

Article | Published: 01 February 2022

SARS-CoV-2 Omicron variant replication in human bronchus and lung ex vivo

nature COMMUNICATIONS

Genomic epidemiology of SARS-CoV-2 under an elimination strategy in Hong Kong

THE LANCET

Transmission of SARS-CoV-2 delta variant (AY.127) from pet hamsters to humans, leading to onward human-to-human transmission: a case study

nature immunology

TECHNICAL REPORT

https://doi.org/10.1038/s41590-020-0773-7

ORF8 and ORF3b antibodies are accurate serological markers of early and late SARS-CoV-2 infection

nature medicine

BRIEF COMMUNICATION

https://doi.org/10.1038/s41591-022-01705-6

OPEN

Neutralizing antibodies against the SARS-CoV-2 Delta and Omicron variants following heterologous CoronaVac plus BNT162b2 booster vaccination

EMERGING INFECTIOUS DISEASES®

Probable Transmission of SARS-CoV-2 Omicron Variant in Quarantine Hotel, Hong Kong, China, November 2021

THE LANCET Microbe

Stability of SARS-CoV-2 in different environmental conditions

nature communications

SARS-CoV-2 specific T cell responses are lower in children and increase with age and time after infection

THE LANCET Respiratory Medicine

Tropism, replication competence, and innate immune responses of the coronavirus SARS-CoV-2 in human respiratory tract and conjunctiva: an analysis in ex-vivo and in-vitro cultures

nature

Pathogenesis and transmission of SARS-CoV-2 in golden hamsters

Clinical Chemistry

Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia FREE

THE LANCET Infectious Diseases

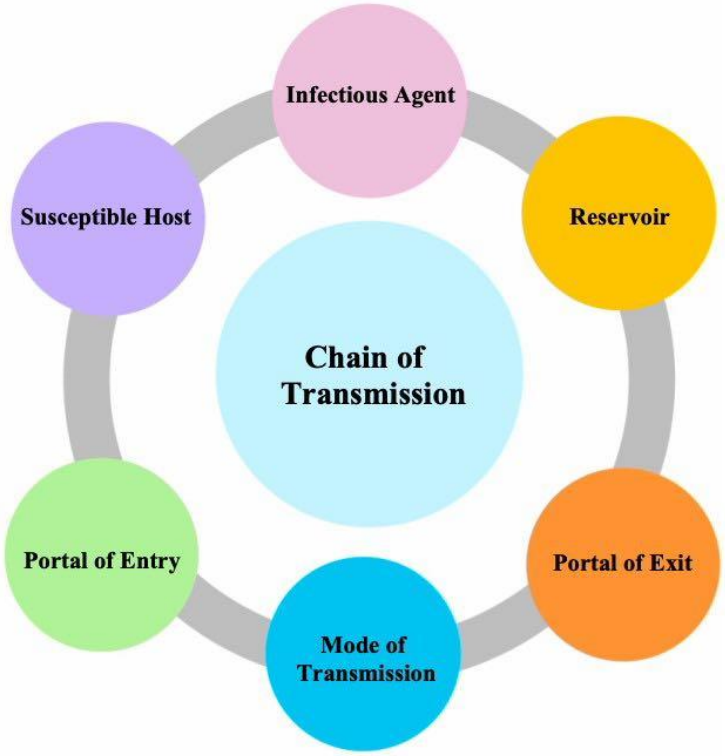
Viral load of SARS-CoV-2 in clinical samples

nature

Infection of dogs with SARS-CoV-2

# Translating science to public health impacts

impact




Technical reports and guidelines:

Food and Agriculture Organization of the United Nations

WORLD ORGANISATION FOR ANIMAL HEALTH

World Health Organization

The Government of the Hong Kong Special Administrative Region

# Early detection of emerging viruses

**10 Jan: First genome in public domain**
**16 Jan: HKU submitted its protocol to WHO**
**24 Jan: WHO posted it for public use**

World Health Organization

IAEA International Atomic Energy Agency
*Atoms for Peace and Development*

PASTEUR NETWORK

★ 13 countries from 4 regions

**Institutions received controls and diagnostic reagents from HKU**


April 2003

**Rapid Diagnosis of a Coronavirus Associated with Severe Acute Respiratory Syndrome (SARS)** FREE

Leo L M Poon ✉, On Kei Wong, Winsie Luk, Kwok Yung Yuen, Joseph S M Peiris, Yi Gu

*Clinical Chemistry*, Volume 49, Issue 6, 1 June 2003, Pages 953–955, https://doi-org.eproxy.lib.hku.hk/10.1373/49.6.953

May 2009

**Rapid Detection of Reassortment of Pandemic H1N1/2009 Influenza Virus** FREE

Leo L M Poon ✉, Polly W Y Mak, Olive T W Li, Kwok Hung Chan, Chung Lam Cheung, Edward S Ma, Hui-Ling Yen, Dhanasekaran Vijaykrishna, Yi Guan, J S Malik Peiris

*Clinical Chemistry*, Volume 56, Issue 8, 1 August 2010, Pages 1340–1344,

May 2013

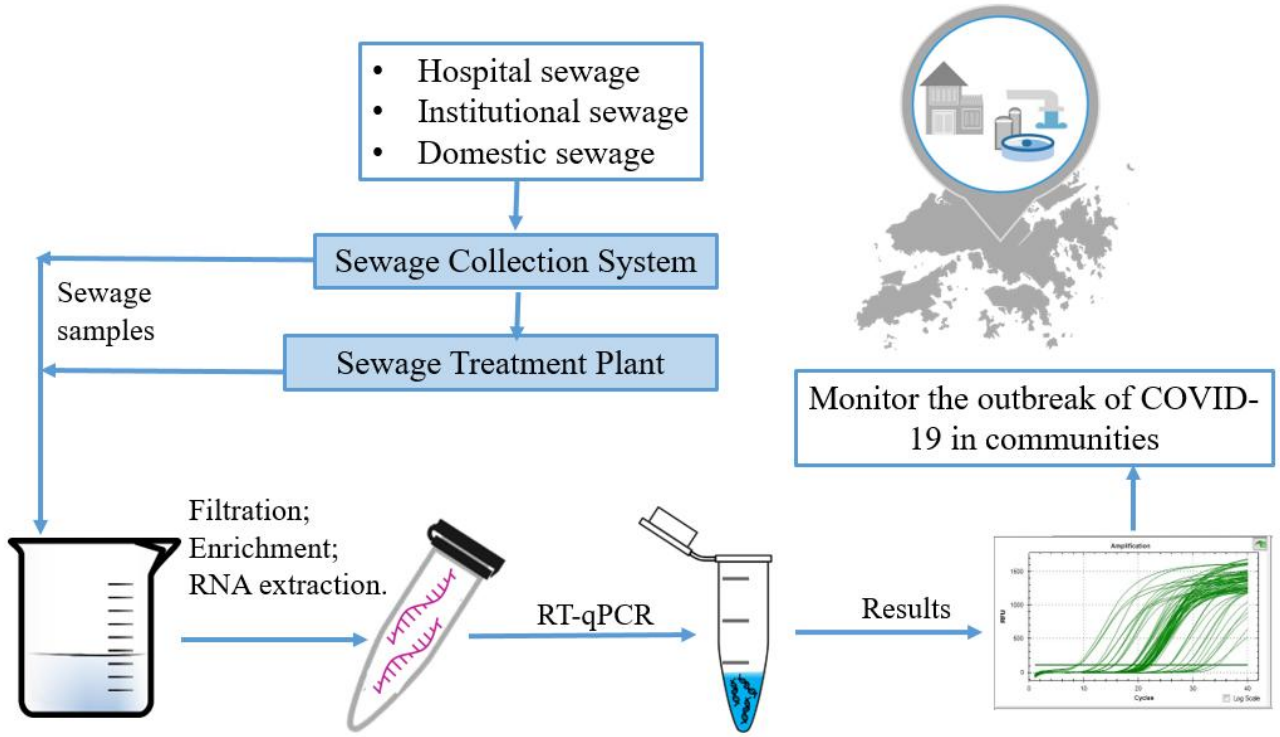
**Molecular Detection of Human H7N9 Influenza A Virus Causing Outbreaks in China** FREE

Chloe KS Wong, Huachen Zhu, Olive TW Li, Yin Hung C Leung, Michael CW Chan, Yi Guan, Joseph SM Peiris, Leo LM Poon ✉

*Clinical Chemistry*, Volume 59, Issue 7, 1 July 2013, Pages 1062–1067,

Reference reagents and protocol were immediately available to different stakeholders

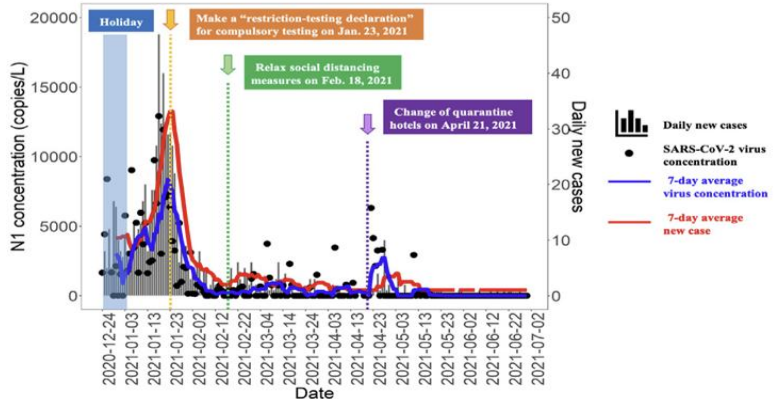
# Sewage Testing Tool for COVID-19 and Influenza




Led by Zhang Tong (HKU Engineering)

Targeted community COVID-19 testing


Monitoring




Faculty of Engineering
THE UNIVERSITY OF HONG KONG

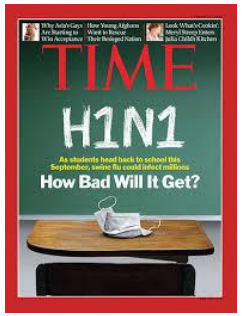
SCHOOL OF PUBLIC HEALTH
THE UNIVERSITY OF HONG KONG
香港大學公共衛生學院

渠務處

Sci Total Environ. 2021, 2022a, 2022b, 2022c 2022d
Environ Health Perspect. 2022
Water Res. 2022, 2023

# Public health emergency of international concern

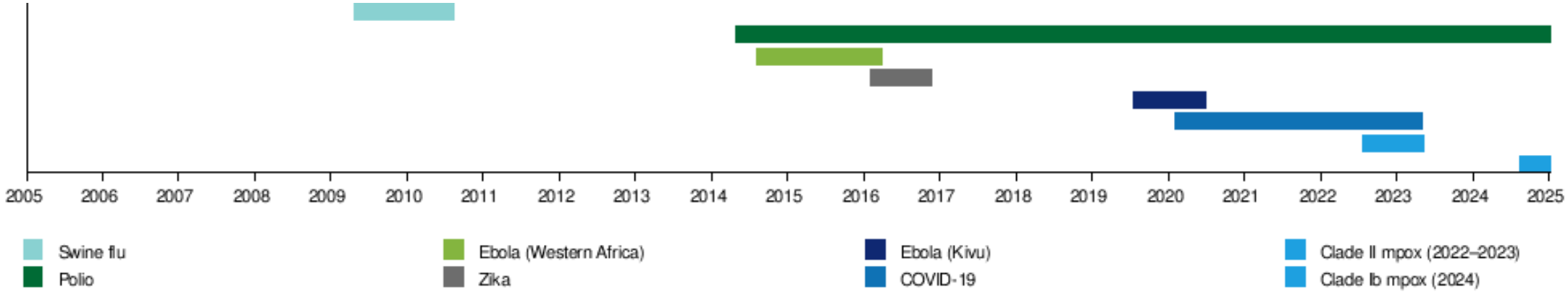
World Health Organization











The Hong Kong Jockey Club
Global Health Institute
香港賽馬會環球衞生研究院

Funded by
捐助機構

香港賽馬會慈善信託基金
The Hong Kong Jockey Club Charities Trust

HKU Med
LKS Faculty of Medicine
The University of Hong Kong
香港大學李嘉誠醫學院

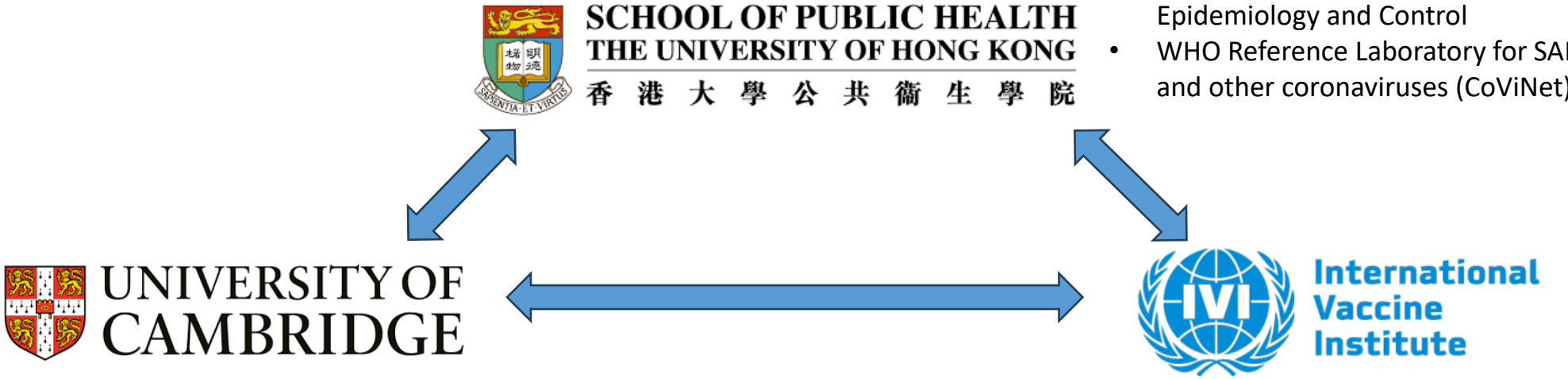
UNIVERSITY OF CAMBRIDGE

International Vaccine Institute

# Establishment of GHI

A 5-year project on pandemic and epidemic preparedness

- WHO Collaborating Centre for Infectious Disease Epidemiology and Control
- WHO Reference Laboratory for SARS, H5N1, COVID and other coronaviruses (CoViNet)




Institute of Therapeutic Immunology and Infectious Disease

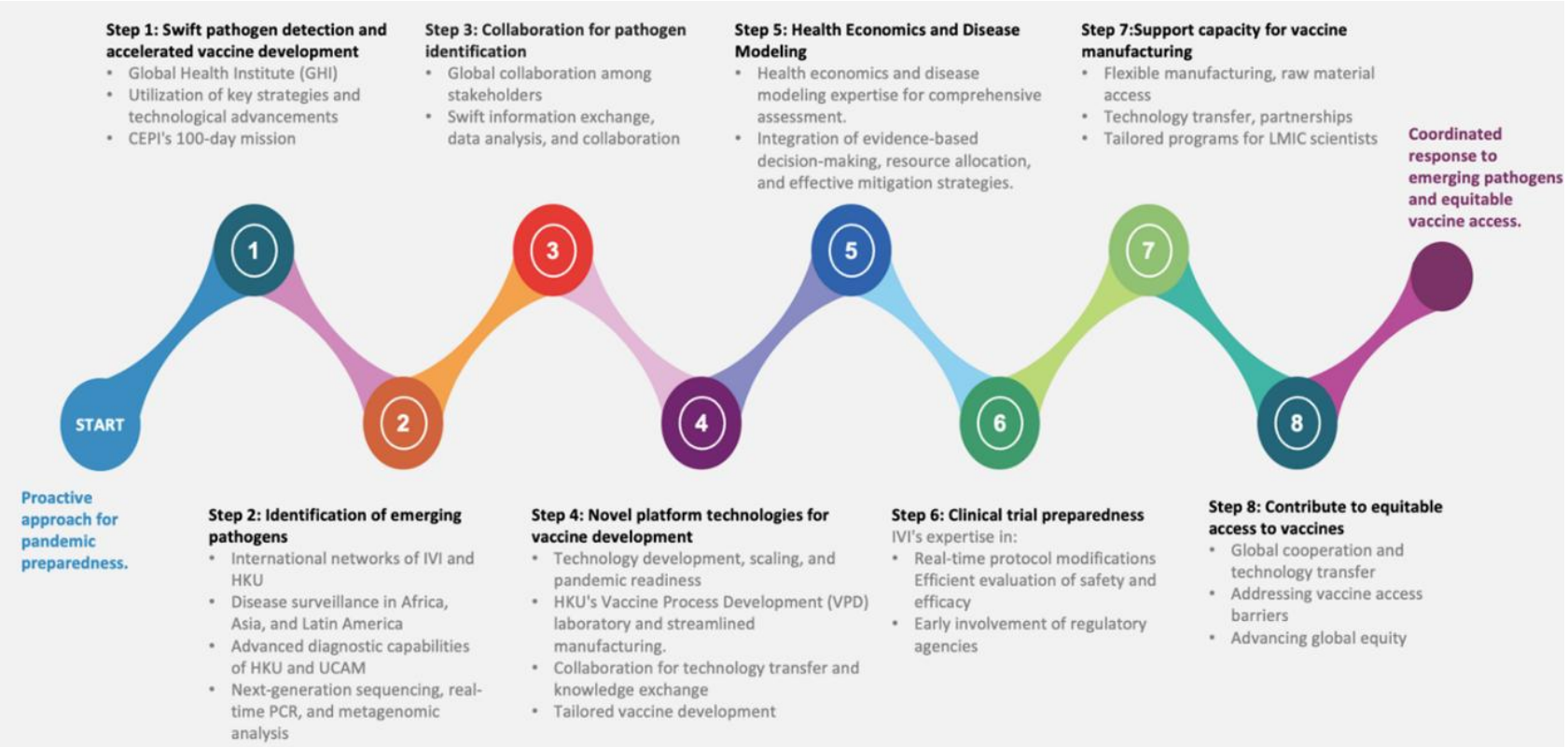
A nonprofit international organization

**Objectives:**

a. advance pandemic preparedness at the academic, industrial and policy levels.
b. translate research into practical interventions that prevent epidemic and endemic infectious diseases with national/regional/global impact.
c. make the world safer by advancing access, equity, and affordability to critical prevention technologies.

# Six functional components in HKJC-GHI

a. Pandemic preparedness/Epidemiology
b. Health Economics
c. Vaccine Process Development
d. Vaccine Platform Development
e. Immunology
f. Capacity Building and Training & Enhancing Global Partnerships



# GOVERNANCE

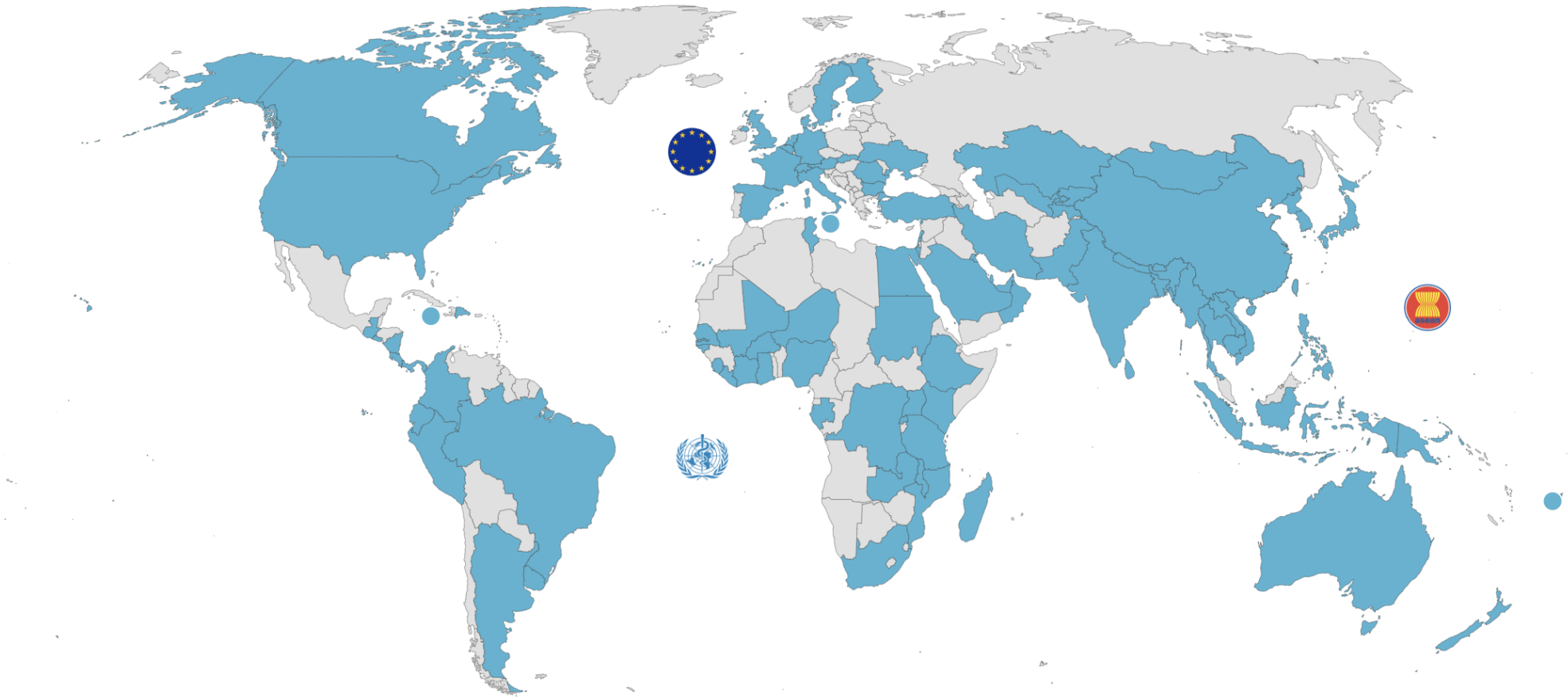
## Co-Directors

**Professor Ravindra Gupta**
Co-Director of HKJCGHI

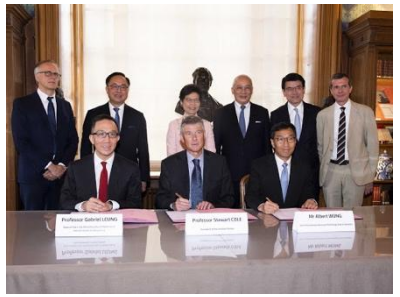
**Professor Florian Marks**
Co-Director of HKJCGHI

**Professor Leo Poon**
Co-Director of HKJCGHI

# IVI's Global Network of Project Sites, Collaborators, and Member States



HKU Med
LKS Faculty of Medicine
HKU-Pasteur Research Pole
香港大學-巴斯德研究中心

20th Anniversary HKU Pasteur Research Pole

2000 2010 2013 2017 2018 2020


C2I Centre for Immunology & Infection
免疫與感染研究中心

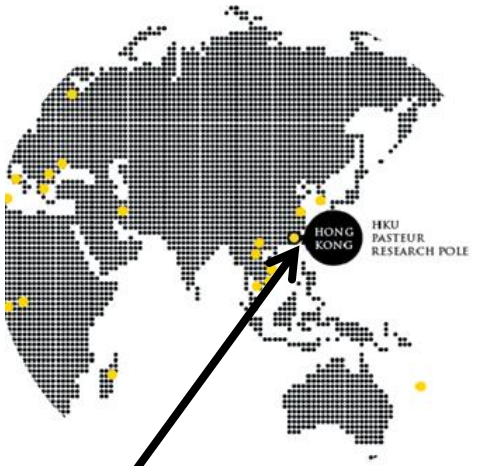
HKU Med
LKS Faculty of Medicine
HKU-Pasteur Research Pole
香港大學-巴斯德研究中心

Research


Education

Global

Epicenter of zoonotic and emerging viruses in Asia




**Co-Directors**

Leo

Roberto

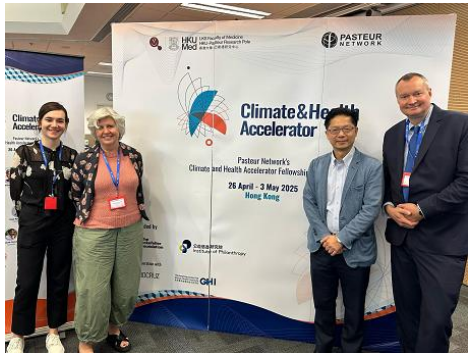
HKU-Pasteur was established in 2000 to develop programs of excellence in research and education that will confront the challenges and advance the understanding of infectious diseases.


9th HKU-Pasteur Cell Biology Course
October 27 - November 2, 2019
HKU Med LKS Faculty of Medicine HKU-Pasteur Research Pole 香港大學-巴斯德研究中心
Proteomics
Deadline for Applications:
9 AUGUST 2019
15th HKU-Pasteur Virology Course
7 - 13 July, 2019
HKU Med LKS Faculty of Medicine HKU-Pasteur Research Pole 香港大學-巴斯德研究中心
Coronaviruses
10th HKUPasteur Immunology Course
香港大學 - 巴斯德研究中心 HKU-Pasteur Research Pole
SCHOOL OF PUBLIC HEALTH THE UNIVERSITY OF HONG KONG 香港大學公共衛生學院
December 3 - 14, 2018
NEW deadline for applications:
1 - 7 July 2018
Croucher Summer Course
EMERGING VIRAL INFECTIONS
THE ONE-HEALTH APPROACH
Over 1,000 participants from >60 countries
Teaching to resu
HKU Med LKS Faculty of Medicine HKU-Pasteur Research Pole 香港大學-巴斯德研究中心
18 - 23 June 2023
Croucher
SUMMER COURSE
Emerging Viral Infections
Sponsored by the Croucher Foundation
OUTBREAK INVESTIGATION & RESPONSE TO PANDEMIC
3rd CROUCHER SUMMER COURSE IN ADVANCED IMAGING 2019
Deep learning in Imaging & Cell Biology
AUGUST 25-30 2019
LKS Faculty of Medicine, The University of Hong Kong, Hong Kong
Topics:
Content Aware Image Restoration (CARE)
Exploring Cells & Systems via Image Analysis
Quantitative Imaging and Nanobiophysics
Imaging Tissue Mechanics
Deep Learning for Biology
Sian Culley
Florian Jug
Musa Mhlanga
Gaia Pigino
Pavel Tomancak
Martin Weigert
Marino Zerial
Christophe Zimmer
HKU-PASTEUR VIROLOGY COURSE
26 July 2013
HKU-Pasteur Research Pole, Hong Kong
10 years
Anniversary Scientific Symposium
10th HKUPasteur Immunology
December 14, 2018
Topics
Epidemiology of viral hepatitis;
Diagnostic tests and ethical considerations;
Surveillance: purpose and methods, optimizing screening strategies, risk reduction;
Prevalence and burden of disease of chronic hepatitis, cirrhosis, HCC;
Surveillance: management, data analysis for communication and assessment of surveillance;
Prevention and treatment: vaccines and antivirals;
Access to treatment, infrastructure to monitor delivery and compliance;
Role of government, NGOs, patients, industry.
Confirmed Faculty
Roberto Bruzzone (Hong Kong);
Benjamin Cowie (Australia);
Hoang Quoc Cuong (Vietnam);
Jennifer MacLachlan (Australia);
Nguyen Thi Na (Vietnam);
Yusuke Shimakawa (France);
Participants' Profile
The course is specifically designed for health personnel, mainly but not exclusively from countries in South East Asia, including medical and health professionals, policy makers, disease researchers interested in expanding their critical understanding of the complex issues to combat viral hepatitis in the context of the global WHO strategy towards its elimination as a public health threat.
Applications
NEW DEADLINE FOR APPLICATIONS:
September 7, 2018
No registration fees
Accommodation will be provided

PASTEUR NETWORK

# An alliance of 32 institutes, spanning 25 countries across 5 continents


**Dec 2024: Avian H5 meeting for Asian Partners**

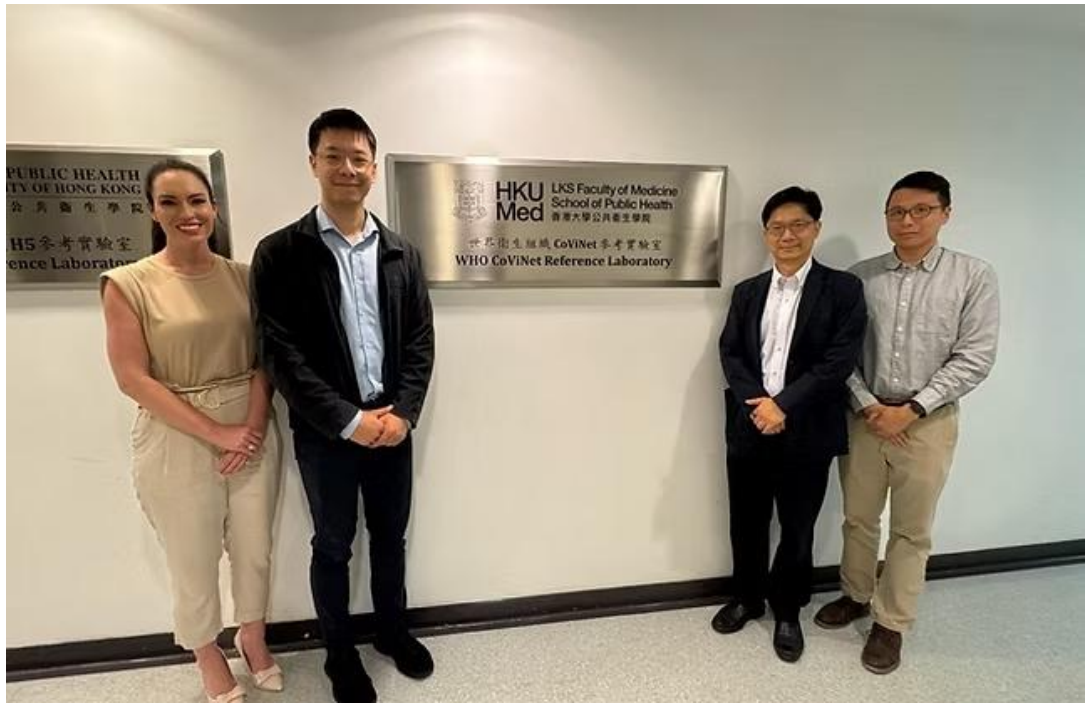



**Climate and Health Workshop in May 2025**


Croucher Summer Course on Emerging Viral Infections, July 2025

# New initiative

Gates Foundation




## Reference lab for global health diagnostic products

- Since May 2025
- Supported by Gates Foundation
- To accelerate development of affordable and effective in vitro diagnostic (IVD) products on major infectious diseases, including malaria, other respiratory diseases,
- To address unmet needs of Low or Middle-Income Countries (LMIC) markets,
- Looking forward, create a knowledge exchange platform to host seminars & international conferences on IVD innovation
- Biobanking
- Assay evaluation
- Training


とうも
VIELEN DANK
감사합니다
THANK YOU
MERCI
شكرا جزيل
धन्यवाद
OBRIGADO
KIITOKSIA OIKEIN PALJON
XIN CẢM ƠN
Огромное спасибо
ممنون
GRACIAS
GURA MÍLE
Ευχαριστώ πολύ
MULȚUMESC
ASANTE
ধন্যবাদ
多謝
TEŞEKKÜRLER
DZIĘKUJĘ
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TUSEN TACK
GRAZIE
KÖSZÖNÖM
TÄNAN TEID VÄGA
QUJANARSUAQ

# Q&A

# 问答

PATH

# Day 1 Closing Remarks

# 第一天结束语

Thank you &
see you tomorrow!

PATH


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The Hong Kong Jockey Club
Global Health Institute
香港賽馬會環球衞生研究院
GHI

October 2025

# Malaria RDT workshop for Chinese manufacturers

# 中国生产商疟疾快速诊断检测研讨会

Market trends and key processes to support development and commercialization of high-quality malaria RDTs for LMIC markets

面向中低收入国家（LMIC）市场的高质量疟疾快速诊断检测：
市场趋势及支撑其研发与商业化的关键流程

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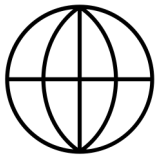
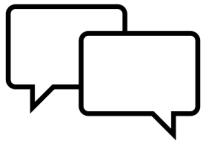
The Hong Kong Jockey Club Global Health Institute
香港賽馬會環球衞生研究院

# Webinar Information 会议须知



**Language & Interpretation 语言与同声传译**

- This webinar offers simultaneous interpretation in Chinese and English
  本次研讨会提供**中文与英文**的同声传译。
- To access, click the globe “Interpretation” icon on your Zoom toolbar 请点击工具栏上的“口译”功能，
- Select your preferred language and adjust audio settings as needed 并选择你希望听到的语言频道

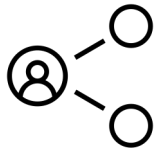


**Question & Feedback 提问与反馈**

- Use the Zoom Chat to submit comments, feedback, or questions throughout the webinar
  (Note your name, organization, and who your question is posed to (if specific) for any questions raised)
  请通过聊天提交评论或问题，注明姓名、机构和提问对象。
- Questions will be monitored and shared during the Q&A sessions 问题将在问答环节汇总分享。

**Interactive Participation 互动参与**

- Mentimeter will be used for polls and reflections during the webinar. More information to follow
  研讨会将使用投票工具收集意见，详情稍后说明。



**Recording & Materials 录制与资料**

- Recording of the webinar and material presented will be shared with participants after the webinar
  会议将录制，会后分享录音和资料。

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# Agenda 议程

## Day 1 第一天

| Session<br>场次 | Speaker<br>演讲者 | Duration时长 |
|---|---|---|
| Webinar Information 会议须知 | PATH | 5m |
| Welcome and Day 1 opening remarks<br>欢迎辞及第一天开幕致辞 | Gates Foundation, HKJCGHI, PATH | 10m |
| Introduction to Next-Generation mRDTs<br>新一代疟疾快检试剂介绍 | PATH | 15m |
| Key considerations for mRDT product development and clinical study design<br>疟疾快检产品开发及临床研究设计的关键考量因素 | PATH | 20m |
| Reagent resources available to support manufacturers<br>可用于支持生产商的试剂资源 | Fapon Biotech | 20m |
| Break茶歇 | | 10m |
| Regulatory pathways and strategy监管途径与策略 | PATH | 15m |
| WHO PQ overview世卫组织预认证概述 | PATH | 20m |
| Manufacturer experience with WHO PQ<br>生产商在世卫组织预认证（WHO PQ）方面的经验 | InTec | 20m |
| Research resources available to support manufacturers<br>可用于支持生产商的研究资源（预录版） | HKJCGHI | 20m |
| Q&A问答 | PATH, HKJCGHI | 20m |
| Day 1 closing remarks第一天结束语 | PATH, HKJCGHI | 5m |

## Day 2 第二天

| Session<br>场次 | Speaker<br>演讲者 | Duration<br>时长 |
|---|---|---|
| **Welcome and Day 2 opening remarks<br>欢迎辞及第二天开幕致辞** | **Gates Foundation, HKJCGHI, PATH** | **10m** |
| **Public sector market insights<br>公共部门市场洞察** | **PATH** | **20m** |
| **Private sector market insights<br>私营部门市场洞察** | **PATH** | **20m** |
| **Participant survey参会者调查** | **PATH, All** | **10m** |
| **Break茶歇** | | **10m** |
| **Manufacturer experience with LMIC markets<br>生产商在中低收入国家市场的经验** | **Wondfo** | **20m** |
| **Partner experience with mRDTs<br>合作伙伴在疟疾快速诊断检测方面的经验** | **Centre Pasteur du Cameroun** | **30m** |
| **Q&A问答** | **PATH, HKJCGHI** | **30m** |
| **Day 2 (final) closing remarks<br>第二天（最后一天）结束语** | **Gates Foundation, HKJCGHI, PATH** | **20m** |

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# Welcome Back and Day 2 Opening Remarks

# 欢迎回来暨第二天开幕致辞

# Public Sector Market Insights

# 公共部门市场洞察

# Contents目录



PATH

# What is, and what is not, the public sector?公共部门包含什么，不包含什么?

For the purposes of this presentation, we generally mean the RDT market that is **financed by major donors** like the Global Fund, the US government, and UN agencies (e.g. UNICEF, UNDP, etc.) 在今天的研讨会中，我们所指的快检产品市场，通常是由全球基金、美国政府及联合国机构（如联合国儿基会、联合国开发计划署等）这类主要捐赠方提供资金支持的市场。

## Public sector – general market size well known.

公共部门 —— 整体市场规模已广为人知。

Market size 市场规模

- **Major donors 主要捐赠者** – Global Fund and the United States government (USG). Procures only WHO prequalified (PQ) or Global Harmonization Task Force (GHTF) founding member approved RDTs. 全球基金和美国政府。仅采购经WHO PQ或全球协调工作组（GHTF）创始成员批准的快检试剂。GHTF 创始成员包括：澳大利亚、加拿大、欧盟、日本和美国。
- **Ministries of health –卫生部**
  - **Donor-funded**捐赠资助: Procures WHO PQed or GHTF founding member approved RDTs. 采购通过WHO PQ或GHTF创始成员批准的快检产品。
  - **Domestic funding**国内资金**:** Can procure WHO PQed or non-PQed RDTs. Regulatory requirements differ by country. **Not included in this analysis.** 可采购通过WHO PQ批准或非预认证的快检试剂。监管要求因国家而异。**本分析不包含此内容。**
- **Smaller donors小额捐赠者** – mainly WHO, UNICEF, UNDP. Procures only WHO PQed or GHTF founding member approved RDTs. 主要涉及WHO、UNICEF和UNDP。仅采购经WHO PQ或GHTF创始成员批准的快检产品。

## Private sector – market size not defined.

## 私营部门——市场规模未定义。

- Health facilities not run by the government 非政府运营的医疗机构
- Private retail clinics and pharmacies 私人零售诊所和药店
- Contains many PQed RDTs 包含多款已通过WHO PQ的快检试剂


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# Contents目录



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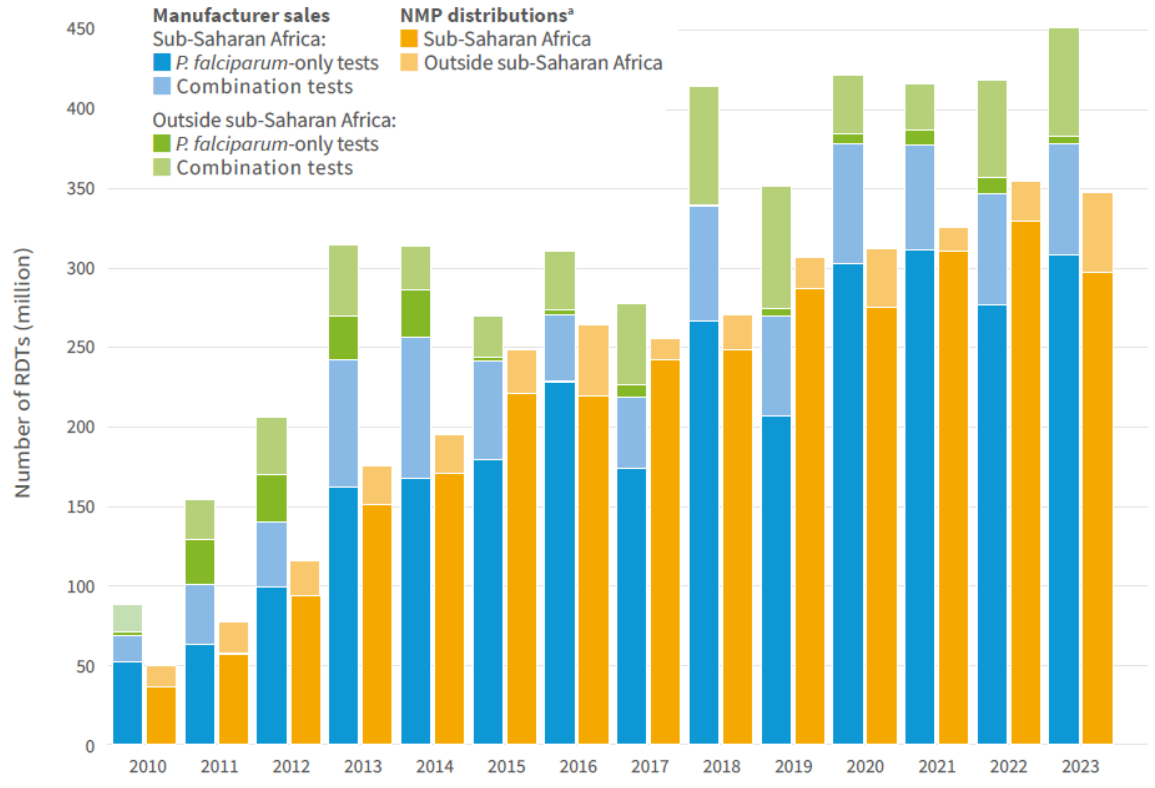
# Malaria RDT market size 疟疾快检试剂市场规模

## The global malaria RDT market size was at least 450 million RDTs in 2023

## 2023年全球疟疾快检试剂市场规模至少为4.5亿份

### 2024 World Malaria Report (2024年世界疟疾报告)

**Fig. 7.6. Number of RDTs sold by manufacturers and distributed by NMPs for use in testing suspected malaria cases, 2010–2023[a]** *Sources: NMP reports and sales data from manufacturers eligible for the WHO Malaria RDT Product Testing Programme.*




NMP: national malaria programme; *P. falciparum*: *Plasmodium falciparum*; RDT: rapid diagnostic test; WHO: World Health Organization.
[a] NMP distributions do not reflect RDTs that are still in storage and are yet to be delivered to health facilities and community health workers.

- The 2024 World Malaria Report (WMR) noted that manufactures sold 450 million RDTs in 2023
《2024年世界疟疾报告》指出，生产商在2023年销售了4.5亿个快检试剂盒。
- However, this only includes manufacturers that are eligible for the WHO Malaria RDT Product Testing Programme.
然而，这仅包含有资格参与WHO疟疾快检试剂产品检测项目的生产商。
- This means that sales from manufacturers that have not met the WHO's quality standards, or do not want to be part of the Testing Programme are not included in these data.
这意味着，未达到WHO质量标准或不愿参与该检测项目的生产商所产生的销售额，并未被纳入这些数据中。
- The global health community does not have good data on how many RDTs are sold by other manufacturers.
全球卫生界目前缺乏关于其他生产商销售了多少份快检试剂的可靠数据。
- That said, RDTs sold by non-eligible manufactures are mainly sold in the private sector, where sales volumes are much lower because many patients prefer to directly purchase ACTs rather than pay for a diagnosis
尽管如此，不符合资格的生产商所销售的快检试剂主要流向私营部门；由于许多患者更倾向于直接购买青蒿素类复方疗法药物（ACTs）而非支付诊断费用，因此其销售量要低得多。

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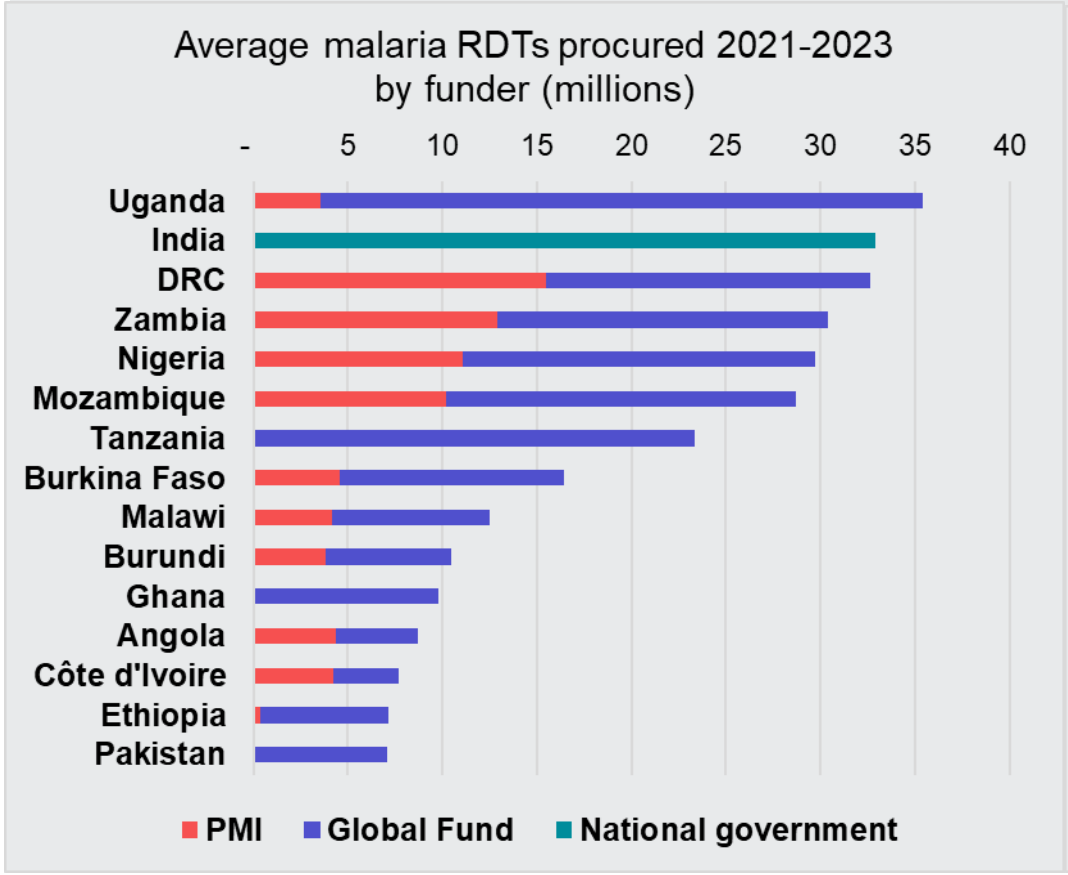
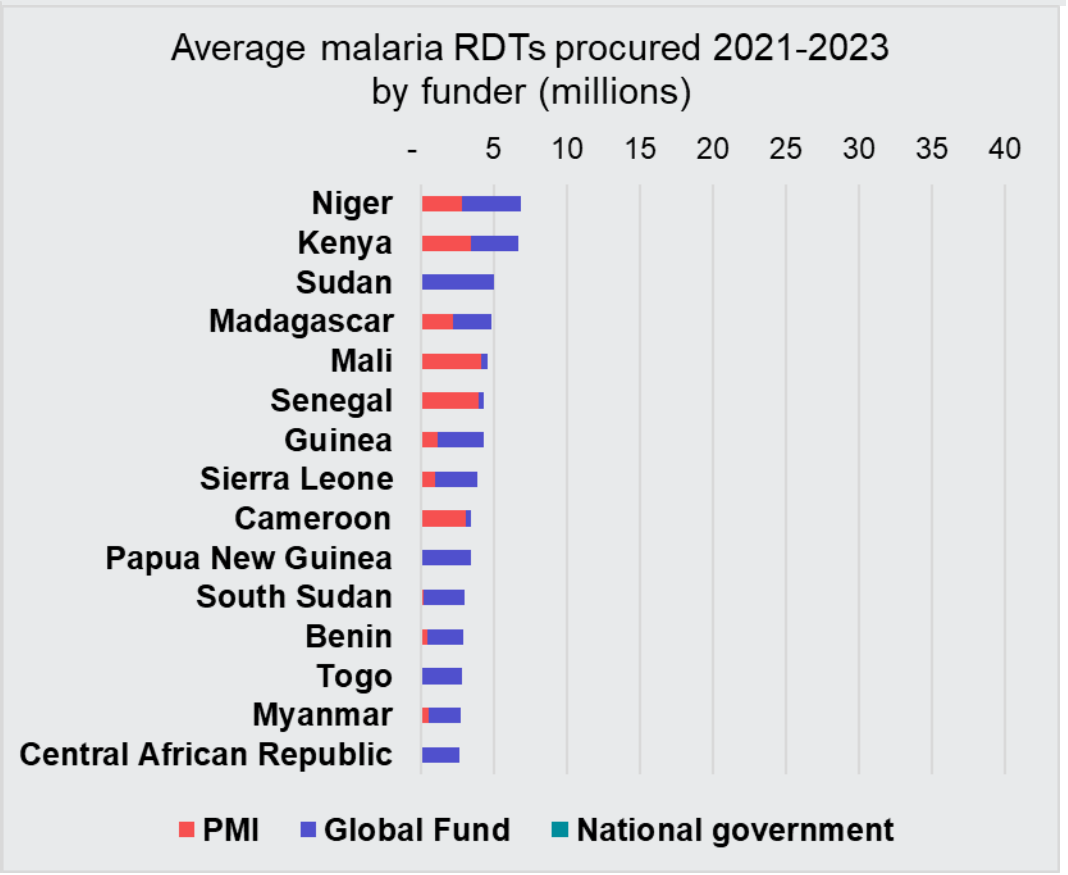
# Major country markets and donor funding source主要国家市场和捐赠资金来源

Outside of India, the largest RDT markets are in Africa, which bears most of the the world's malaria burden. The Global Fund has typically been the largest funder of malaria RDTs, followed by the United State's Presidents Malaria Initiative. 除印度之外，最大的快检试剂市场位于非洲 —— 该地区承担着全球大部分疟疾疾病负担。全球基金通常是疟疾快检试剂的最大资助方，其次是美国总统疟疾防治倡议（United State's Presidents Malaria Initiative）。

## Top 30 country RDT markets全球前30的国家疟疾快检试剂市场




Methods: Average annual RDT procurement volumes taken from 2024 WMR. Percent breakdown by funder **estimated** based on PMI and Global Fund procurement data from 2020-2022. 方法：快检试剂的年均采购量数据源自《2024 年世界疟疾报告》。按资助方划分的占比数据，基于 2020-2022 年美国总统疟疾防治倡议（PMI）及全球基金的采购数据估算得出。

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# Funding trends for RDTs 快检试剂的资助趋势

The US government has drastically scaled back funding for global health, and this will affect RDT procurement, but likely to a lesser degree than many other areas of global health. 美国政府已大幅削减全球卫生领域的资金投入，这将对快检试剂的采购产生影响，但相较于全球卫生领域的其他诸多领域，其受影响程度可能会更低。

**America First Global Health Strategy – September 2025**
**“美国优先” 全球卫生战略 ——2025 年 9 月**

- “Maintain 100% of Frontline Support, Including All Commodity Purchases and Funding for Frontline Healthcare Workers”维持 100% 的一线支持，包括所有物资采购以及为一线医疗工作者提供的资金支持
- “In FY 2026, the United States will continue to cover 100% of all frontline costs that the U.S. government is currently supporting in all countries. After FY 2026, the United States will cover a proportion of these costs as countries will have required co-investment levels based on each country’s income level. The commodities covered will include: 2026 财年，美国将继续全额承担其政府目前在各国支持的所有一线费用。2026 财年之后，美国将承担部分此类费用，因为各国需根据自身收入水平达到相应的联合出资标准。所涵盖的物资将包括：
  - Insecticide-treated nets and spray经杀虫剂处理的蚊帐及杀虫剂喷洒（服务）
  - **Malaria diagnostic tests疟疾诊断检测（试剂 / 服务）**
  - Anti-malaria medicines, including seasonal malaria chemoprevention for children抗疟药物，包括用于儿童的季节性疟疾化学预防药物
  - Malaria vaccines”疟疾疫苗

**Global Fund GC7 Programmatic Reprioritization Approach – June 2025**
**全球基金第七届理事会（GC7）项目优先级调整方法 ——2025 年 6 月**

- The Global Fund experiencing a budget shortfall and has asked countries to reprioritize their existing funding.全球基金正面临预算短缺，并已要求各国对现有资金重新调整优先级。
- Guidance from the Global Fund for included:全球基金的相关指导意见包括：
  - “Countries should: […] Focus procurement on lifesaving HIV, TB and malaria health products.”“各国应：[……] 采购重点聚焦于可挽救生命的艾滋病（HIV）、结核病（TB）和疟疾防治相关医疗产品。”
  - “Countries should include at a minimum: commodities (ACTs, RDTs, IVAS, RAS & CQ, PQ in Pv contexts) and essential supply chain costs…”“各国至少应纳入以下内容：物资（青蒿素类复方疗法药物（ACTs）、快检试剂、静脉注射青蒿素类药物（IVAS）、蒿甲醚 - 本芴醇复方制剂与氯喹（RAS & CQ）、卵形疟原虫（Pv）感染场景下的伯氨喹（PQ））及必要的供应链成本……”
  - “Ensure effective diagnosis and treatment at public facility and community level with continued attention to drug resistance mitigation strategies (multiple first-line therapies). ““确保在公立医疗机构及社区层面实现有效的诊断与治疗，同时持续关注耐药性缓解策略（如多种一线治疗方案）。”

**<u>Downside risk:</u> A decrease in US government funding will still put downward pressure on the malaria RDT market**
**<u>下行风险</u>：美国政府资金投入减少，仍将对疟疾快检试剂市场构成下行压力。**

- Many essential health systems programs that supported the quantification and delivery of RDTs have been cut. 许多曾为快检试剂的数量统计与配送提供支持的重要卫生系统项目已被削减。
- Far fewer US government staff and contractors are expected to procure a similar level of malaria commodities as before 2025. 预计 2025 年后，能够采购与此前规模相当的疟疾相关物资的美国政府工作人员及承包商数量将大幅减少。
- Funding cuts have negatively impacted WHO malaria-related activities, like WHO prequalification product testing. 资金削减对WHO与疟疾相关的活动产生了负面影响，例如WHO PQ产品检测工作。
- **US funding for malaria will shift to national budgets in the coming years, fragmenting purchase orders and supply chains.**
  **未来几年，美国对疟疾防控的资助将转向各国国家预算，这会导致采购订单与供应链的碎片化。**

# Status quo RDT prices are typically less than $ 0.30目前快检试剂的价格通常低于 0.30 美元

The Global Fund pays approximately $0.22 for a *P.f.* RDT and $0.28 for a *P.f./P.v.* RDTs, and the median Global Fund order size is 1.5m RDTs, or less than half a percent of the approximate donor-funded annual market size of ~400 million RDTs　全球基金为Pf快检试剂支付的单价约为 0.22 美元，为Pf/Pv快检试剂支付的单价约为 0.28 美元；全球基金的订单规模中位数为 150 万份快检试剂，这一规模不足捐赠方资助的快检试剂年均市场规模（约 4 亿份）的 0.5%。

The table below displays data from the Global Fund's Transaction Summary data base. Important information about these data:下表展示的数据来源于全球基金交易摘要数据库。关于这些数据的重要信息如下：

- All **transactions since January 1, 2019** are included and the data was downloaded on April 1, 2025. 数据包含 2019 年 1 月 1 日以来的所有交易，且该数据的下载时间为 2025 年 4 月 1 日。
- All transactions where the average RDT price was more than $ 1.00 were excluded as these were from very low volume transactions atypical of procurements meant for case management. 所有快检试剂均价超过 1.00 美元的交易均已排除，因为此类交易的量极低，不属于用于病例管理的典型采购范畴。
- The Presidents Malaria Imitative (PMI) accounted for approximately 40% of donor-funded RDT procurement, and the table below does not include any PMI data. PMI does not publish price data. PMI约占捐赠方资助的快检试剂采购量的 40%，但下表未包含任何该计划的数据 —— PMI暂不公开价格数据。

| RDT Type<br>快检试剂类型 | Reference price, EXW, USD* 参考价格，厂商交货价、美元 | Weighted average price<br>加权平均价格 | Total RDTs<br>快检试剂总量 | % of RDTs ordered<br>快检试剂订购占比 | Average order size<br>平均订单规模 | Median order size<br>订单规模中位数 | n |
|---|---|---|---|---|---|---|---|
| **Pf** | $ 0.24 | $ 0.22 | 426,042,380 | 51% | 1,963,329 | 1,500,000 | 217 |
| **Pf PfLDH** | $ 0.40 | $ 0.21 | 1,660,000 | 0% | 1,660,000 | 1,660,000 | 1 |
| **Pf HRP2/PfLDH** | $ 0.40 | $ 0.32 | 1,301,825 | 0% | 433,942 | 216,000 | 3 |
| **Pf / Pv** | $ 0.35 | $ 0.28 | 187,781,050 | 22% | 881,601 | 288,000 | 213 |
| **Pf / Pan** | $ 0.36 | $ 0.30 | 100,478,245 | 12% | 1,456,206 | 778,350 | 69 |
| **"Malaria Rapid Diagnostic Test"*** | | $ 0.33 | 104,650,187 | 12% | 1,175,845 | 500,000 | 89 |
| **Pan** | | $ 0.04 | 16,309,800 | 2% | 5,436,600 | 352,000 | 3 |

**Sources:** * The Global Fund, Pooled Procurement Mechanism Reference Pricing: RDTs, version Q2 2025, revision 1

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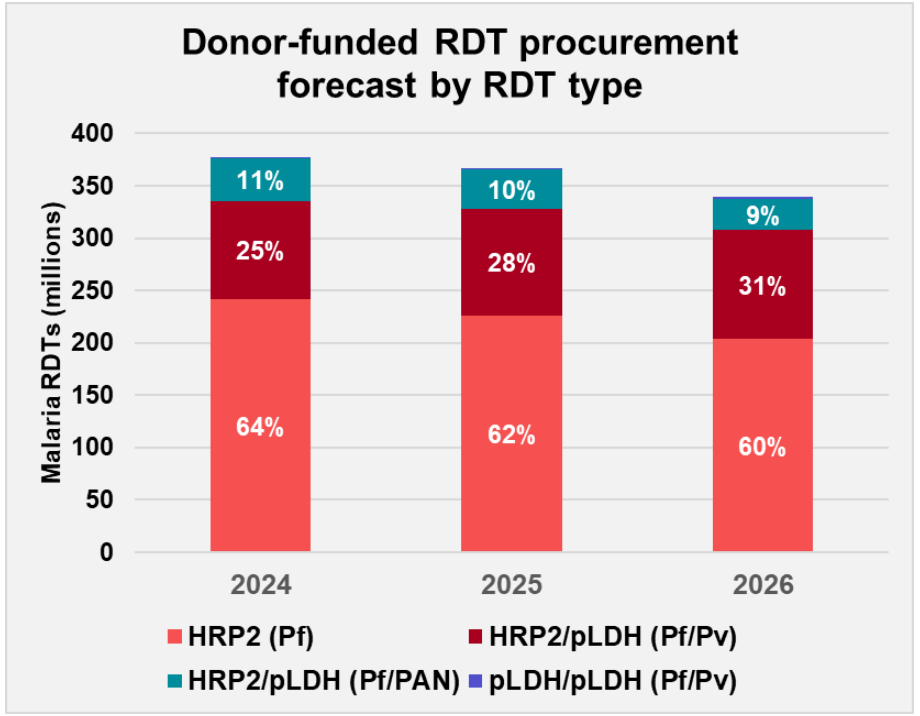
# Market share by type of RDT按快检试剂类型划分的市场份额

Sources cite different market share figures for the various RDT types; however, the figures are broadly similar. Pf HRP2 RDTs make up the majority of the market, followed Pf/Pv (HRP2/PvLDH) or Pf/Pan (HRP2/PanLDH) RDTs

不同来源对各类快检试剂的市场份额数据表述有所差异，但整体趋势基本一致。Pf HRP2型快检试剂占据市场主导地位，其次是Pf/Pv（基于 HRP2/PvLDH 检测靶点）或Pf/Pan（基于 HRP2/PanLDH）型快检试剂。

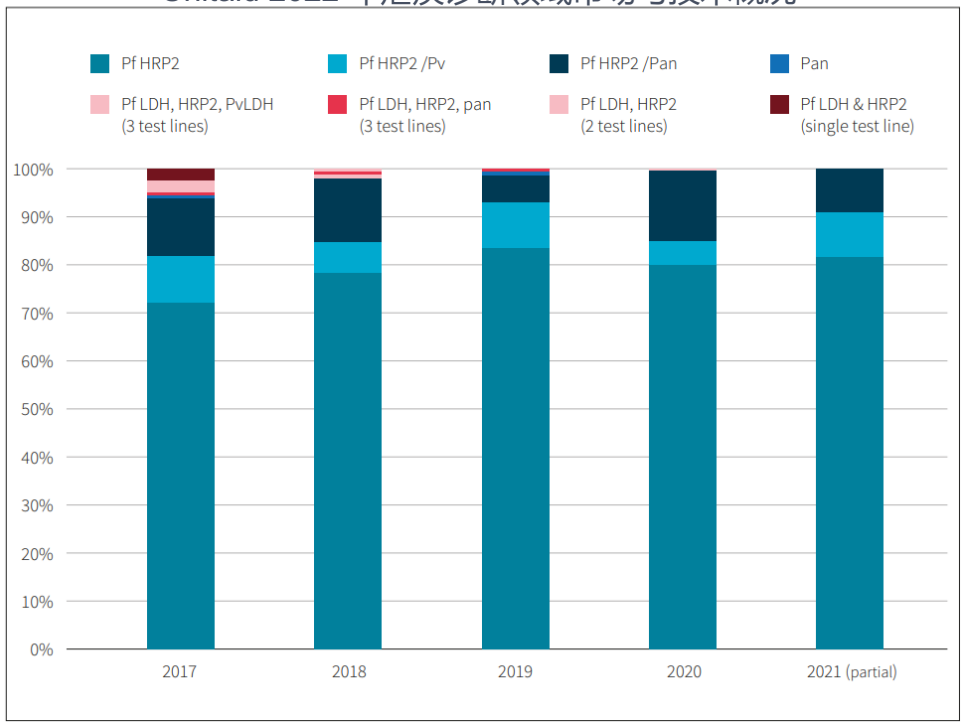
## CHAI short-term procurement forecast

克林顿健康获取倡议组织（CHAI）短期采购预测




## Unitaid 2022 Malaria Diagnostics Market and Technology Landscape

Unitaid 2022 年疟疾诊断领域市场与技术概况




- An analysis of 522 million RDTs purchased by the Global Fund indicated 74% were Pf only, 13% were Pf/Pv, and 13% were Pf/Pan
  对全球基金采购的 5.22 亿份快检试剂的分析显示，74% 为仅检测Pf型，13% 为Pf/Pv型，13% 为Pf/Pan型。
- This figure, along with the Unitaid report, may indicate the CHAI short-term procurement forecast is overestimating the market share of Pf/Pv RDTs.该数据与Unitaid的报告相结合，或许表明CHAI的短期采购预测高估了Pf/Pv型快检试剂的市场份额。

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# Countries and product types国家和产品类型

The Global Fund publishes detailed data on RDT procurement, which can be used to understand country RDT preferences and market share. However, this data is imperfect and should be used with caution. 全球基金会公布快检试剂采购的详细数据，这些数据可用于了解各国对快检试剂的偏好及市场份额。然而，该数据并非完美，使用时需谨慎。

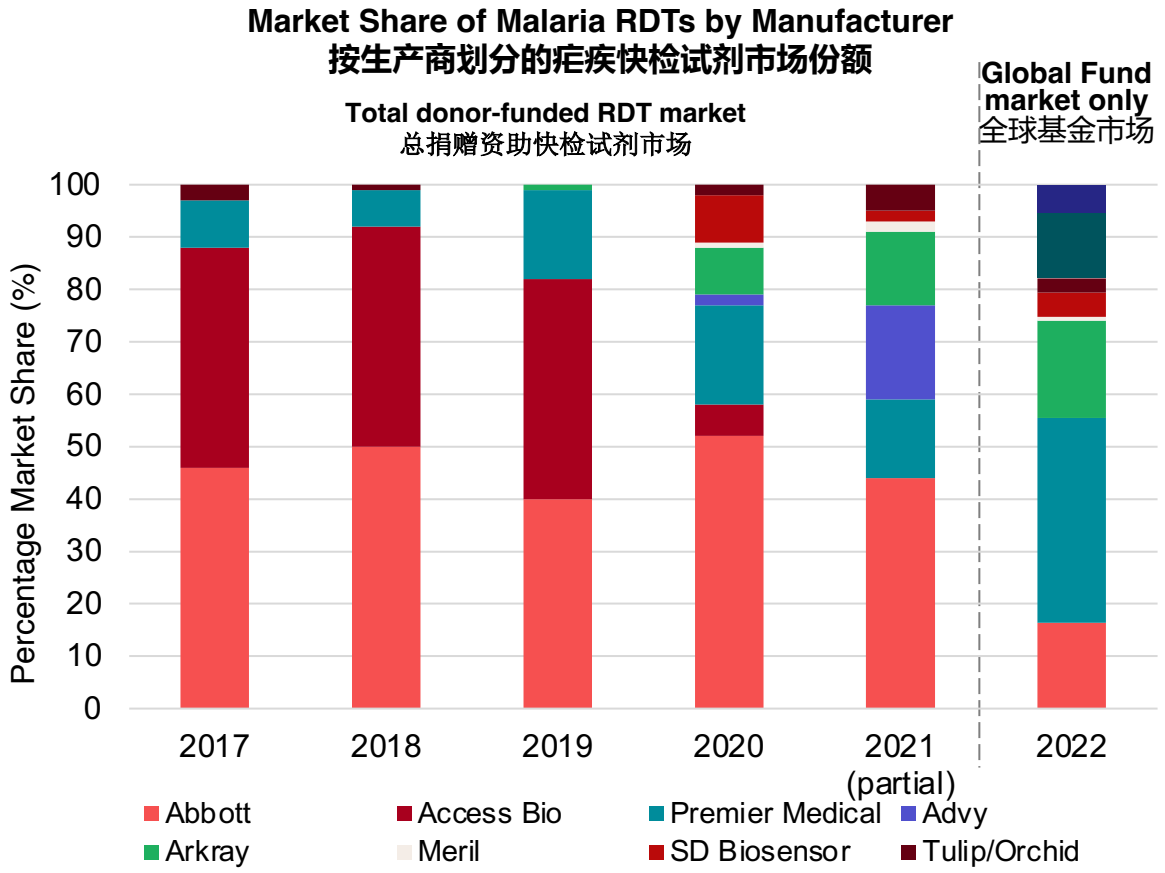
| Country | Product | Volume | | |
|---|---|---|---|---|
| | | 2020 | 2021 | 2022 |
| Uganda | First Response Malaria Ag **HRP2** [I13FRC25/30] | - | 41,736,075 | - |
| Uganda | First Response Malaria Ag **P.f./P.v.** (**HRP2/pLDH)** Card Test [PI19FRC25s] | - | - | 14,484,875 |
| Uganda | STANDARD Q Malaria **P.f.** Ag Test 25T/kits [09MAL10D] | - | 9,072,125 | 4,554,275 |
| Uganda | CareStart Malaria **Pf (HRP2)** Ag RDT 25T non-CE [RMOM 02571] ex-G0141 | 27,348,800 | - | - |
| Uganda | First Response Malaria Ag. **pLDH/HRP2** Combo Card Test [I16FRC25/30/40] | - | 1,300,000 | - |
| Uganda | SD Bioline Malaria Ag **Pf** 25s [05FK50] | - | 8,465,000 | - |

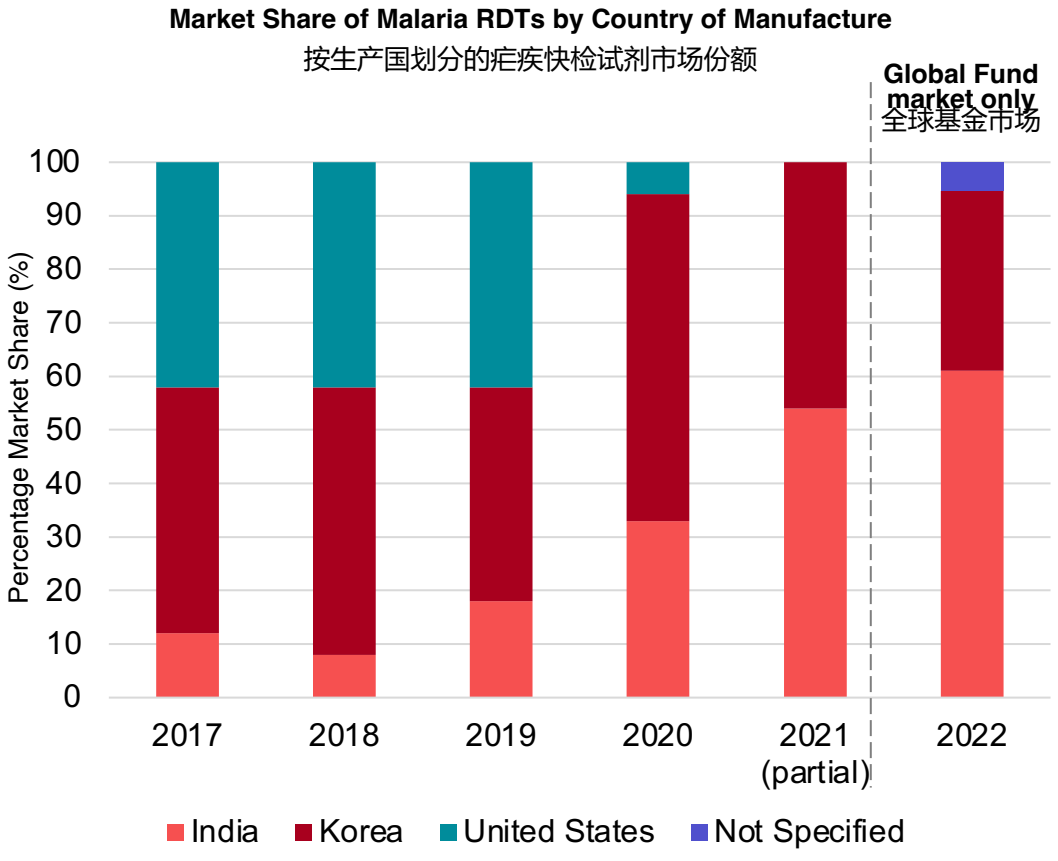
| Country | Product | Volume | | |
|---|---|---|---|---|
| | | 2020 | 2021 | 2022 |
| Zambia | Malaria RDT **(please upload invoice)** ⇦ | 3,059,950 | - | - |
| Zambia | First Response Malaria Ag **P.f./P.v. (HRP2/pLDH)** Card Test [PI19FRC25s] | - | 3,000,000 | 4,184,725 |
| Zambia | SD Bioline Malaria Ag **Pf** 25s [05FK50] | 12,738,700 | 8,824,750 | - |
| Zambia | STANDARD Q Malaria **P.f.** Ag Test 25T/kits [09MAL10D] | - | 3,220,725 | - |

| Country | Product | Volume | | |
|---|---|---|---|---|
| | | 2020 | 2021 | 2022 |
| Nigeria | First Response Malaria Ag **P.f./P.v. (HRP2/pLDH)** Card Test [PI19FRC25s] | - | - | 4,760,825 |
| Nigeria | Malaria RDT **(please upload invoice)** ⇦ | - | 4,290,250 | - |
| Nigeria | CareStart Malaria **Pf (HRP2)** Ag RDT 25T non-CE [RMOM 02571] ex-G0141 | 5,569,575 | - | - |
| Nigeria | First Response Malaria Ag **HRP2** [I13FRC25/30] | - | 17,153,725 | - |

# Manufacturer and country of manufacture market share生产商及生产国市场份额

Abbot and Access Bio dominated the market for years; however, Access Bio has dropped out of the market and Abbott has seen it's market share fall. Recently there has been an increase in RDTs manufactured in India entering global markets and many major manufactures are exploring opening factories or establishing manufacturing partners in Africa 多年来，雅培公司（Abbot）与爱科赛生物公司（Access Bio）一直在市场中占据主导地位；然而，爱科赛生物公司已退出市场，雅培公司的市场份额也出现下滑。近期，印度生产的快检试剂进入全球市场的数量有所增加，且多家主要生产商正考虑在非洲开设工厂或建立生产合作伙伴关系。




*Source: Global donor-funded market data for 2017-2021 from Unitaid malaria diagnostic market and technology landscape 2022, and data for 2022 from Global Fund Price and Quality Report only.*

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# Interviews: Uncertainty for investments in next gen RDTs 访谈：下一代快检试剂投资存在不确定性

Manufacturers want to know future demand. National malaria programs cite the importance of WHO guidance. Researchers note uncertainty of *pfhrp2/3* deletion spread. Budget-conscious donors are aware of opportunity costs. 生产商希望了解未来需求。各国疟疾防控项目提及WHO指南的重要性。研究人员指出pfhrp2/3基因缺失扩散情况存在不确定性。关注预算的捐赠方知晓机会成本。

## Manufacturers 生产商

- Expressed that there were **many market intelligence gaps** inhibiting decision-making.表示当前存在诸多市场情报缺口，对决策造成阻碍。
- Noted the **uncertainty around** the **spread of *pfhrp2/3* deletions**, the price customers **are willing to pay** for LDH/HRP2-based RDTs, **partner support**, and the experience of previously **"getting burned"**. 指出以下方面存在不确定性：pfhrp2/3基因缺失的扩散情况、客户愿意为基于LDH/HRP2检测靶点的快检试剂支付的价格、合作伙伴的支持力度，以及此前 "遭遇损失" 的过往经历。
- Consensus that **LDH/HRP2-based RDTs will cost more** than current RDTs but would not say exactly how much more. 各方共识是，基于LDH/HRP2检测靶点的快检试剂成本将高于现有快检试剂，但未明确说明具体高出多少。

## National Malaria Programs 国家疟疾计划

- Cited **desire to follow WHO guidance** and would switch RDTs once reaching ≥5%. 表示希望遵循WHO的指南，且当（某指标）达到 5% 及以上时，会更换快检试剂。
- **Preferred PfLDH/HRP2 RDTs if same price.若价格相同，更倾向于选择PfLDH/HRP2型快检试剂。**
- **RDT transition timelines average about 1.5 years**: 6-12 months on the policy change process, and 6-12 months on implementation (procurement, training and distribution).快检试剂的更换周期平均约为 1.5 年：其中政策变更流程需 6-12 个月，实施（包括采购、培训和分发）也需 6-12 个月。
- **Prefer** to use multiple brands to encourage **competition**. 倾向于使用多个品牌，以促进竞争。
- **NMPs would *consider* RDTs that were 20% more expensive if donors willing to pay;** RDTs that were 70% more expensive seemed unreasonable若捐赠方愿意承担费用，各国疟疾防控项目（NMPs）会考虑采购价格高出 20% 的快检试剂；而价格高出 70% 的快检试剂则被认为不合理。

## Donors捐赠方

- **Want** to see a **diverse supplier base**, a **pipeline of innovation** to meet emergent threats, and products available at the **lowest sustainable price**.希望看到多元化的供应商群体、能够应对突发威胁的创新产品线，以及以最低可持续价格供应的产品。
- **Difficult to pay for more expensive RDTs** when budgets are stable or declining, will really need to justify value and need. 在预算稳定或缩减的情况下，难以承担价格更高的快检试剂，因此确实需要充分论证其价值与必要性。

## Researchers 研究者

- **Uncertainty around pace of *pfhrp2/3* deletions spread**, but research being done to track it. pfhrp2/3基因缺失的扩散速度存在不确定性，但目前已有相关研究对其进行追踪。
- Outside of Horn of Africa there is evidence of clinically relevant *pfhrp2/3* deletions, but not at ≥ 5% level. 在非洲之角以外地区，已有证据表明存在具有临床意义的pfhrp2/3基因缺失情况，但该缺失率尚未达到 5% 及以上。
- **Elimination areas more at risk** due to more monoclonal infections.消除疟疾地区因单一克隆感染更多，面临的风险相对更高

## Implementers 实施者

- **Expect total RDT demand to increase** due to increases in cases and the use of more community health workers, but this likely change after funding cuts.预计由于疟疾病例增加以及社区卫生工作者使用量上升，快检试剂的总需求将有所增长，但在资金削减后，这一情况可能会发生变化。
- See a 20% increase in RDT prices as unlikely to be affordable, would require a strong value-proposition. 认为快检试剂价格上涨 20% 后，大概率会超出可承受范围，因此需要有力的价值论证来支撑这一涨价。
- Believe some countries would strictly follow WHO guidance while others would develop own policies. 认为部分国家会严格遵循WHO的指南，而另一些国家则会制定本国政策。

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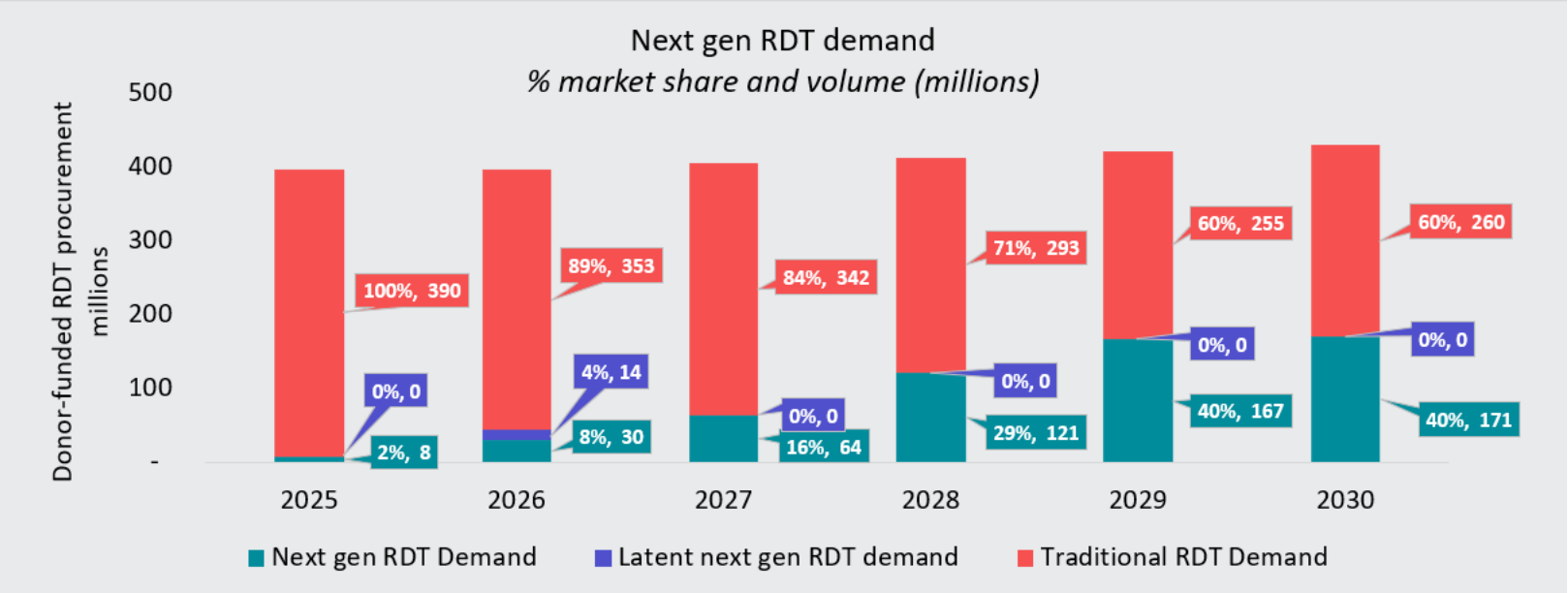
# Next gen RDT demand forecast新一代快检试剂需求预测

Demand for next gen RDTs is expected to rise as *hrp2/3* deletions spread, new suppliers enter the market, and prices decrease. 随着hrp2/3基因缺失的扩散、新供应商进入市场以及价格下降，预计新一代快检试剂的需求将有所增长。




- Estimates of the spread of *hrp2/3* deletions are the primary driver of demand behind these estimates. hrp2/3基因缺失扩散情况的估算数据，是支撑上述新一代快检试剂需求估算的核心驱动因素。
- Current demand for next gen RDTs is limited to Ethiopia, Eretria, and Djibouti at around 8 million RDTs. 目前，新一代快检试剂的需求仅集中在埃塞俄比亚、厄立特里亚和吉布提三国，需求量约为 800 万份。
- If modeling estimates are correct, *hrp2/3* deletions will cause the need for next gen RDTs to rise to 44 million in 2026, however, limited suppliers may only be able to provide 30 million RDTs for the market. 若模型估算结果准确，到 2026 年，hrp2/3 基因缺失将导致新一代快检试剂的需求量增至 4400 万份；然而，供应商数量有限，届时或仅能为市场提供 3000 万份。
- By 2027 the supply of next gen RDT should be able to meet demand as more manufacturers enter the market. 随着更多供应商进入市场，到 2027 年，新一代快检试剂的供应量应能满足需求。
- Given the current funding environment, there model is likely overestimating the speed that the market will shift to new RDTs. 考虑到当前的资金环境，该模型对市场向新型快检试剂转型速度的估算可能偏高。

# Key takeaways 核心要点

1. Overall malaria RDT demand is likely to remain steady, however there is significant downside risk with the decline in US government funding for global health.
总体而言，疟疾快检试剂的需求可能保持稳定，但美国政府对全球卫生领域的资金投入减少，带来了显著的下行风险。
    - Domestic country financing will increase in importance, likely resulting in less centralized procurement via large donors.
各国国内资金的重要性将不断提升，这可能导致通过大型捐赠方进行的集中采购规模有所减少。

2. Next gen RDTs are expected to increase in market share as *hrp2/3* deletions spread and more affordable RDTs with combined HRP2/PfLDH lines enter the market. 随着hrp2/3基因缺失的扩散，以及更多搭载 HRP2/PfLDH 联合检测线且价格更亲民的试剂进入市场，预计下一代快检试剂的市场份额将逐步扩大。

3. Manufacturer market share is shifting with more RDTs being manufactured in India. 由于印度生产的快检试剂数量增多，生产商的市场份额格局正发生变化。

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# New RDT demand forecast framework and phases 新型快检试剂需求预测框架及阶段

**Framework:** A relatively simple framework is used to calculate the expected number of new RDTs procured in country given donor- and country-side demand factors
**框架**：采用相对简单的框架，结合捐赠方与各国层面的需求因素，计算各国预计采购的新型快检试剂数量。

Probability a donor will procure new RDTS
捐赠方采购新型快检试剂的概率

X

Probability a country will adopt new RDTs
各国采用新型快检试剂的概率

X

Maximum potential volume of new RDTs a country could procure
一国可能采购新型快检试剂最大潜在数量

=

Expected number of new RDTs procured in a country
一国新采购的快检试剂预期数量

**X16 focus countries + 60 other countries**
**16 个重点国家 + 60 个其他国家**

**Phases:** The framework above is used across 4 phases that simulate different RDT product and regulatory dynamics
**阶段**：上述框架适用于 4 个阶段，这些阶段模拟了不同的快检试剂产品动态与监管动态。

**1 ERPD approved new RDT**

x x =

**>1 ERPD approved new RDTs**

x x =

**1 WHO PQ-ed new RDT, and >1 ERPD approved new RDTs**

x x =

**>1 WHO PQ-ed new RDTS**

x x =

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# Private Sector Market Insights

# 私营部门市场洞察

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# Why do we care about the private sector? 我们为何关注私营部门?

Many patients first seek care at private sector facilities – about **half of suspected malaria cases in sub-Saharan** Africa go to private providers initially (5). However, RDT use remains low due to added costs and a preference for presumptive treatment, like antimalarials. Approximately **4%** of donor-financed RDTs target private markets (6). As U.S. government funding declines, strengthening private engagement will be increasingly critical to sustain RDT availability and use.
许多患者首先在私营部门寻求治疗——在撒哈拉以南非洲地区，约一半的疑似疟疾病例最初是通过私营提供者治疗的（5）。然而，由于额外的成本和对抗疟药物等推定治疗的偏好，快检试剂的使用率仍然较低。大约4%的捐助者资助的快检试剂瞄准了私营市场（6）。随着美国政府资金的减少，加强私营部门的参与对于维持快检试剂的可用性和使用将变得越来越重要。

## Estimated Value估计价值

The availability of RDTs or microscopy among anti-malarial stocking private outlets was < 40 % in several African countries (1)在多个非洲国家，存有抗疟药物的私营销售点中，配备快检试剂或显微镜的比例不足 40%（1）

Average RDT coverage in public sector ~64 %, formal private ~48% (patients often cross sectors (e.g., test in public after consulting in private or vice versa) (2)公共部门的快检试剂平均覆盖率约为 64%，正规私营部门约为 48%（患者往往会跨部门就诊，例如在私营部门咨询后前往公共部门检测，或反之）(2)。

In studies enhancing RDT usage in private outlets in Sub-Saharan Africa, RDT uptake among febrile clients sometimes exceeded two-thirds and correct dispensing per result >75 % in some settings (3)在撒哈拉以南非洲地区旨在提高私营销售点快检试剂使用率的研究中发现，部分场景下发热患者快检试剂的使用率有时会超过2/3，且根据检测结果正确配药的比例超过75%（3）。

Countries like Ghana, Nigeria, Uganda include test, treat, and track policies for the private sector in their strategic plans and have piloted RDT use / malaria interventions in private facilities (4)加纳、尼日利亚、乌干达等国在其战略规划中纳入了针对私营部门的 “检测、治疗与追踪” 政策，并已在私营医疗机构试点推广快检试剂的使用及疟疾干预措施（4）

## Signals for Private Sector Entry 私营部门进入信号

Significant “white space” for diagnostic penetration用于诊断产品渗透存在的显著的 “空白领域”

Private sector is trailing public sector reach; covers a sizable share of the population.私营部门覆盖范围落后于公共部门，但覆盖了相当大比例的人口。

It is possible to achieve good RDT use if interventions are well designed and supported. 若干预措施设计合理且配套支持到位，快检试剂便可实现良好的使用效果。

Market entry strategies should consider countries where private sector is already a policy priority. 市场准入策略应考虑那些已将私营部门列为政策重点的国家。

## So what? 即便如此，又会怎样呢?

**The private sector in Africa represents a large, under-served, and increasingly strategic growth channel for malaria RDTs.**
**非洲的私营部门是疟疾快检试剂一个规模庞大、服务覆盖不足但战略重要性日益提升的增长渠道。**

**There’s an opportunity to shape how the next generation of malaria diagnostics reach and serve millions of patients beyond the public system.**
**有机会对新一代疟疾诊断产品的触达方式及服务范围进行规划，使其能覆盖公共体系之外的数百万患者并为他们提供服务。**

# Private Sector Landscape: Background & Aim 私营部门现状：背景与目标

**The "Problem" "问题"**

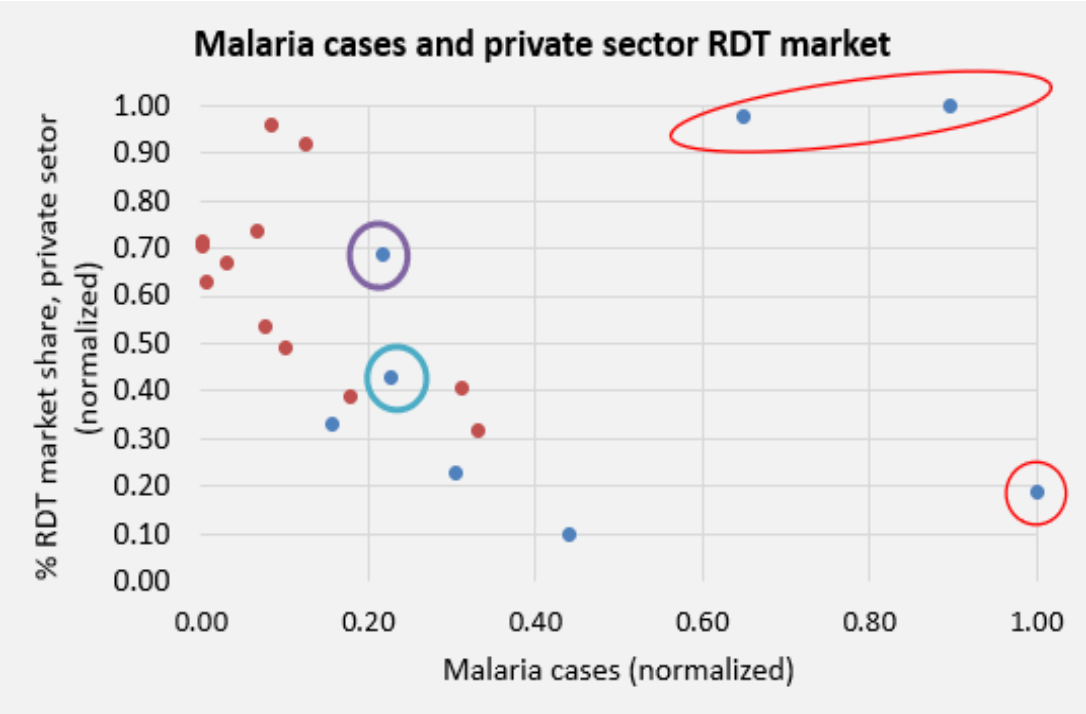
Despite accounting for nearly half of malaria case management in sub-Saharan Africa, the private sector remains a "black box", with limited visibility into how malaria RDTs are procured, distributed, and used. Data on supply chains, pricing, and diagnostic quality are often fragmented or absent from national reporting systems, making it difficult for governments and partners to engage effectively. This information gap prompted PATH's market research.
在撒哈拉以南非洲地区，私营部门虽承担了近半数的疟疾病例管理工作，却仍是一个 "暗箱"—— 人们对疟疾快检试剂的采购、分销及使用流程了解有限。供应链、定价及诊断质量相关数据在国家报告体系中往往零散不全或完全缺失，导致各国政府及合作伙伴难以有效开展工作。这一信息缺口促使 PATH开展了此次市场调研。

**PATH's market research aim/primary objective: PATH市场调研的目标/主要目的：**

1. To assess the structure, dynamics, and challenges of private-sector supply chain for malaria RDTs in three African countries, with a focus on identifying pathways to private sector markets for quality assured manufacturers producing improved sensitivity malaria RDTS.
评估三个非洲国家私营部门疟疾快检试剂供应链的结构、动态及面临的挑战，重点为生产高灵敏度疟疾快检试剂且质量有保障的生产商寻找进入私营部门市场的路径。

2. Generate actionable insights that support more effective engagement between governments, national malaria elimination programs (NMEPs), and private-sector stakeholders—including manufacturers, distributors, retailers, and providers—with the goal of improving access to quality-assured malaria diagnostics and strengthening public–private collaboration.
形成可以操作的见解，支持各国政府、国家疟疾消除计划与私营部门利益相关方（包括厂商、分销商、零售商及医疗服务提供方）开展更有效的协作，最终目标是提高民众获取质量有保障的疟疾诊断产品的可及性，并加强公私部门之间的合作。

# Research Scope: Country Selection Process 研究范围：国家选择流程




Uganda, Nigeria, DRC
乌干达、尼日利亚、刚果民主共和国
Ghana加纳
Malawi马拉维

- ❑ Regional analysis of 3 African countries
  三个非洲国家的区域分析
- ❑ Criteria for down-selection process 筛选流程标准:
  - Malaria Burden 疟疾负担 (Source: 2023 World Malaria Report2023年世界疟疾报告)
  - Private sector activity/Malaria tests consumed in private sector 私营部门活动 / 私营部门消耗的疟疾检测试剂 (Source: Malaria Atlas Project (MAP)疟疾地图集项目)
  - Regional representation 区域代表性
  - PATH Presence PATH 机构驻在情况
- ❑ Scoring: Malaria cases (A), Malaria Diagnosis in Private sector (B) = Weighted Index (A+B) [50% and 50%]
  评分方式：疟疾病例数（A）、私营部门疟疾诊断情况（B）= 加权指数（A+B）[权重各占 50%]

## Methodology 研究方法

- PATH conducted a combination of **secondary desk research and primary qualitative research**. Sources included partner reports, policies, and peer-reviewed publications, supplemented by semi-structured in-person stakeholder interviews. Particular attention was given to **demand drivers, brand usage, pricing, procurement processes, and private-sector preferences** for malaria RDTs. PATH采用了二手案头研究与一手定性研究结合的方式。研究资料来源于合作伙伴报告、相关政策文件及同行评审出版物，并辅以半结构化的实地利益相关方访谈。研究重点关注疟疾快检试剂的需求驱动因素、品牌使用情况、定价、采购流程以及私营部门对该类试剂的偏好。
- A total of **20 stakeholders** were interviewed across Kampala, Abuja, and Accra. Engagement included diagnostic manufacturers (2), private-sector distributors (5), mRDT retailers (5), and regulatory bodies – including NMEPs, National Drug Authorities, Pharmacy Council (8).在坎帕拉（乌干达首都）、阿布贾（尼日利亚首都）和阿克拉（加纳首都）三地，共访谈了 20 名利益相关方。参与访谈的主体包括：诊断试剂生产商（2 家）、私营部门分销商（5 家）、疟疾快检试剂零售商（5 家），以及监管机构 —— 涵盖国家疟疾消除计划、国家药品管理机构、药房委员会（共 8 家）。

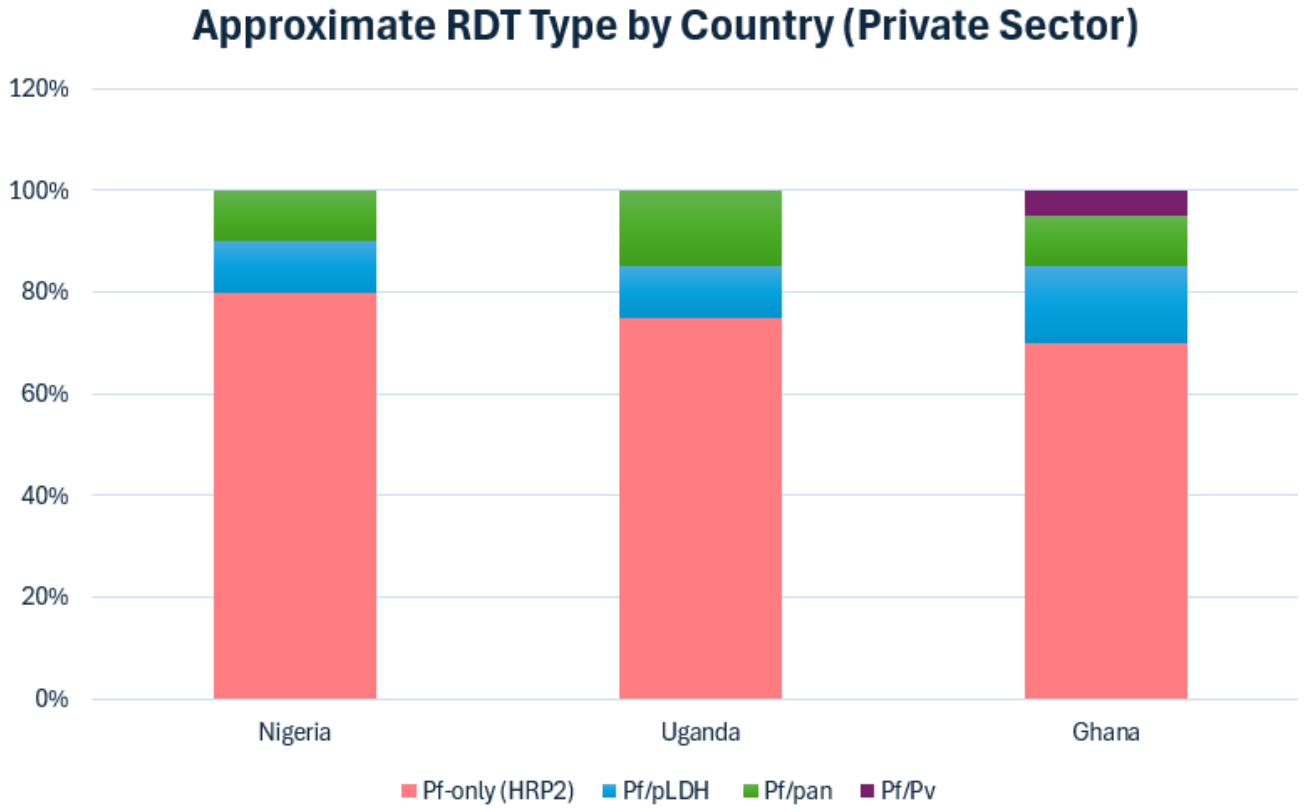
# Types of RDTs by Volume – Research Countries
# 按产量划分的快检试剂类型 – 研究国家

| Country 国家 | PfHRP2 | Pf/pLDH | panLDH/ Pf-pan | Pf/ PvLDH |
|---|---|---|---|---|
| Nigeria尼日利亚 | X | X | X | Limited |
| Uganda乌干达 | X | X | X | Limited |
| Ghana 加纳 | X | X | X | X |

**Nigeria** 尼日利亚
- NAFDAC registered several brands of PfHRP2-only tests. Retailers/PPMV interviews mentioned Pf/pan options available in some outlets. Pf/pLDH test are registered but limited in the private sector.
  NAFDAC已注册多个仅含PfHRP2的检测试剂品牌。通过对零售商及私立药房的访谈发现，部分门店可提供Pf/pan检测试剂。恶性疟原虫乳酸脱氢酶（Pf/pLDH）检测试剂虽已完成注册，但在私营部门的供应和使用较为有限。

**Uganda**乌干达
- Distributors mentioned Pf-only tests have the highest sales; although there is now a rising demand for Pf/pan tests. There are limited pilots for Pf/pLDH tests.
  分销商表示，仅检测Pf的试剂销量最高；不过目前检测Pf/pan的试剂需求正逐步上升。而针对Pf/pLDH试剂的试点应用较为有限。

**Ghana加纳**
- Retailers noted selling mostly PfHRP2-only test and even local Pan RDTs from Letap Pharmaceuticals. Pf/pLDH tests are registered in country but roll out and uptake is relatively slow.
  零售商表示其销售的试剂以仅含PfHRP2的检测试剂为主，同时也销售生产的本土泛疟原虫检测试剂。该国虽已注册Pf/pLDH检测试剂，但该类试剂的推广及普及速度相对较慢。




Pf-only HRP2 tests dominate the private and public sector, but combos and Pf/pan tests are slowly emerging
仅检测恶性疟原虫的HRP2检测试剂在私营和公共部门均占据主导地位，但联合检测试剂（combos）及Pf/pan检测试剂正逐步兴起。

# Most Common Brands in Research Countries 研究国家中最常见的品牌

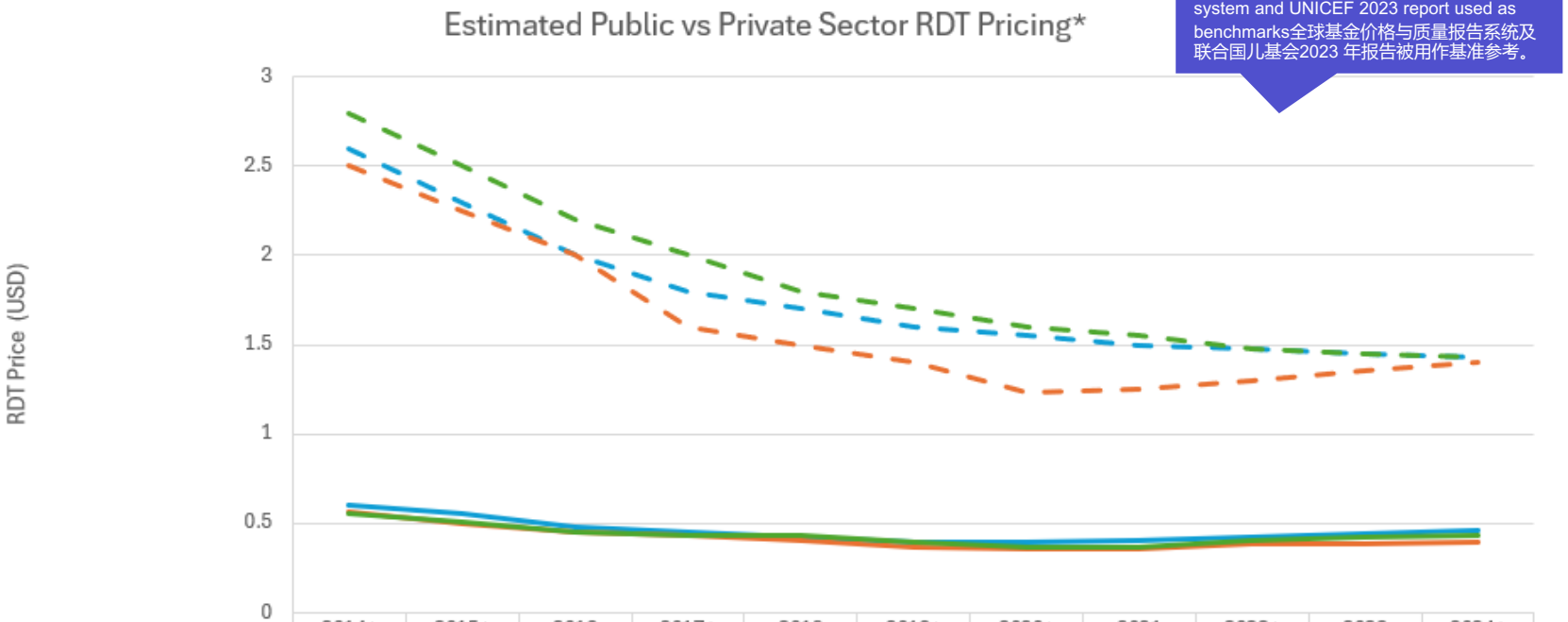
| Brand<br>品牌 | Type<br>类型 | Manufacturer<br>生产商 | Sector<br>部门 | Country<br>国家 |
|---|---|---|---|---|
| CareStart | PfHRP2 | Abbott/Access Bio | Public, Limited Private | Nigeria, Uganda, Ghana |
| SD Bioline | PfHRP2<br>Pf/Pan | Abbott | Public, Limited Private | Nigeria, Uganda, Ghana |
| Standard Q | PfHRP2 | SD Biosensor | Public + Private | Nigeria, Uganda, Ghana |
| First Response | PfHRP2<br>Pf/Pan | Premier Medical | Public + Private | Nigeria, Uganda, Ghana, |
| Microhaem Pf | PfHRP2 | Microhaem Scientifics | Public | Uganda |
| Paracheck Pf | PfHRP2 | Orchid Biomedical | Private | Uganda |
| AdvDx | PfHRP2 | Advy Chemical | Private | Uganda, Nigeria |
| Oscar | PfHRP2 | Oscar Medicare | Private | Uganda, Ghana |
| ParaHit | Pf/Pan | Arkray Healthcare | Private | Nigeria |
| MeriScreen | Pf/Pv<br>Pf/Pan | Meril Diagnostics | Public + Private | Ghana |
| Healgen | Pf/Pan | Healgen Scientific Ltd<br>(rebranded by MedTest Ghana) | Private | Ghana |

The primary suppliers to the private sector are independent distributors that sell a mix of WHO-prequalified and non-WHO-prequalified mRDT kits due to fewer regulatory constraints. 私营部门的主要供应商是独立分销商，由于监管限制较少，这些分销商销售的疟疾快检试剂盒中，既有通过WHO PQ的产品，也有未通过的产品。

Source: PATH stakeholder interviews, ACTwatch Nigeria 2024, Unitaid, The Global Fund list of RDT kits for Malaria, import data

# Pricing & Affordability – Research Countries 定价与可负担性 — 研究涉及的国家

Global Fund Price & Quality Reporting system and UNICEF 2023 report used as benchmarks全球基金价格与质量报告系统及联合国儿基会2023 年报告被用作基准参考。




| | 2014* | 2015* | 2016 | 2017* | 2018 | 2019* | 2020* | 2021 | 2022* | 2023 | 2024* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Nigeria Public Sector | 0.6 | 0.55 | 0.48 | 0.45 | 0.42 | 0.39 | 0.39 | 0.4 | 0.42 | 0.44 | 0.46 |
| Uganda Public Sector | 0.56 | 0.5 | 0.45 | 0.43 | 0.4 | 0.37 | 0.36 | 0.36 | 0.38 | 0.38 | 0.39 |
| Ghana Public Sector | 0.55 | 0.51 | 0.45 | 0.43 | 0.43 | 0.39 | 0.37 | 0.37 | 0.4 | 0.42 | 0.43 |
| Nigeria Private Sector | 2.6 | 2.3 | 2 | 1.8 | 1.7 | 1.6 | 1.55 | 1.5 | 1.48 | 1.45 | 1.43 |
| Uganda Private Sector | 2.5 | 2.25 | 2 | 1.6 | 1.5 | 1.4 | 1.23 | 1.25 | 1.3 | 1.35 | 1.4 |
| Ghana Private Sector | 2.8 | 2.5 | 2.2 | 2 | 1.8 | 1.7 | 1.6 | 1.55 | 1.48 | 1.45 | 1.43 |

*Limited data available for year-by-year datasets for RDT pricing for both public- and private-sector RDT prices for Nigeria, Uganda, and Ghana. Public prices represent procurement unit costs, not patient fees; assumed relatively flat with mild decade dip and slight recent uptick. Private retail prices anchored to known ranges (ACTwatch reports); gentle compression over time due to competition and targeted subsidies. Where annual data was unavailable, values were **interpolated and imputed based on market trends and assumptions**. All prices are presented in USD/test, rounded to two decimals.
关于尼日利亚、乌干达和加纳三国公共部门与私营部门疟疾快检试剂价格的逐年数据集，目前可获取的数据有限。其中，公共部门价格仅代表采购单位成本，而非患者支付的费用；据推测，该价格整体相对平稳，过去十年间略有下降，近期则小幅回升。私营部门零售价格以已知价格区间（来源于ACTwatch 报告）为基准；受市场竞争及定向补贴影响，该价格长期呈缓慢下降趋势。对于无法获取年度数据的情况，相关数值已根据市场趋势及合理假设通过插值法与推算得出。所有价格均以 “美元/份检测试剂” 为单位呈现，并保留两位小数。

## Key Observations主要观察结果

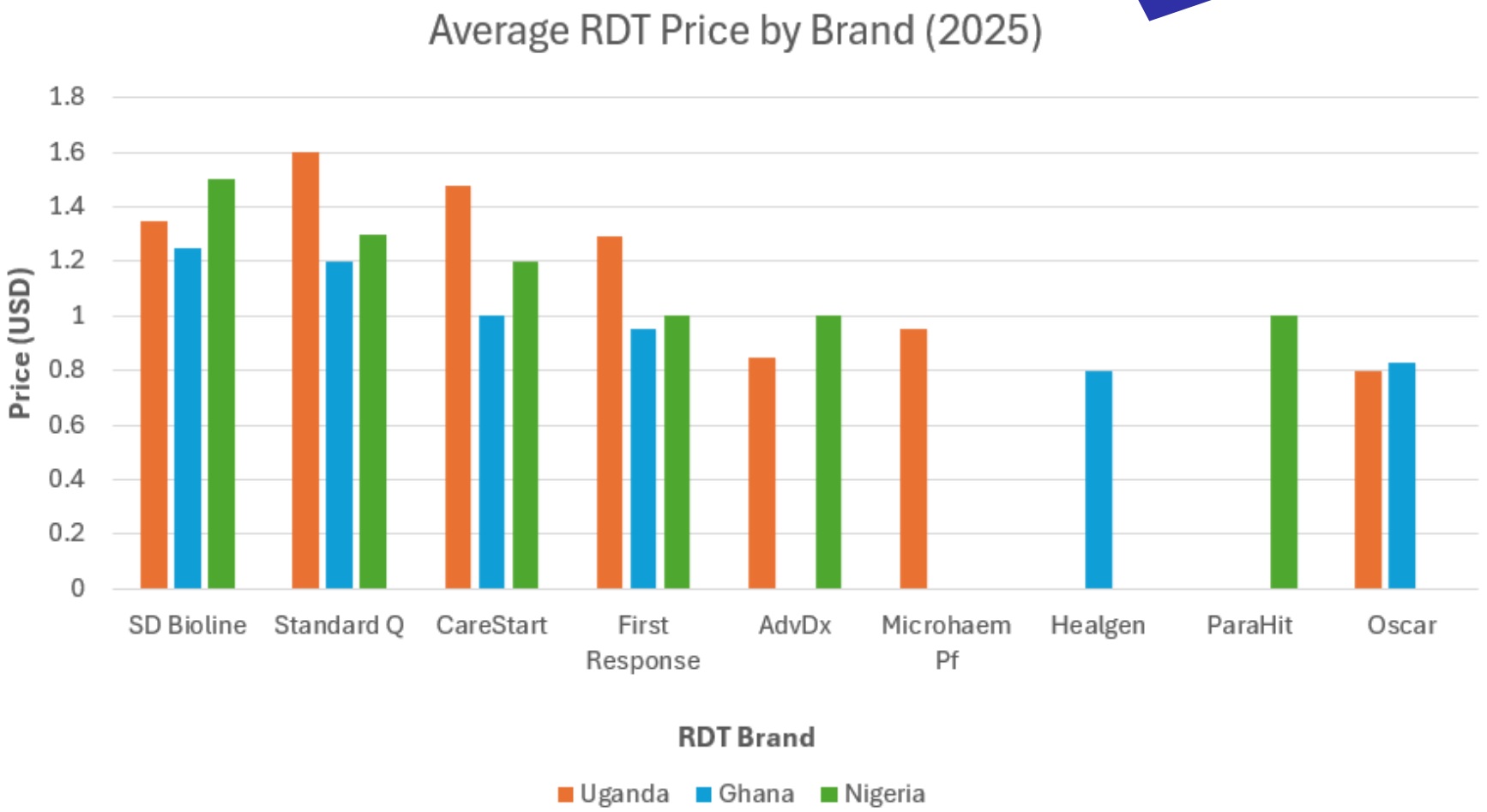
- Rising inflation, import costs, and reduced donor funding contributed to increase diagnostics costs starting in 2020 (1)通胀上升、进口成本和捐助资金减少导致诊断成本从2020年开始增加[1]
- In Nigeria, new partnership with Codix (local manufacturer) is expected to reduce reliance on imports, stabilize prices, and improve access. (1)在尼日利亚，与Codix（当地生产商）的新合作伙伴关系预计将减少对进口的依赖，稳定价格并改善获取途径。[1]
- The Global RDT market became highly concentrated leading to limited competition, and vulnerability to supply chain shocks, especially post COVID-19全球疟疾快检试剂市场集中度大幅提高，这不仅导致竞争受限，还使市场易受供应链冲击影响，2019 冠状病毒病疫情后尤为明显。
- UNICEF’s Malaria RDT Market & Supply Update (2023) reports that the Weighted Average Price (WAP) for malaria RDTs declined from about USD 0.65 in 2013 to USD 0.36 in 2021 (2)联合国儿基会《疟疾快检试剂市场与供应最新报告》显示，疟疾快检试剂的加权平均价格从 2013 年的约 0.65 美元降至 2021 年的 0.36 美元。[2]
- Across Uganda, Nigeria, Ghana, public-sector procurement prices are essentially aligned with global donor-negotiated rates (~$0.25–0.35/test).Variation year-to-year is minimal compared to private sector retail, where prices are typically $1.00–2.50/test.在乌干达、尼日利亚和加纳三国，公共部门的采购价格基本与全球捐赠方协商确定的价格（约 0.25–0.35 美元 / 份检测试剂）保持一致。与私营部门的零售价格（通常为 1.00–2.50 美元 / 份检测试剂）相比，公共部门采购价格的年度波动幅度极小。

# Private Sector RDT Pricing By Common Brands
# 私营部门常见品牌疟疾快检试剂定价

Across ACTwatch countries, markup ratios usually fall between **3× and 5×**
在 ACTwatch 覆盖的国家中，加价倍数通常在 3~ 5 倍之间。

## Caveats 注意事项

1. These are retail/private sector end-user prices 这些是零售端 / 私营部门的终端用户价格。
2. Ranges reflect median observed values in ACTwatch surveys and market reports, plus inflation and recent (2020–2023) retail compression.价格区间基于 ACTwatch 调查与市场报告中观察到的中位数值，并结合了通货膨胀因素及近期（2020-2023 年）零售价格下降趋势。
3. Actual price can vary by country, distribution chain, and subsidies. 实际价格会因国家、分销链及补贴政策的不同而存在差异。
4. Generics (Healgen, Oscar) often undercut PQ-listed brands but come with quality risks 仿制药品牌（如 Healgen、Oscar）的价格通常低于通过WHO PQ的品牌，但存在质量风险。

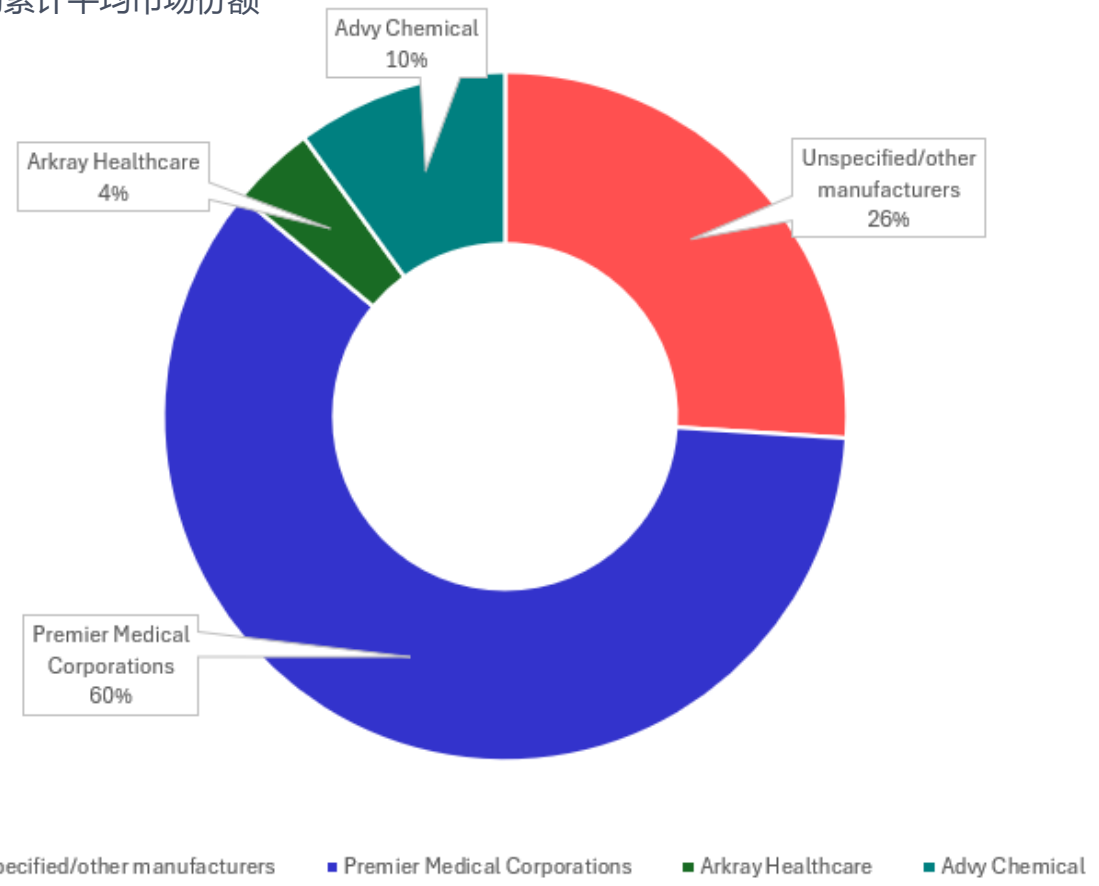


# Manufacturer Presence in Private Sector 生产商在私营部门的参与情况

The malaria RDT market in Nigeria's private sector is fragmented but dominated by a few known players. 尼日利亚私营部门的疟疾快检试剂市场呈现分散态势，但仍由少数知名企业主导。

- **Premier Medical Corporation:** the leading supplier, accounting for the majority of RDTs in Kano and substantial shares in Abia and Lagos. 卓越医疗公司作为主要供应商，其在卡诺州的疟疾快检试剂市场中占据主导份额，同时在阿比亚州和拉各斯州也拥有相当大的市场占比。
- **Advy Chemical:** smaller but consistent presence across Nigeria states, with higher visibility in laboratories and for-profit facilities. 艾德维化学公司在尼日利亚各州的市场份额虽较小，但布局持续稳定，且在实验室及营利性医疗机构中的知名度更高。
- **Arkray Healthcare:** modest share, generally under 10%, though noted across multiple outlet types. 爱科来医疗保健公司市场份额不大，通常低于 10%，但在多种销售渠道中均有分布。
- Based on publicly available import data, other manufacturers include Meril Diagnostics and Salvavidas Pharmaceutical.根据可公开获取的进口数据，其他生产商还包括梅里尔诊断公司（Meril Diagnostics）和萨尔瓦维达斯制药公司（Salvavidas Pharmaceutical）

Cumulative average market share for RDT manufacturers across three states (Abia, Kano, and Lagos)* 三种快检试剂生产商在三个州（阿比亚、卡诺、拉各斯）的累计平均市场份额 *




*Manufacturer data in Abia and Lagos is sparse. Most RDTs in these states were either microscopy-based or lacked clear manufacturer attribution.
阿比亚州和拉各斯州的生产商数据较为稀缺。这两个州的大多数疟疾快检试剂要么是基于显微镜检测的类型，要么未明确标注生产商信息。

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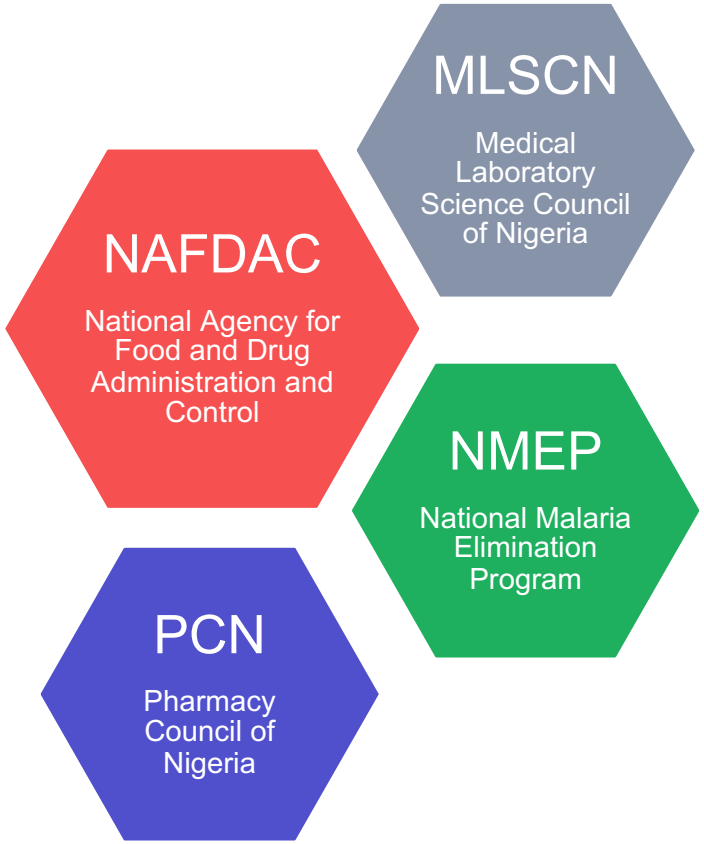
Source: ACTwatch Lite Nigeria 2024 report

Nigeria尼日利亚

# Private Sector Regulatory Landscape for mRDTs
# 私营部门疟疾快检试剂的监管环境




| Regulator<br>监管机构 | Role<br>职责 | Timeline for approval<br>审批时间表 |
|---|---|---|
| NAFDAC<br>尼日利亚国家食品药品监督管理局 | Product registration & quality assurance of in-vitro diagnostics; required approval for all in-country IVDs.体外诊断产品注册与质量保证；所有国内体外诊断产品均需获得批准。 | Up to 18 months. Accelerated timeline with WHO-PQ or other trusted regulators最长 18 个月。若通过WHO PQ或获得其他权威监管机构认证，审批流程可提速。 |
| PCN<br>尼日利亚药学委员会 | Licenses pharmacists, pharmacy technicians, and PPMVs. Inspects pharmacies to ensure compliance. Collaborates with NMEP and NAFDAC.为药师、药学技术人员及私立药房颁发执业许可；对药房进行检查以确保合规经营；与NMEP及NAFDAC开展合作。 | No fixed duration stated on website. Process involves location approval, pre-registration inspection, routine inspections, annual renewal deadlines. 官网未注明固定时长。流程包含经营场所审批、注册前检查、常规检查，以及年度续期截止时限。 |
| MLSCN<br>尼日利亚医学检验科学委员会 | Sits under the Federal Ministry of Health; works with Federal, State, Local Governments and Private Health Institutions to ensure accreditation of laboratory services, and regulation of RDTs in diagnostic facilities. 隶属于联邦卫生部，与联邦、州、地方各级政府及私立医疗机构合作，确保实验室服务获得认证，并对诊断机构中的快检试剂实施监管。 | 6–12 months<br>(cost ₦250,000 for product evaluation and listing).<br>6-12 个月（产品评估及备案费用为 25 万尼日利亚奈拉，₦为尼日利亚奈拉货币符号） |
| NMEP<br>尼日利亚国家疟疾消除项目 | NMEP collaborates with NAFDAC to ensure that RDTs are nationally approved and meet quality standards. Limited oversight of private sector. NMEP与NAFDAC开展合作，确保快检试剂获得全国性批准且符合质量标准。（该项目）对私营部门的监管力度有限。 | 3-6 months for endorsement and inclusion in policies (not a common pathway for private sector suppliers). 获得认可并纳入政策的流程需 3-6 个月（这并非私营部门供应商常用的渠道）。 |

PATH

# Private Sector Stakeholders – Importers/Distributors & Retailers
# 私营部门利益相关方 — 进口商/分销商及零售商

Nigeria尼日利亚

| Importers/Distributors 进口商/分销商 | Role 职责 |
|---|---|
| Codix Pharma 科迪克斯制药公司 | Active local distributor in Nigeria and Ghana bringing in multiple IVD brands and RDTs, including Standard Q (SD Biosensor) and Arkray. Former exclusive distributor for Abbott 's SD Bioline test (1,2). 尼日利亚和加纳当地活跃分销商，引进多个体外诊断试剂品牌及快检试剂，包括 Standard Q（由 SD Biosensor 公司生产）和爱科来（Arkray）品牌产品。曾是雅培（Abbott）公司 SD Bioline 检测试剂的独家分销商 [1,2] |
| JNC international JNC 国际公司 | Importer and distributor of a range of medical equipment and diagnostics. Over 1,200 import/export records linked to medical instruments, including diagnostics, however specific volumes for malaria RDTs are not publicly broken out (3). 各类医疗设备及诊断品的进口商与分销商。有超过 1200 条进出口记录与医疗器械（含诊断品）相关，但疟疾快检试剂的具体交易量未公开披露 [3]。 |
| MicroHaem Scientifics 麦科希姆科学公司 | Manufacturer and distributor of diagnostic kits, including malaria RDTs. MicroHaem supported distribution and supply chain development for RDTs in retail outlets (PPMVs, pharmacies) in Ogun, Anambra, and Cross River states (1,4). 诊断试剂盒（含疟疾快检试剂）的生产商与分销商包括麦科希姆科学公司，其曾在奥贡州、阿南布拉州和克罗斯河州，为零售渠道（私立药房、药店）的快检试剂提供分销支持及供应链建设协助 [1,4]。补 |

| Types of Retailer 零售商类型 | Role 职责 |
|---|---|
| Community Pharmacies (licensed by PCN)社区药房（由 PCN 授权） | Concentrated in urban areas (Lagos, Abuja, Kano); stock RDTs inconsistently due to limited demand and supply.集中分布于城市地区（拉各斯、阿布贾、卡诺）；因供需有限，快检试剂的库存不稳定。 |
| Patent and Proprietary Medicine Vendors (PPMVs)专利与专卖药品销售点 | The largest retail footprint in Nigeria; critical for rural access; often stock ACTs but not RDTs consistently.是尼日利亚零售网络覆盖最广的渠道，对农村地区获取医疗产品至关重要；通常会储备青蒿素类复方疗法药物（ACTs），但快检试剂的库存不稳定。 |
| Private Clinics/ Hospitals (for-profit and not-for-profit)私立诊所 / 医院（含营利性与非营利性） | Higher stocking rates of RDTs; rely on distributors/importers like Codix and MicroHaem.快检试剂的备货率较高，依赖科迪克斯制药公司（Codix）、麦科希姆科学公司（MicroHaem）等分销商/进口商供货。 |
| Diagnostic Laboratories诊断实验室 | Regulated by MLSCN; sometimes stock RDTs but more reliant on microscopy.受尼日利亚医学检验科学委员会（MLSCN）监管；有时会储备快检试剂，但更依赖显微镜检测技术。 |
| E-pharmacies/Online Retailers线上药房/网络零售商 | Emerging distribution channel, though limited regulation by regulatory bodies属于新兴分销渠道，不过目前各监管机构对其监管仍有限。 |

## Distributor Key Insights分销商主要发现

- Many PQ-listed manufacturers do not operate directly in Nigeria. Instead, they rely on local agents or appointed distributors (e.g., Codix Pharma, MicroHaem, JNC International) to handle registration with NAFDAC and MLSCN, navigate customs, and manage tender submissions.许多通过预认证的生产商并不直接在尼日利亚运营。相反，它们依赖当地代理商或指定的分销商（如Codix、MicroHaem、JNC）来处理NAFDAC和MLSCN的注册、办理海关事宜和管理投标文件的提交。
- Market dominated by few large importers of PQ brands; limited public data available on importer and distributors. 通过WHOPQ 品牌的进口市场由少数几家大型进口商主导；关于进口商和分销商的公开数据较为有限。
- Non-PQ generics widely imported through informal channels.未通过WHO PQ类的仿制药通过非正规渠道大量进口。
- Distributors are largely concentrated in Lagos/Abuja; regional distribution via wholesalers.分销商主要集中在拉各斯和阿布贾；区域分销则通过批发商来进行。
- Price markups accrue along supply chain (importer → wholesaler → retail chain)供应链各环节（进口商→批发商→零售连锁）均会产生价格加价。
- Weak regulatory oversight of import licenses. 进口许可证的监管力度较弱

## Retailer Key Insights零售商主要发现

- Retailers noted limited stock of RDTs due to low demand/turnover, perception is that customer won't pay for RDT and ACT. RDTs are typically priced 4-5x higher than public procurement.零售商表示，由于需求/周转率较低，快检试剂库存有限；认为消费者不愿为快检试剂和青蒿素类复方疗法药物付费。通常情况下，快检试剂的售价是公共采购价的 4 至 5 倍。
- Another common reason for low RDT stockage is logistical and procurement challenges (well known brands are often out of stock). 快检试剂库存偏低的另一常见原因是物流与采购难题（知名品牌常出现缺货情况）。
- Sales volume, retailer margins, and brand-level sales at the outlet-level are rarely published. 零售门店层面的销售量、零售商利润率及品牌销售额，均鲜有公开数据。
- Quality concerns with expired tests and buffer issues were noted from one Nigerian retailer. Many non-WHO PQ test are sold in the private sector.尼日利亚某零售商指出，市场上存在检测试剂过期及缓冲液异常的质量问题。私营部门销售的检测试剂中，有大量未通过WHO PQ的产品。
- The 2024 ACTwatch Lite study includes scoping of e-pharmacy / online retail as part of the private sector RDT supply chain, though mapping is still nascent. These platforms may offer opportunities to increase reach; however regulatory and quality issues are common. 2024 年 ACTwatch 简化版研究已将线上药房/网络零售纳入私营部门快检试剂供应链的调研范围，但目前相关梳理工作仍处于初期阶段。这些平台或为扩大（检测试剂的）覆盖范围提供机遇，但普遍存在监管与质量问题。

# Manufacturer Presence in Private Sector

## 生产商在私营领域的参与情况

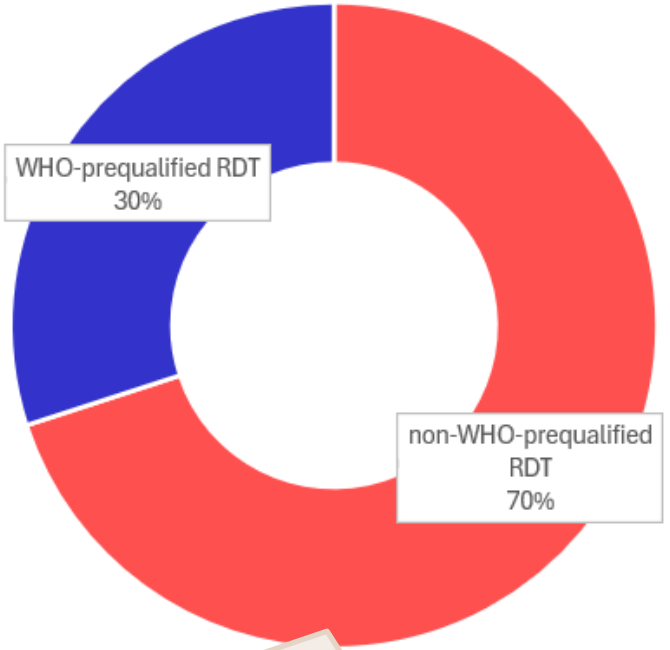
Malaria RDTs in Uganda private outlets remains low, with no single dominate brand, though a few manufacturer's have notable presence in pharmacies, drug shops, and private clinics.
乌干达私营销售点的疟疾快检试剂供应仍处于较低水平，市场中尚无单一主导品牌，不过有少数生产商在药房、药店及私立诊所中占据显著市场份额。

| Common WHO-PQ'd test in Private Markets 私营市场中常见的通过WHO PQ的检测试剂 | Common Non-WHO-PQ's Tests in Private Markets 私营市场中常见的未通过WHO PQ的检测试剂 |
|---|---|
| Standard Q (SD Biosensor) | Oscar Pf RDT (Oscar Medicare) |
| First Response (Premier Medical) | CareStart (Access Bio) |
| Paracheck Pf (Orchid Biomedical) | Zhengzhou Fortune Bioscience |
| AdvDx (Advy Chemical) | Hangzhou Clongene Biotech |

**Microhaem Scientifics (MHS):** local manufacturer recently received government approval and GMP certification for its malaria, HIV, and sickle cell RDTs. Initial distribution contract is with the MoH via National Medical Stores (NMS), covering 30% of Uganda's annual demand in the public sector. MHS low-cost, self-test kits and high production capacity position it well for future private sector distribution.
乌干达当地一家生产商近期获得了政府批准及GMP认证，可生产疟疾、艾滋病及镰状细胞病快检试剂。该厂商的首份分销合同由卫生部通过国家医疗物资储备局签订，覆盖乌干达公共部门年度需求量的 30%。MHS凭借低成本的自检试剂盒及高产能，为未来布局私营部门分销奠定了良好基础。

Data suggest that non-WHO-prequalified malaria RDTs make up the majority of the private sector market. In Uganda, most audits and surveys focus on the availability and use of RDTs, rather than examining brand-level or quality (PQ vs non-PQ) market share.
数据显示，私营市场中，未通过WHO PQ的疟疾快检试剂占据主要份额。在乌干达，大部分审计与调查关注在快检试剂的可及性和使用，而非品牌层面或质量类别的市场份额。

Estimated values based on limited import data



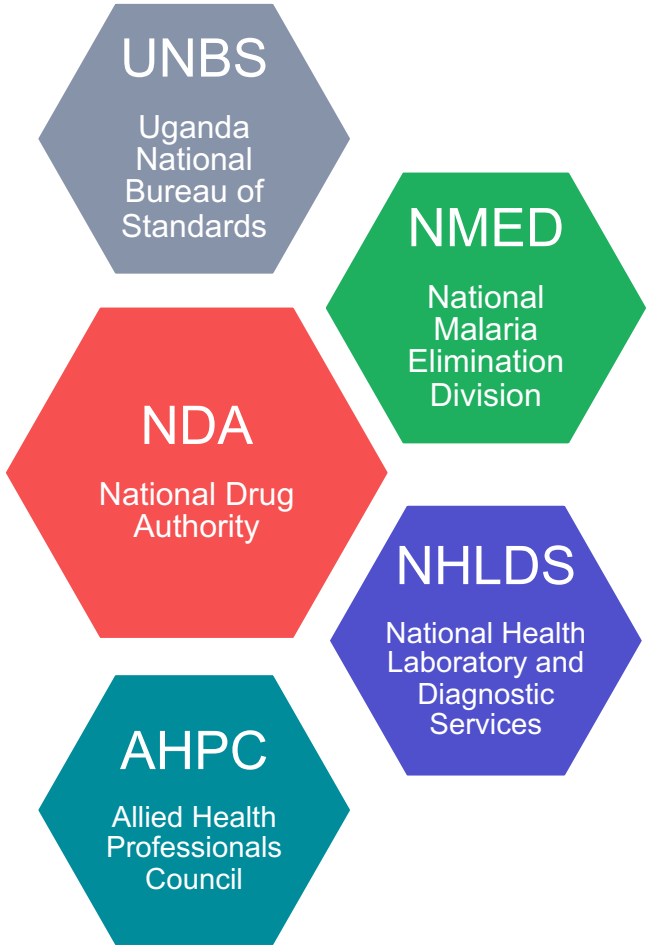

Includes non-WHO prequalified brands from India and China and many rebranded imports without clear manufacturer identification 包含来自印度和中国的未通过WHO PQ的品牌，以及众多无明确生产商标识的贴牌进口产品。

*Source: Data compiled from stakeholder interviews and publicly available import data. Not based on nationally representative data.*

Uganda乌干达

# Private Sector Regulatory Landscape for mRDTs

## 私营部门疟疾快检试剂的监管环境




| Regulator<br>监管机构 | Role<br>职责 | Timeline for approval<br>审批时间表 |
|---|---|---|
| NDA<br>国家药品管理局 | Approves registration and importation of malaria RDTs and other IVDs. Oversees quality assurance, post-market surveillance, and inspection of facilities. Issues certificates of registration and import permits.负责批准疟疾快检试剂及其他体外诊断试剂的注册与进口工作，监督质量保证、上市后监测以及机构检查，核发注册证书与进口许可证。 | • **6-9 months** for products with **WHO PQ** or stringent regulatory approval (expedited review).对于已通过WHO PQ或获得严格监管机构批准的产品，审批周期为 6-9 个月（加急审核）。<br>• **9-12 months** for **non-WHO-PQ** products requiring full technical and lab evaluation.对于需完成全面技术评估与实验室评估的未通过WHO PQ的产品，审批周期为 9 -12 个月。 |
| NMED<br>国家疟疾消除司 | Division under the Ministry of Health. Coordinates malaria case management, including RDT use and policy adoption. Ongoing efforts to work closely with NDS on regulatory and implementation guidelines隶属于卫生部，统筹疟疾病例管理工作（包括快检试剂的使用与相关政策推行），目前正持续推进与国家疾病服务机构的紧密合作，共同制定监管及实施指南。 | Does not approve private sector diagnostics不审批面向私营部门的诊断试剂。 |
| UNBS<br>乌干达国家标准局 | Develops standards for medical devices, diagnostic products, and packaging/labelling.Works in coordination with NDA to ensure quality and safety compliance.制定医疗器械、诊断产品及包装 / 标签的相关标准，与国家药品管理局协同工作，确保产品符合质量与安全要求。 | If not already covered by NDA inspection, UNBS verifies packaging, labeling, and conformity to national standards (~2-3 weeks). 若NDA尚未对相关产品进行检查，UNBS将对产品的包装、标签及是否符合国家标准进行核查（约 2-3 周）。 |
| NHLDS<br>国家卫生实验室诊断服务局 | Provides technical guidance on diagnostic use and validation. Participates in evaluation and approval processes for diagnostic technologies. Hosts or coordinates laboratory evaluations before NDA registration. 为诊断试剂的使用及验证提供技术指导，参与诊断技术的评估与审批流程，在国家药品管理局注册前主导或统筹实验室评估工作。 | ~3-4 months. If WHO-PQ data already available, NHLDS may conduct desk review only, shortening timeline to 4-6 weeks.约 3 - 4 个月。若已具备WHO PQ相关数据，NHLDS或仅开展文件审查，此举可将周期缩短至 4-6 周。 |
| AHPC<br>辅助医疗专业人员委员会 | Ensures personnel conducting diagnostic testing are qualified and licensed. Regulates training, registration, and licensing of all allied health professionals (including laboratory technicians). 确保开展诊断检测工作的人员具备相应资质并持有执业许可，对所有相关卫生专业人员（包括实验室技术人员）的培训、注册及执业许可事宜进行监管。 | **Individual licensing:** approx.1-2 months 个人许可：约1-2月<br>**Facility licensing (including inspection):** approx. 2–3 months 机构许可（包括检查）：约2-3月<br>**Renewals:** Typically, within 4–6 weeks 许可续期：通常在 4-6 周内完成。 |

Uganda乌干达

# Private Sector Stakeholders – Importers/Distributors & Retailers
# 私营部门利益相关方 — 进口商/分销商及零售商

| Importers/Distributors<br>进口商/分销商 | Role<br>职责 |
|---|---|
| Aafiya Africa Ltd<br>乌干达疟疾快检试剂进口商及分销商 | Importer and distributor of malaria RDTs in Uganda. Imports approximately 6 million RDTs per year into Uganda. Focuses entirely on the private sector, including pharmacies, clinics, and hospitals. Also supplies outside Uganda, positioning itself as a regional distributor for East Africa; other countries include South Sudan, Congo, and Burundi. 该企业每年向乌干达进口约 600 万份疟疾快检试剂，业务完全聚焦于私营领域，涵盖药店、诊所及医院。此外，该企业还向乌干达境外供应产品，并将自身定位为东非地区分销商，业务覆盖的其他国家包括南苏丹、刚果和布隆迪。 |
| Joint Medical Store (JMS)<br>半私营、基于宗教信仰的医疗物资供应与采购机构 | Semi-private, faith-based medical supply and procurement agency serving both private facilities and NGO-supported programs. Issues approximately 107,000 packs of 25-test malaria RDT kits per year (~2.6 million tests annually).Works through a tender system every two years, sourcing directly from WHO-prequalified suppliers.该机构为私营医疗机构及NGO支持的项目提供服务，每年供应约 10.7 万盒疟疾快检试剂，每盒含 25 人份试剂（即每年供应约 260 万人份试剂）。该机构每两年通过招标系统运作，直接从通过WHO PQ的供应商处采购物资。 |

| Types of Retailer<br>零售商类型 | Role<br>职责 |
|---|---|
| Over-the-counter Medicine (OCTM) Vendors<br>非处方药销售商 | Small, privately owned medicine outlets licensed by the NDA to sell medicines, including antimalarials and (in some cases) diagnostics. High accessibility; largest private health provider group for malaria treatment. 由国家药品管理局颁发许可的小型私营药品销售点可销售药品（包括抗疟药），在某些情况下还可提供诊断服务。其优势在于可及性高，是疟疾治疗领域规模最大的私营医疗服务提供群体。 |
| Private Pharmacies<br>私人药店 | Retail outlets staffed by licensed pharmacists or pharmacy technicians. Typically stock quality-assured ACTs and occasionally malaria RDTs (WHO PQ brands by SD Biosensor or Access Bio). Serve urban and middle-income clients seeking private care. 配备持证药师或药学技术人员的零售药店通常储备经质量认证的青蒿素类复方疗法药物，部分药店还会供应疟疾快检试剂，且多为 SD 生物公司或爱科森生物公司生产的通过WHO PQ品牌的产品。其服务对象主要是寻求私营医疗服务的城市地区客户及中等收入群体。 |
| Private Clinics/ Health Centers<br>私营诊所/健康中心 | Licensed private medical facilities offering outpatient and inpatient care, often run by clinicians or nurses. Provide malaria diagnosis (RDT or microscopy) and treatment services to paying clients. 持许可资质的私营医疗机构可提供门诊和住院诊疗服务，通常由临床医生或护士运营。他们为付费患者提供疟疾诊断（采用快检试剂或显微镜检测）与治疗服务。 |
| Faith-based and NGO-Affiliated Facilities基于宗教信仰的机构及附属于NGO的机构 | Function as semi-private procurement and service delivery hubs, purchasing RDTs and ACTs for affiliated health centers. 充当半私营的采购与服务提供枢纽，为附属医疗中心采购疟疾快检试剂和青蒿素类复方疗法药物。 |

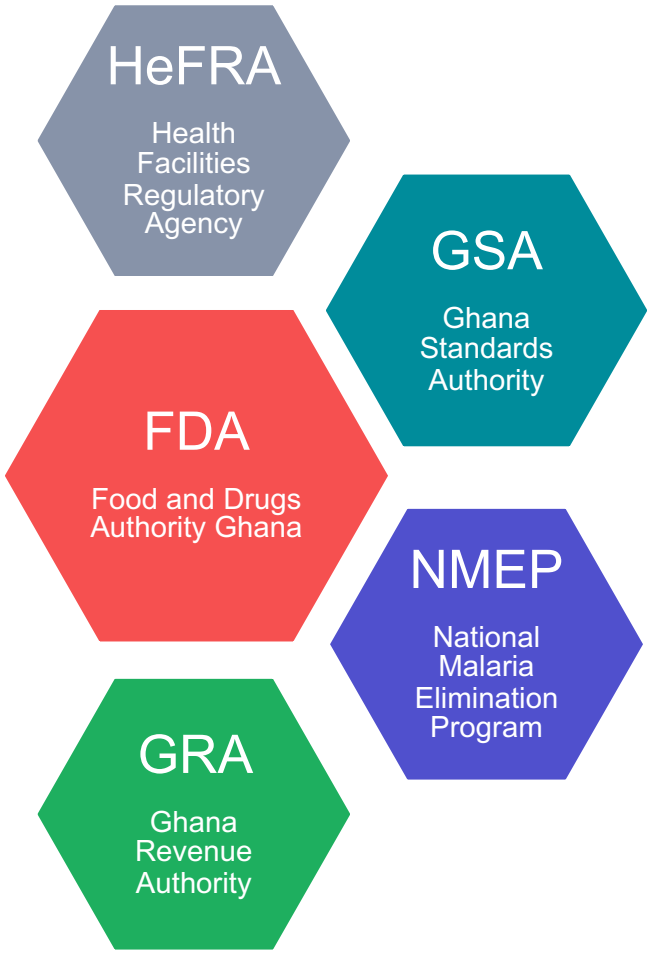
## Distributor Key Insights 分销商主要发现

- Both Aafiya and JMS focus primarily on private clinics, pharmacies, and NGO-linked facilities, which are key entry points for private-sector mRDT scaling. Aafiya和 JMS 均主要面向私营诊所、药店及与非政府组织有合作关系的机构，这些机构是私营部门疟疾快检试剂推广应用的关键切入点。
- New market entrants could partner with Aafiya for market access & distribution flexibility and with JMS for volume-based supply contracts.新进入市场的企业可与Aafiya合作，以获取市场准入渠道及灵活的分销服务；也可与 JMS 合作，签订基于采购量的供应合同。
- Heat-stable, longer shelf-life RDTs that reduce expiration risk will be more attractive to distributors and retail outlets.具备耐热性、保质期更长且能降低过期风险的疟疾快检试剂将对分销商和零售网点更具吸引力。
- JMS's preference for WHO-PQ tests and Aafiya's GMP and NRA checks reflect that manufacturers must be certified and transparent to gain trust in Uganda's distribution networks.JMS 对通过WHO PQ检测试剂的偏好，以及 Aafiya 对GMP和NRA相关审核的要求，这两点表明在乌干达的分销网络中，生产商必须具备相应认证且保持运营透明，才能赢得信任。
- JMS procurement cycles are rigid, and Aafiya deals with private demand fluctuations, manufacturers must offer flexibility in supply (e.g. smaller batches, adjustable delivery) to match market dynamics. JMS 的采购周期较为固定，而 Aafiya 则需应对私营部门的需求波动。因此，生产商必须在供应方面具备灵活性（例如提供小批量供货、可调整的交付安排等），以适应市场动态变化。

## Retailer Key Insights 零售商主要发现

- OCTM Vendors/Drug shops dominate private sector access and represent the primary entry point for expanding RDT use。 非处方药零售商/药店在私营领域的服务可及性方面占据主导地位，是扩大疟疾快检试剂使用范围的主要切入点。
- Pharmacies and clinics serve as trusted outlets for higher-quality diagnostics. 药店和诊所是提供更高质量诊断服务（或诊断试剂）的可信渠道。
- Faith-based and NGO-affiliated facilities typically maintain stricter quality control and report data to the NMED; Often the most reliable channel for consistent RDT supply and data reporting. 基于宗教信仰的机构及附属于NGO的机构通常会实施更严格的质量管控，并向国家疟疾防治项目上报数据；这类机构往往是能稳定供应疟疾快检试剂且规范上报数据的最可靠渠道。
- Informal vendors are common in remote areas but rarely stock RDTs due to regulatory restrictions and lack of training. 非正规零售商在偏远地区较为常见，但由于监管限制及缺乏相关培训，这类零售商很少储备疟疾快检试剂。

# Private Sector Regulatory Landscape for mRDTs
# 私营部门疟疾快检试剂的监管环境

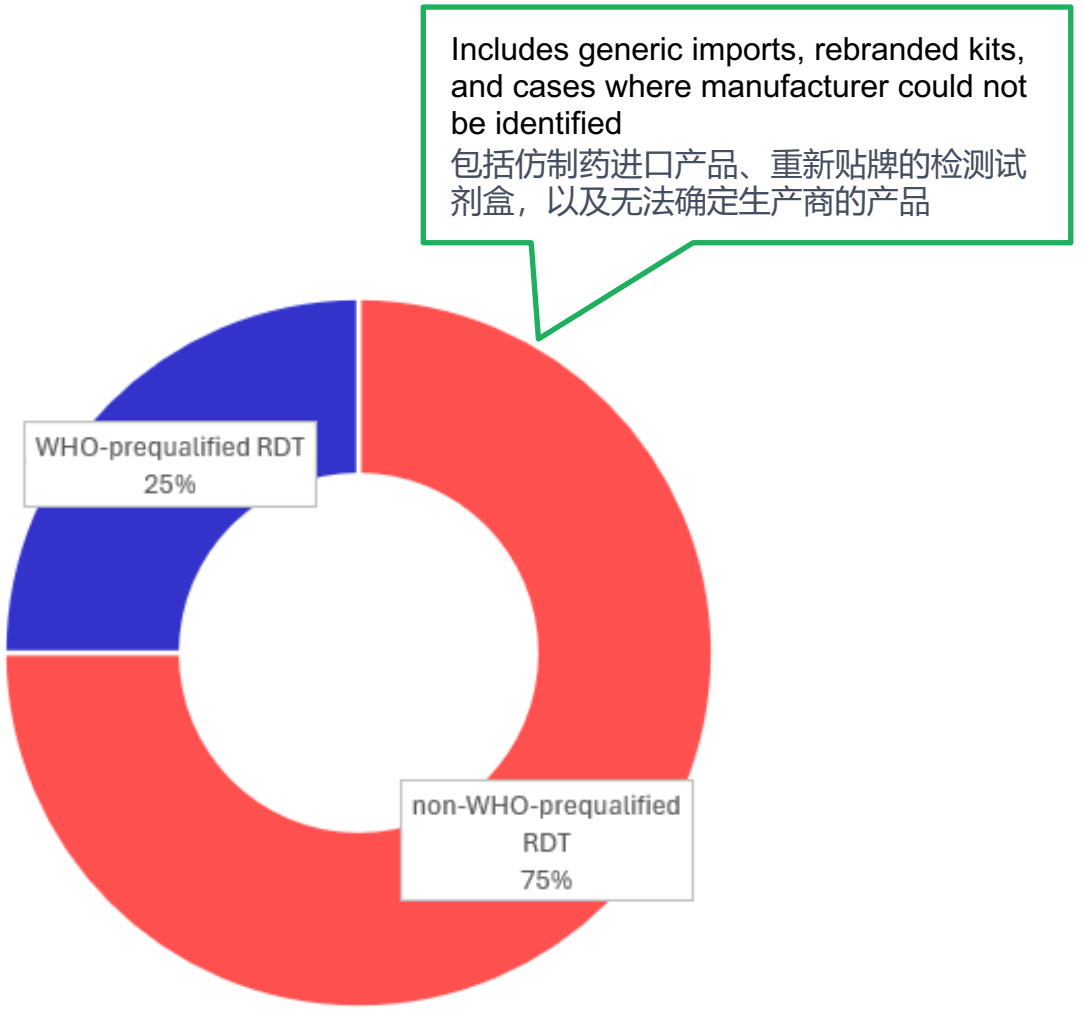



| Regulator<br>监管机构 | Role<br>职责 | Timeline for approval<br>审批时间表 |
|---|---|---|
| FDA Ghana<br>加纳食品药品监督管理局 | Regulates the manufacture, importation, exportation, distribution, sale, and use of medical devices and IVDs. Oversees registration, quality assurance, and post-market surveillance.负责监管医疗器械和体外诊断试剂的生产、进口、出口、分销、销售及使用环节，同时监督管理相关产品的注册、质量保证与上市后监测工作。 | • WHO-PQ or SRA-approved products: 4-6 months (fast-tracked) 通过WHO PQ或国家监管机构批准的产品：4-6 个月（快速审批通道）<br>• Non-WHO-PQ / new products: 8-12 months (full evaluation and testing). 未通过WHO PQ/新产品：8-12 个月（全面评估与检测）<br>*Registration valid for 5 years, renewable.*注册有效期为 5 年，可申请续期。 |
| HeFRA<br>卫生设施监管局 | Licenses and monitors health facilities, both public and private, to ensure compliance with national standards.为确保符合国家相关标准，对公立及私营医疗设施进行许可审批与监督管理。<br>*Relevant for private labs, clinics, and pharmacies offering diagnostic testing.该职能与提供诊断检测服务的私营实验室、诊所及药店密切相关。* | 2-3 months for new facility registration; renewals within 4-6 weeks.新设施注册需2-3个月；续期需4-6周。 |
| GSA<br>加纳国家标准局 | Develops and enforces product standards and labeling requirements across sectors, including medical devices and IVDs. Works in coordination with FDA Ghana to verify conformity to Ghana Standards and international ISO references. May conduct batch or sample testing at import or market level.制定并执行跨行业的产品标准及标签要求，涵盖医疗器械与体外诊断试剂领域。该机构与加纳FDA协同合作，核查产品是否符合加纳国家标准及ISO相关标准。此外，还可能在产品进口环节或市场流通环节开展批次检测或抽样检测。 | Approx. 2-4 weeks (conducted in parallel with FDA or customs clearance).<br>约 2-4 周（与加纳FDA审批或海关清关同步进行） |
| NMEP<br>国家疟疾消除项目 | The NMEP (under the Ministry of Health and Ghana Health Service) leads the national malaria control and elimination strategy, including test-treat-track policy, case management guidelines, and integration of diagnostics primarily in public health systems.NMEP（隶属于卫生部及加纳卫生服务局）主导全国疟疾防控与消除战略，具体包括 “检测 - 治疗 - 追踪” 政策、病例管理指南，以及将诊断工作（主要在公共卫生体系内）进行整合的相关工作。 | Limited direct authority over private markets. Indirectly shape what’s permitted or recommended in the private sector.对私营市场的直接管控权有限，主要通过间接方式影响私营部门内许可或推荐的产品 / 服务范围。<br>National guideline revision cycle are typically every 2-3 years, or ad hoc for high-priority innovations.国家指南的修订周期通常为每 2-3 年一次；对于优先级较高的创新成果，也会启动临时修订。 |
| GRA<br>加纳税务局 | Handles import/export clearance. Works with FDA Ghana and GSA for product release.负责处理进出口清关事宜，并与加纳FDA及政府供应机构（GSA）协作，完成产品放行流程。 | Approx 1-2 weeks, if all approvals and permits are in place.若所有审批及许可文件均已齐备，（流程）约需 1-2 周。 |

# Manufacturer Presence in Ghana Private Sector
# 生产商在私营领域的参与情况

The malaria RDT market in Ghana's private sector is similarly fragmented, with a few dominate brands and many small players.
加纳私营领域的疟疾快检试剂市场同样呈现分散态势：既有少数主导品牌，也存在众多小型参与者。

| Common WHO-PQ'd test in Private Markets 私营市场中常见的通过WHO PQ的检测试剂 | Common Non-WHO-PQ's Tests in Private Markets 私营市场中常见的未通过WHO PQ的检测试剂 |
|---|---|
| First Response (Premier) | Oscar Pf RDT (Oscar Medicare) |
| (Standard Q) SD Biosensor | Healgen Pf and Pf/pan RDTs |
| MeriScreen (Meril Diagnostics) | Malaria Pf/Pv Cupid Ltd |




Estimated values calculated from 26 distinct products from publicly available data

*Source: Data compiled from stakeholder interviews and publicly available data. Not based on nationally representative data.*

Ghana加纳

# Private Sector Stakeholders – Importers/Distributors & Retailers

# 私营部门利益相关方 — 进口商/分销商及零售商

| Importers/Distributors<br>进口商/分销商 | Role<br>职责 |
|---|---|
| Codix Pharma<br>Codix 药业集团加纳分公司 | Ghana branch of Codix group, distributing multiple IVD brands and RDTs, including Standard Q (SD Biosensor) and Arkray. Former exclusive distributor for Abbott's SD Bioline test (1,2). 分销多个体外诊断试剂品牌及快检试剂，包括 SD 生物公司的 Standard Q 品牌和Arkray的产品。曾是雅培公司SD Bioline 检测试剂的独家分销商 [1,2]。 |
| MedTest Ghana<br>医疗设备采购公司 | A procurement company focused on medical equipment/devices; acts as a distributor and sourcing agent. Actively distributes Healgen Pf/pan and Pf/Pv RDTs 专注于医疗设备/器械领域，兼具分销商与采购代理双重角色，目前在积极分销Healgen公司的Pf/pan）及Pf/Pv快检试剂。 |
| Tobinco Pharmaceuticals<br>加纳规模最大的私营药品分销商之一 | One of Ghana's largest private pharmaceutical distributors, with occasional imports/distribution of RDTs (malaria, Covid-19, HIV). Distribution mainly ties to pharmacy network.偶尔会进口并分销快检试剂，涵盖疟疾、新冠（Covid-19）、艾滋病检测品类，其分销业务主要与药店网络绑定。 |

| Types of Retailer<br>零售商类型 | Role<br>职责 |
|---|---|
| Community Pharmacies (licensed by Pharmacy Council of Ghana)社区药店（由加纳药剂师委员会授权） | Primary commercial outlet for malaria RDTs in cities and towns. Source products from large distributors (Tobinco, MedTest, Codix) 城镇地区疟疾快检试剂的主要商业销售渠道，产品源自大型分销商（如Tobinco、MedTest和Codix公司）。 |
| OTCM vendors (licensed by the Pharmacy Council )非处方药零售商（经药房委员会许可） | Community-based outlets licensed to sell non-prescription drugs. Often serve as the first point of care for febrile illness.获许可销售非处方药的社区级销售点，常作为发热类疾病患者的首诊接触点。 |
| Private Clinics/ Hospitals私营诊所 / 私立医院 | Registered medical facilities with licensed clinicians. More consistent RDT use, especially in urban centers.拥有持证临床医师的注册医疗机构，疟疾快检试剂的使用规范性更强，在城市中心区域尤为明显。 |
| Diagnostic Laboratories & Medical Supply Stores诊断实验室及医疗用品商店 | Independent labs and lab supply outlets that also retail test kits. Stock CE-IVD or WHO-PQ-approved RDTs for retail or institutional supply.同时零售检测试剂盒的独立实验室及实验室用品销售点，库存有欧盟体外诊断器械认证或WHO-PQ批准的快检试剂，供零售或机构采购。 |
| Faith-based / NGO-Affiliated Facilities基于宗教信仰的机构 / 附属于NGO的机构 | Private not-for-profit facilities. Provide quality-assured testing services often supported by donor programs.私营非营利性机构，通常在捐赠项目支持下提供质量有保障的检测服务。 |

## Distributor Key Insights分销商主要发现

- Distributors like Codix and MedTest already hold import licenses; partnering with them can shorten registration timelines. Codix和MedTest 等分销商已持有进口许可证，与其合作可缩短注册周期。
- Many private distributors import small, ad hoc orders, limiting scale and affordability.许多私营分销商的进口订单量小且为临时采购，在规模和成本可负担性上均存在局限。
- Large pharmaceutical chains like Tobinco, offer high-volume retail channels, while diagnostic-focused distributors like MedTest provides technical credibility. Tobinco等大型医药连锁企业拥有大量零售渠道，而 MedTest 这类以诊断产品为核心业务的分销商则具备技术公信力。
- Co-investing in activities with distributors like marketing campaigns, training programs, digital tools for reporting and stock management can strengthen brand visibility and build loyalty among retailers.与分销商共同投资开展各类活动，如营销宣传、培训项目、用于报告及库存管理的数字化工具开发等，有助于提升品牌知名度，并增强零售商对品牌的忠诚度。

## Retailer Key Insights零售商主要发现

- Pharmacies are the main retail outlet for mRDTs and they tend to stock quality/trusted tests. Although sales remain secondary to ACTs, there is an opportunity for manufacturers to partner with pharmacies to leverage their network for awareness campaigns and brand visibility. 药店是疟疾快检试剂的主要零售渠道，且往往会储备质量可靠、市场认可的检测试剂。尽管疟疾快检试剂的销量仍低于青蒿素类复方疗法药物，但生产商仍有机会与药店合作，借助其销售网络开展宣传活动，提升品牌知名度。
- OCTM vendors are widespread in rural areas and have a large reach as the common first point of care for many febrile illness. Only a few perform testing or sell RDTs due to training constraints, however with structured trainings and simplified packaging, OCTMs could potentially unlock diagnostic access. 非处方药零售商在农村地区覆盖范围广，是许多发热疾病患者常见的首诊接触点。目前，由于培训条件限制，仅有少数这类零售商提供检测服务或销售疟疾快检测试剂；但通过系统化培训和简化包装设计，非处方药零售商有望成为拓展诊断试剂获取渠道的重要力量。
- Private clinics and hospitals routinely use RDTs and purchase bulk WHO-PQ and FDA-approved products from distributors due to patient trust and procurement policies; making them a demand driver and core target purchaser for distributors. 私营诊所和医院通常会常规使用疟疾快检试剂，且出于患者信任度及采购政策考虑，会从分销商处批量采购经WHO-PQ和FDA批准的产品，这使其成为分销商的需求驱动者和核心目标采购方。
- Urban diagnostic centers and lab shops often resell RDTs to pharmacies, small clinics, and NGOs. Can serve as "micro-distributors".城市诊断中心及实验室用品商店常将疟疾快检试剂转售给药店、小型诊所和NGO，可充当 "微型分销商" 的角色。

# Key Challenges关键挑战

**Low stocking rates:** Many private pharmacies, clinics, and drug shops do not regularly stock mRDTs.
**库存率低**：许多私营药店、诊所及药房并未常规储备疟疾快检试剂。

**Affordability:** RDTs often cost as much as antimalarials, discouraging patients from testing and leading them to seek treatment directly. Likewise, providers typically earn higher margins from selling antimalarials than from conducting tests, discouraging them from offering RDTs.
**可负担性问题**：疟疾快检试剂的价格往往与抗疟药物相当，这不仅降低了患者的检测意愿，促使他们直接寻求治疗；同样，医疗服务提供方销售抗疟药物的利润率通常高于开展检测服务，这也导致他们缺乏提供疟疾快检试剂的动力。

**Regulation & Quality Assurance:** limited enforcement and visibility of private sector volumes and test types, fragmented registries, and RDT leakages from public to private sector disrupts pricing and undermines sustainable market growth. Quality monitoring for RDTs in the private sector is minimal or ad hoc.
**监管与质量保障**：私营部门的销量及试剂类型缺乏有力监管与清晰统计，注册体系分散，且公共部门的检测试剂流向私营部门，既扰乱了市场定价，也不利于市场的可持续发展。同时，私营部门对疟疾快检试剂的质量监测力度极小或多为临时抽查。

**Supply chain:** Fragmented, import-dependent distribution limits availability and drives variability in quality
**供应链**：分销体系分散且依赖进口，这不仅限制了试剂的可及性，也导致产品质量参差不齐。

**Coordination:** Limited data sharing and engagement between public and private sector weakens system visibility. Many NMCPs focus more on public-sector testing.
**协作**：公共与私营部门之间的数据共享及合作参与度有限，降低了整个体系的透明度。此外，许多国家疟疾防控项目（NMCP）的工作重心更多放在公共领域的检测服务上。

# Key Opportunities关键机遇

While public-sector procurement still dominates RDT volumes, the **private sector represents a fast-emerging commercial and strategic growth opportunity** that is driven by large patient volumes, policy shifts toward universal testing, and regional moves to localize manufacturing.尽管公共部门采购在疟疾快检试剂的采购量中仍占主导地位，但**私营部门已成为一个快速崛起的商业和战略增长机遇。**这一机遇的驱动因素包括庞大的患者数量、向全民检测转型的政策导向，以及各地区推进本土化生产的举措。

**Private distributor partnerships:** Partnering with established importers, distributors, and pharmacy chains (e.g., Codix in Ghana; Ecopharm in Uganda) offers rapid access to private networks. **私营分销商合作**：与成熟的进口商、分销商及医药连锁企业（如加纳的Codix公司、乌干达的 Ecopharm 公司）合作，可快速接入私营部门的销售网络。

**Co-branding:** Manufacturers can supply to wholesalers or pharmacy brands under joint branding, which is a growing model in fast-moving health goods. **联合品牌策略**：生产商可通过联合品牌模式向批发商或药店品牌供应产品，这种模式在快速流通类健康产品领域正逐渐兴起。

**Bundled offerings:** Offering RDT + ACT combo packs or “test & treat kits” can enhance value and encourage uptake by pharmacies and clinics. **捆绑式产品组合**：推出疟疾快检试剂与青蒿素类复方疗法药物的组合套装，或 “检测 + 治疗” 一体化试剂盒，可提升产品价值，同时推动药店和诊所采购使用。

**Confidence-building pilots:** Demonstrate product accuracy through field validation and community engagement; promote visible certification of quality RDTs in outlets. **建立信任的试点项目**：通过实地验证和社区参与的方式证明产品精准度；推动在销售点公示优质疟疾快检试剂的资质认证信息。

**Regulatory efforts**: Typically, WHO-prequalified RDT are fast-tracked for in-country registration. **监管层面助力**：通常情况下，通过WHO PQ的疟疾快检试剂，在各国进行本土注册时可享受快速审批通道。

The private sector is critical to achieving malaria elimination goals. Success depends on bridging the gap between availability and use. Manufacturers that deliver affordable, high-quality RDTs, build strong local partnerships, and drive provider and consumer demand will be best positioned to succeed in this growing market.私营部门对于实现消除疟疾目标至关重要。能否达成该目标，关键在于缩小疟疾快检试剂“可获取性” 与 “实际使用” 之间的差距。对于生产商而言，若能提供价格可负担、质量达标的疟疾快检试剂，建立稳固的本土合作关系，并推动医疗服务提供方及患者对产品的需求，便能在这一不断增长的市场中占据最有利的竞争地位。

# Participant Survey
# 参会者调查

PATH

# Mentimeter Survey Questions 互动调查问题

Please go to www.menti.com with your **phone or laptop** and **enter the code displayed on the slide below**.
当系统提示时，请用手机或笔记本电脑访问 www.menti.com 网站，并输入幻灯片上显示的代码。

All questions and responses will be anonymous.
所有问题及反馈均为匿名形式。

Mentimeter Code:
**4546 0035**

PATH

# Break until 10:10
# 茶歇

# Manufacturer experience with LMIC markets (Wondfo)

# 生产商在中低收入国家市场的经验（万孚生物案例）

# mRDTs进入非洲市场的挑战和机遇

# Challenges and Opportunities for mRDTs Entering the African Market

林丰彬 万孚生物国际公卫项目部负责人

Leon LIN *Head of the Project Department for International Public Health*, Wondfo Biotech

# 30+ 年深耕POCT行业

## with over 30 years of in-depth experience in the POCT industry

专注于快检试剂和仪器的研发，生产，销售和服务Focus on the R&D, production, sales and service of rapid testing reagents and instruments

**Top 100**
医疗器械公司-2022年销售额
Medical Device Company - 2022 Sales Volume

**>100,000**
全世界Finecare装机量
Finecare Installation Volume Worldwide

**>1,000,000,000**
快检试剂年度分发量
Annual Distribution Volume of Rapid Testing Reagents

**3000+** 全球员工 Employees Worldwide

**20+** 子公司 Subsidiary Companies

**2015** 深圳证券交易所上市 Listed on the SZSE

**首家**上市的POCT公司 The 1st listed POCT company
(股票代码Stock code: 300482.SZ)

为**150+** 国家和地区提供服务 Services provided to over 150 countries and regions

**10%+**年度研发与营收比率 Annual R&D-to-Revenue Ratio

**3 Mn+**检测试剂日产能 Daily Production Capacity of Testing Reagents

**□ 注册证书Registration Certificates 600+**

300+ NMPA/ 240+ CE, 15 MDALL 证书

70+ FDA 证书 , 3 WHO prequalification

**□ 有效专利Valid Patents 400+**

450+ 有效专利 Valid Patents

90+ 发明专利 Invention Patents

**中国领先的即时检测（POCT）公司**
**China's Leading POCT manufacturer**

# 里程碑&我们的足迹 Milestones & Our Footprints

我们致力于为实验室，医院和社会提高效率 We are committed to improving efficiency for laboratories, hospitals, and society.

**2009**
中国首批通过美国FDA现场审核的IVD 企业之一One of the 1st IVD companies in China to pass the on-site audit of the US FDA

**2018**
HIV快速检测获得WHO PQ
HIV RDT-WHO PQed

**2022**
HIV Self Test 获得WHO PQ
HIV Self Test-WHO PQed

**2023**
启动非洲本地化生产技术转移项目 Africa Localized Production Technology Transfer Project Launched

**2024**
Malaria Pf Rapid Test 获得WHO PQ
Malaria Pf Rapid Test-WHO PQed

PQ认证：3个产品 Three products WHO PQed
本地生产：1+3 1+3 localized production
国家注册证: 26个证书（3个产品）
Three products registered in 26 countries
指南及标准：10 个国家
Guidelines and Standards: 10 Countries
自测供货国家：6个国家
Self-Test Supply Countries: 6 Countries


One Step HIV1/2 Test


HIV Self-Test


Malaria P.f(HRP2/pLDH) Test

World Health Organization · Pan American Health Organization · Bill & Melinda Gates foundation · UNFPA · The Global Fund To Fight AIDS, Tuberculosis and Malaria · PATH · UNOPS · UNDP · unicef

# 挑战和机遇-疟疾快检试剂

# Challenges and Opportunities of mRDTs

# 400 Mn+

## 非洲三大传染病之一
**市场需求 + 较为集中采购**

**One of the Three Major Infectious Diseases in Africa**
***Market Demand + Relatively Centralized Procurement***

## 1. 公共卫生市场需求巨大
**Enormous demand in the public health market**

超过4亿人份的采购需求，且私立市场需求也旺盛
Procurement demand is over 400 million doses and the demand in the private market is also strong.

## 2. 采购路径相对更集中
**Procurement channels more concentrated**

全球基金(GF)、PMI、Others

## 3. 本地化需求意愿强烈
**Strong willingness for localized demand**

核心品类 Core Product

# 0.25 USD ↓

## 价格下行压力大

**Downside risk of RDTs price**

**大厂为主 + 成本要求高**

**Market led by major manufacturers, with high cost requirements**

## 1. 性能要求增加 mRDT

**Increased Performance Requirements for mRDTs**

高灵敏度要求，以应对基因片段缺失问题，LOD

Increasing sensitivity to respond to pfhrp2/hrp3 gene deletions, with low(er) LOD required

## 2. 大厂内卷和市场价格趋势

**Involution Among Major Manufacturers and Market Price Trends**

疟疾产品传统供应链集中在印度和韩国，成本压力大

The traditional supply chain for mRDTs concentrated in India and South Korea. RDTs' cost is increasing.

## 3. 国家间注册监管要求多样

**Registration and regulatory requirements vary among coutries**

获得WHO PQ认证后，需要满足各国家区域多样化的当地监管注册要求

After a product WHO PQed, it still needs to meet the different regulatory registration requirements in various countries and regions.

# 建议 Suggestions

- 研发阶段充分考虑成本及未来价格趋势

  Cost and future pricing fully considered in the R&D phase

- 清晰的注册认证路径和策略

  Clear paths and strategies for registration & PQ

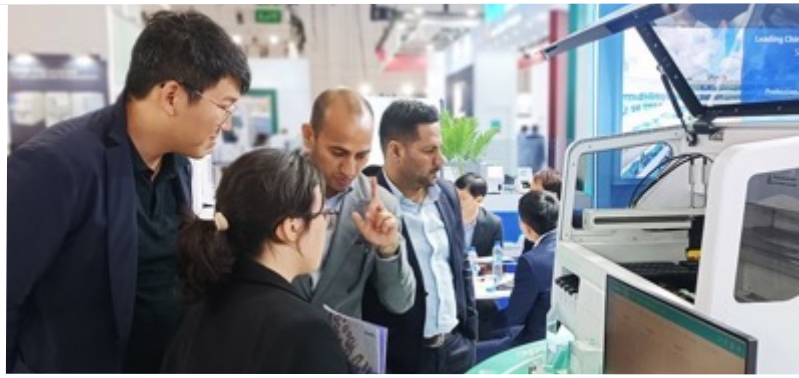
- 提前布局分销网络

  Layout of the distribution network in advance



# 在世界的每个角落，
# 万孚生物都在为人们的健康努力……

## Wondfo Biotech is striving for people's health in every corner of the world...






# THANK YOU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# Partner experience with mRDTs (Centre Pasteur du Cameroun)

# 合作伙伴在疟疾快速诊断检测方面的经验（喀麦隆巴斯德研究所案例）

# Malaria RDTs at a crossroad: Current Practices, unmet needs and opportunities for innovation

**Lawrence Ayong, Ph.D.**

Head, Malaria Research Unit/NRL Malaria Diagnosis

Centre Pasteur Cameroon

CENTRE PASTEUR DU CAMEROUN

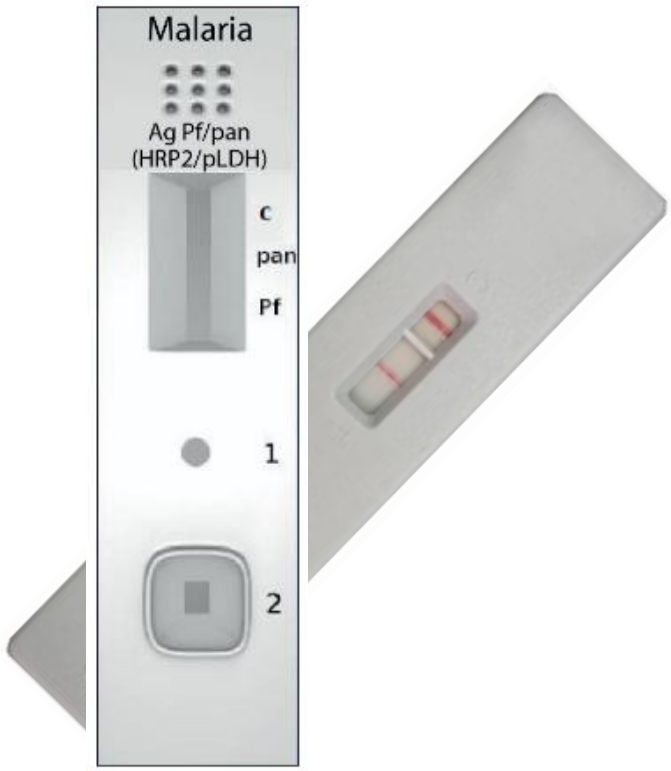
# PLAN

- Introduction
- Place of RDTs in malaria diagnosis
- Challenges associated with RDT use
- Unmet innovation needs for malaria RDTs
- Summary

# Malaria Rapid Diagnostic Tests (mRDTs)

**Microscopy (PCR, LAMP, etc)**

**Nucleic acid amplification (PCR, LAMP, etc)**




**Malaria rapid diagnostic test (mRDT)**

**Applications**

- *Parasitological confirmation of malaria in symptomatic individuals*
- *Strongly recommended for use in areas with limited microscopy resources*
- *Essential for outbreak investigation*
- *Malaria surveillance*

# Operational Attributes of mRDTs

**Merits**

- Simple to perform and interpret
- Fast (provides results in <30 minutes)
- Require very limited training
- No need for special equipment or electricity
- Allow for malaria diagnosis at the community level
- Sufficiently sensitive amongst symptomatic patients

**Limits**

- *Not quantitative*
- *Do not differentiate between Plasmodium species*
- *High false positive rates in drug treated patients*
- *Variable sensitivities, according to parasite density*
- *Expensive USD 2.0-5.0 per test*

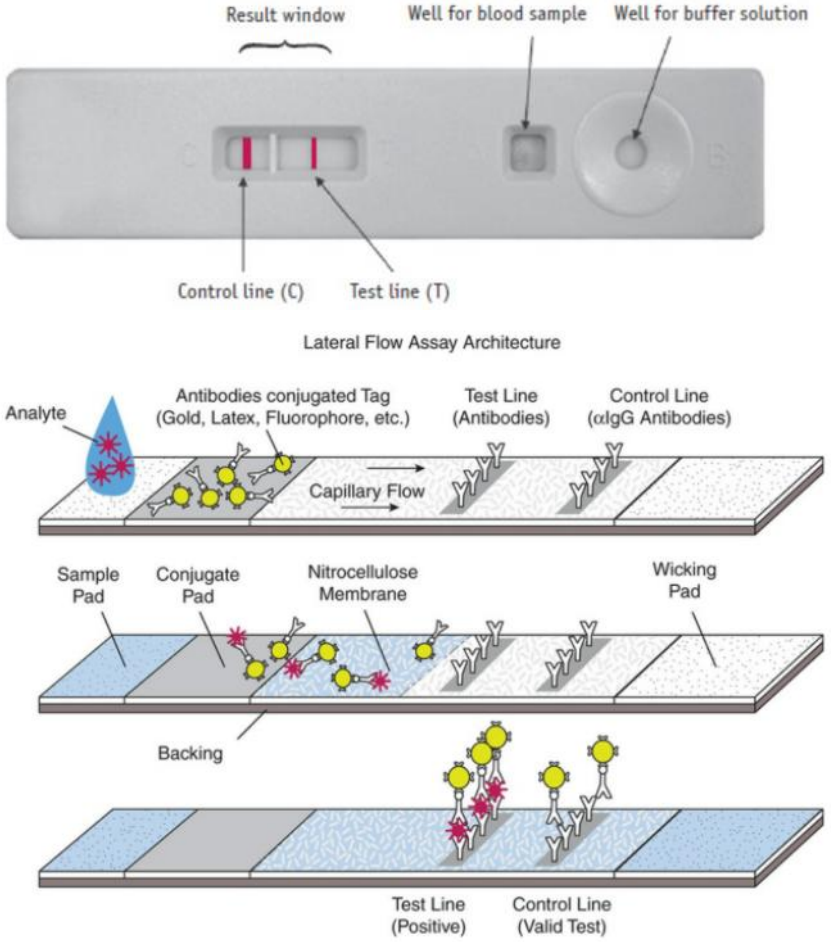
# How mRDTs Works!

- **Antigen-detection** *lateral flow immunochromatographic technique based on nitrocellulose (NC) strips*

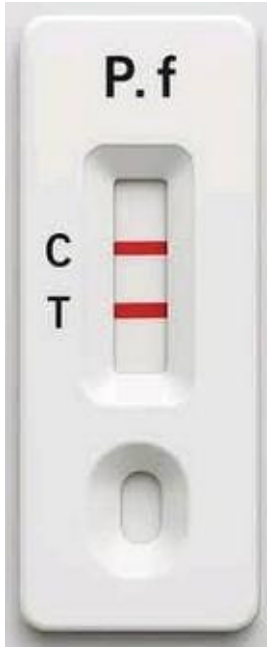
- **Formats**: ***Cassette*** *-NC strip enclosed in a plastic cassette*
  ***Dipstick*** *-NC strip dipped in sample*
  ***Hybrid*** *(combination of cassette & distick format*

- **Visualization**: *Colloidal gold, latex beads or rhodamine-coupled antibodies*

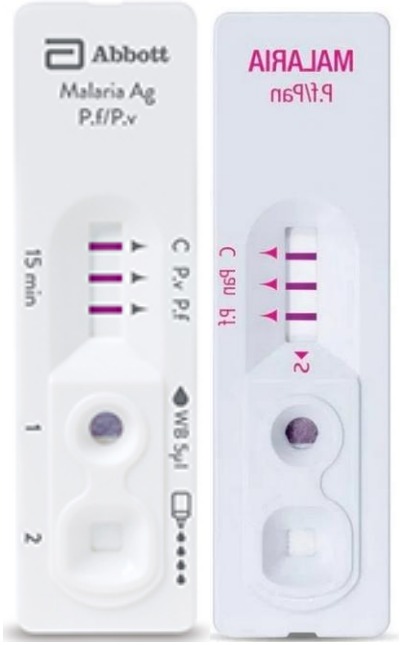
- **Targeted antigens:**
  **Species-specific** *-PfHRP2, PfLDH, PvLDH*
  ***Genus*-species** *-pLDH, Aldolase*



# Classification of mRDTs According to *Plasmodium* Species Detected




**Single species**

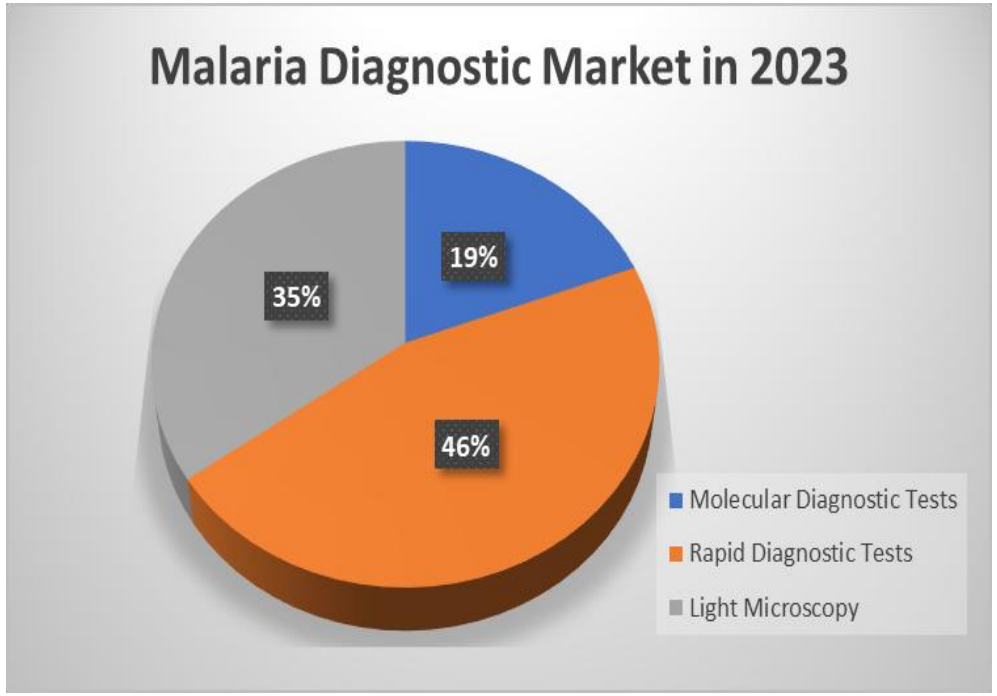


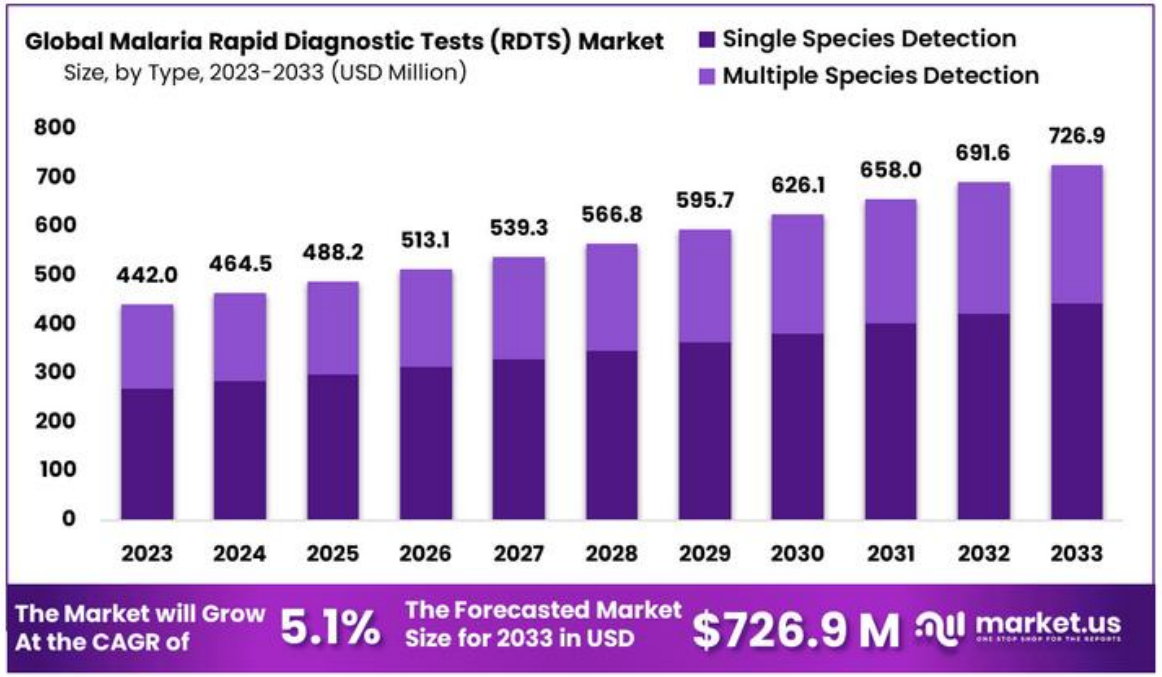

**Multiple species**

| RDT types | Antigens detected | Expected Spp differential detection |
|---|---|---|
| **Type 1** | Line 1: PfHRP2 | Pf |
| **Type 2** | Line 1: PfHRP2<br>Line 2: pan-Aldolase(*) | Pf/*Plasmodium* spp |
| **Type 3** | Line 1: PfHRP2<br>Line 2: pan-LDH(*) | Pf/*Plasmodium* spp |
| **Type 4** | Line 1: PfLDH<br>Line 2: pan-LDH(*) | Pf/*Plasmodium* spp |
| **Type 5** | Line 1: PfLDH<br>Line 2: PvLDH | Pf/Pv |
| **Type 6** | Line 1: PfHRP2<br>Line 2: PvLDH<br>Line 3: pan-LDH(*) | Pf/Pv/*Plasmodium* spp |
| **Type 7** | Line 1: pan-Aldolase(*) | *Plasmodium* spp |

*Gimenez et al., 2021*

# Place of RDTs in Malaria Diagnosis



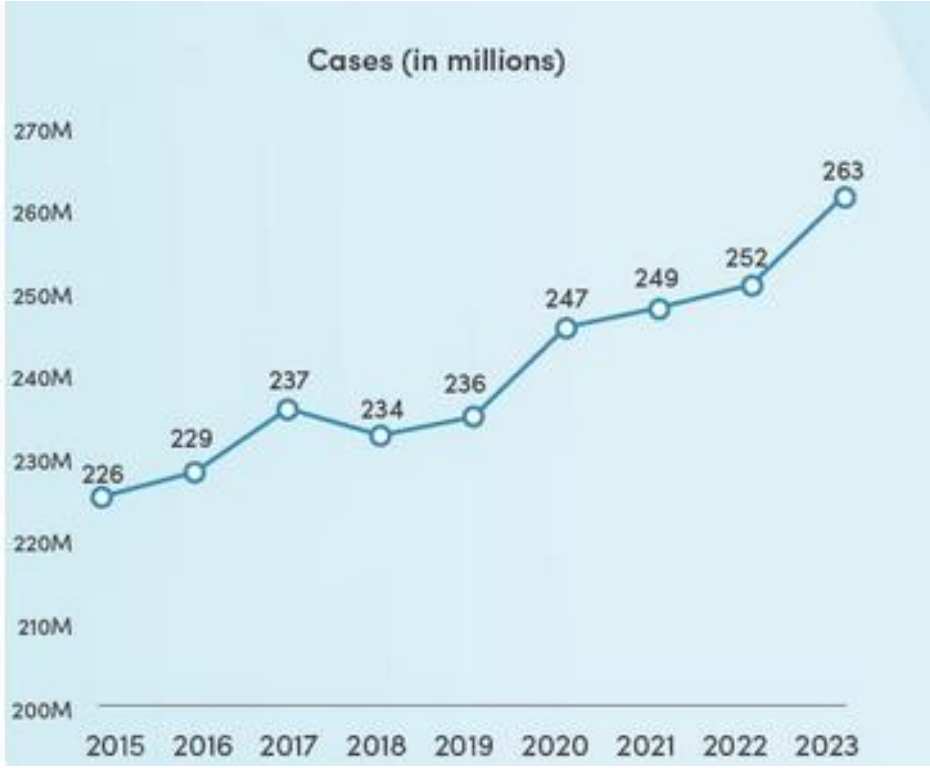




https://market.us/report/global-malaria-diagnostics-market/

# Drivers of mRDTs Procurement

**Drivers**:

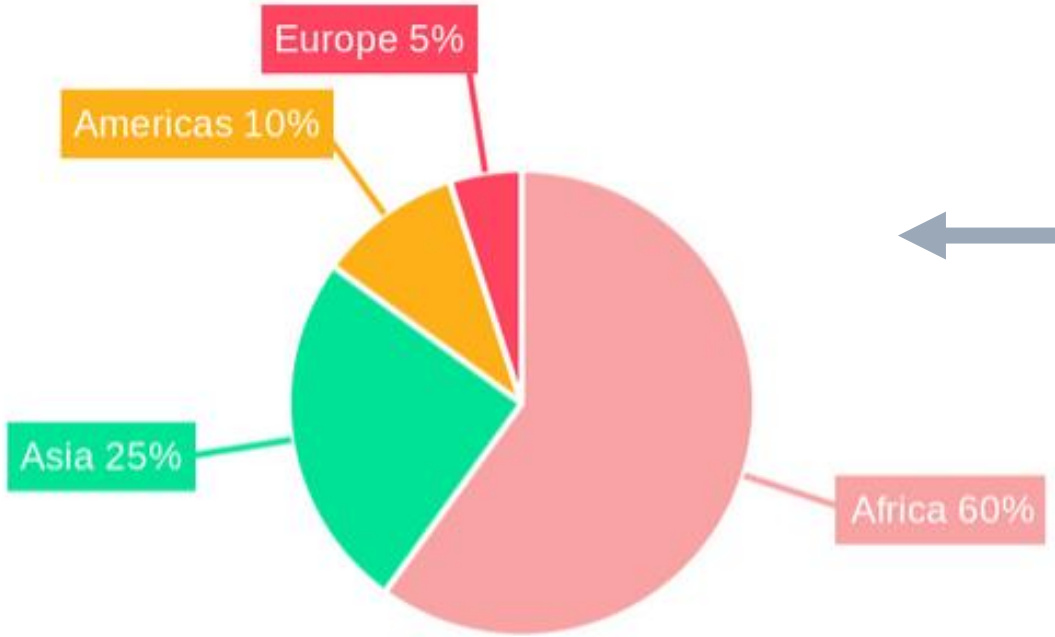
- Rising malaria cases globally
- Global health and government initiatives, promoting parasitological confirmation of infection before treatment
- Rising awareness in endemic countries of the importance of early diagnosis
- Advancement in RDT technology (increased sensitivity, user-friendliness and shelf lives)

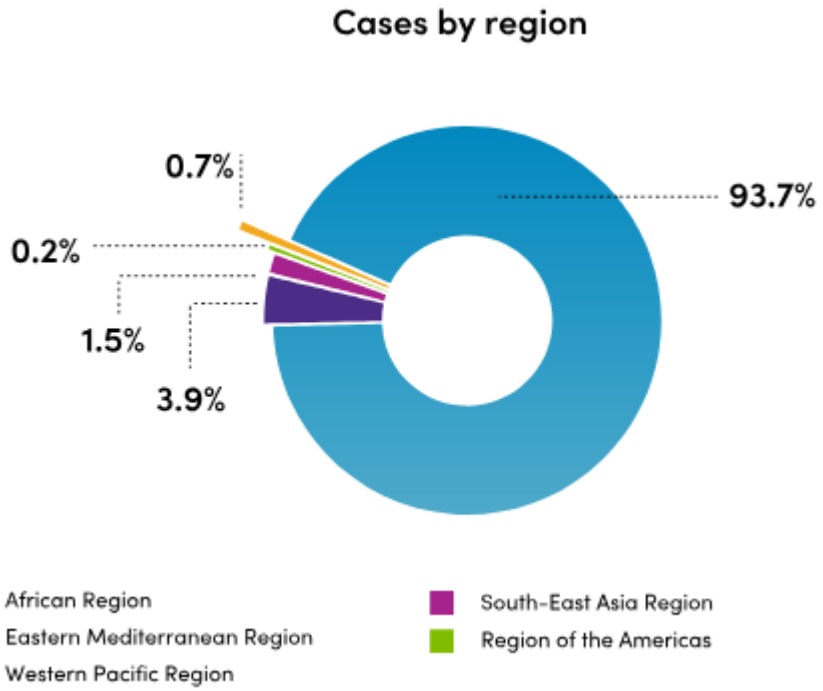



https://www.mmv.org/malaria/about-malaria/malaria-facts-statistics

# Africa Dominates mRDT Markets

**Regional Analysis of RDT Procurement in 2023**




https://www.datainsightsmarket.com/reports/malaria-rapid-diagnostic-tests-rdts-1488631#

https://worldmalariareport2024.org/current-state

# Major Procurers of mRDT

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

- Major procurer of RDTs for hard-hit endemic countries
- Uses a pooled procurement mechanism to aggregate orders and lower prices

PMI U.S. PRESIDENT'S MALARIA INITIATIVE
LED BY USAID FROM THE AMERICAN PEOPLE CDC

- Large international buyer of RDTs
- Collaborates with the WHO and other partners to ensure that the highest quality of RDTs are used in endemic countries

unicef

- Procures millions of mRDTs each year to support endemic country programs
- Especially targets women and children to increase coverage and access to treatment

THE WORLD BANK

- Provides funding to support countries in procuring health products, including mRDTs

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

- Humanitarian organization, providing funding to support its medical activities in malaria endemic countries

MINSANTE
Ministère de la Santé Publique

- Combine own government financing & Global funding to purchase RDTs

# Current Guidelines For mRDT Procurement

**Considerations for RDT Procurement**:

- Depends on *Plasmodium* species to be detected (*Plasmodium falciparum* only and/or non-*falciparum* species)
- Shelf life and temperature stability in intended conditions of storage and use;
- Ease of use, including test format and blood transfer device options;
- Cost (including transport, training and quality control)

**Minimum recommended criteria:**

- Be WHO-prequalified based on:

- **Manufacturing environment**: ISO 13485-certified manufacturer,

- **Test performance**: Panel detection score ≥75% against a 200p/µl panel, False positive rate <10% & invalid test rate <10%

# Challenges in the Use of mRDTs

- **Logistical challenges** associated with distribution and supply chain management
- **Limited skills in RDT key operations** (sample collection, understanding SOP, results interpretations), resulting in misdiagnosis
- **Insufficient sensitivity**, limiting RDT use in low transmission settings
- **Emergence of "diagnostic-resistant"** parasite strains (case of PfHRP2/3 gene deletions), limiting RDT use in affected areas


https://apps.who.int/malaria/maps/threats/#/stories?theme=diagnosis

# Unmet Needs in Malaria Diagnosis Using RDTs

| Manufacturer Product Catalogue number | Product Name | Manufacturer and Manufacturing site address | Format | Number of tests per kit | Shelf life (months) | Recommended storage temperature | Eligibility criteria |
|---|---|---|---|---|---|---|---|
| **For the detection of Plasmodium falciparum only (Pf)** | | | | | | | |
| 05FK50 | Bioline Malaria Ag Pf | Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, | Cassette | 25 | 24 | 1-40°c | |
| **For the detection of Pf and all *Plasmodium* species (Pf and Pan)** | | | | | | | |
| 05FK60 | Bioline Malaria Ag Pf/Pan | Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea | Cassette | 25 | 24 | 1-40°c | |
| **For the detection of *Plasmodium falciparum* and *vivax* (Pf and Pv/Pvom)** | | | | | | | |
| 05FK80 | Bioline Malaria Ag Pf/Pv | Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea | Cassette | 25 | 24 | 1-40°c | |
| **For the detection of all *Plasmodium* species (Pf, Pf and Pv)** | | | | | | | |
| 05FK120 | Bioline Malaria Ag Pf/Pf/Pv (Assay diluent vial, Disposable inverted cup, Sterile lancet, Alcohol swabs) | Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea | Cassette | 25 | 24 | 1-40°c | WHO PQ (follow warnings in HRP2 deletion settings) |
| 05FK123 | Bioline Malaria Ag Pf/Pf/Pv POCT (Each kit contains all necessary accessories) | Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea | Cassette | 25X 1 test per kit (bundle kit) | 24 | 1-40°c | |

- **Multi-species RDTs** *for differentiating Plasmodium species, offering better management of cases*
- **RDTs for drug resistance testing** *to inform decision-making and better management of cases*
- **Quantitative/Semi-quantitative RDTs** *for estimating infection densities*

# Innovation Needs for Next-Generation mRDTs

- **High-sensitivity RDTs** *for detecting low parasite densities*
- **Digitally powered RDTs** *for enhanced surveillance data collection and management*
- ***Innovative packaging and storage solutions*** *to ensure optimal product performance in challenging settings*
- **Improving affordability and accessibility** *in resource-limited settings*

# Summary

- RDTs are a crucial tool for malaria diagnosis
- Technological advancements leading to more accurate, user-friendly, and cost-effective RDTs are propelling their market expansion
- Increased funding along with strategic R&D partnerships are likely to improve the clinical utility of RDTs and raise its market share

**Worthnoting!!**

Prolonged overuse of one antigen-type RDTs can lead to the selection of resistance !

# THANK YOU


PATH

# Day 2 (Final) Closing Remarks
# 第二天（最后一天）结束语


PATH

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dxinfo@path.org


PATH


The Hong Kong Jockey Club
Global Health Institute
香港賽馬會環球衞生研究院
GHI