

Point-of-care diagnostics are medical tools or devices that can diagnose disease in a patient's community, generally outside of a formal clinic setting. By shifting disease diagnosis to the community level, POC diagnostics can save patients money (as they no longer have to travel to clinics), allow earlier diagnosis and expand access to previously under-served populations.

We provide a framework for healthcare delivery organizations in resource-limited settings to assess whether to use a given POC diagnostic. We suggest three steps:

- First, identify the major disease burdens in the community and the major gaps in existing diagnostics. Only choose a given POC diagnostic if it responds to the needs of the community directly and effectively.
- Second, understand whether the diagnostic is suitable for a resource-limited setting by assessing the diagnostic's robustness, ease of use, accuracy and cost. We present a schematic for judging diagnostics on these criteria. Only choose the diagnostic if it is an improvement over the current method of diagnosis.
- Lastly, consider whether the organization has the medical, financial, human and technology resources to adequately support the diagnostic and any required follow-up medical and support interventions.

To close, we present sample assessments of diagnostics for malaria and typhoid, as well as relevant selected resources.

# Management for the World Module: *Assessing point-of-care diagnostics for resource-limited settings*

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# What are point-of-care (POC) diagnostics?

Point-of-care diagnostics are medical tools or devices that can diagnose disease in a patient's community, outside of a hospital setting. They include both low-tech and high-tech methods and devices and are typically portable, fast, and relatively inexpensive.

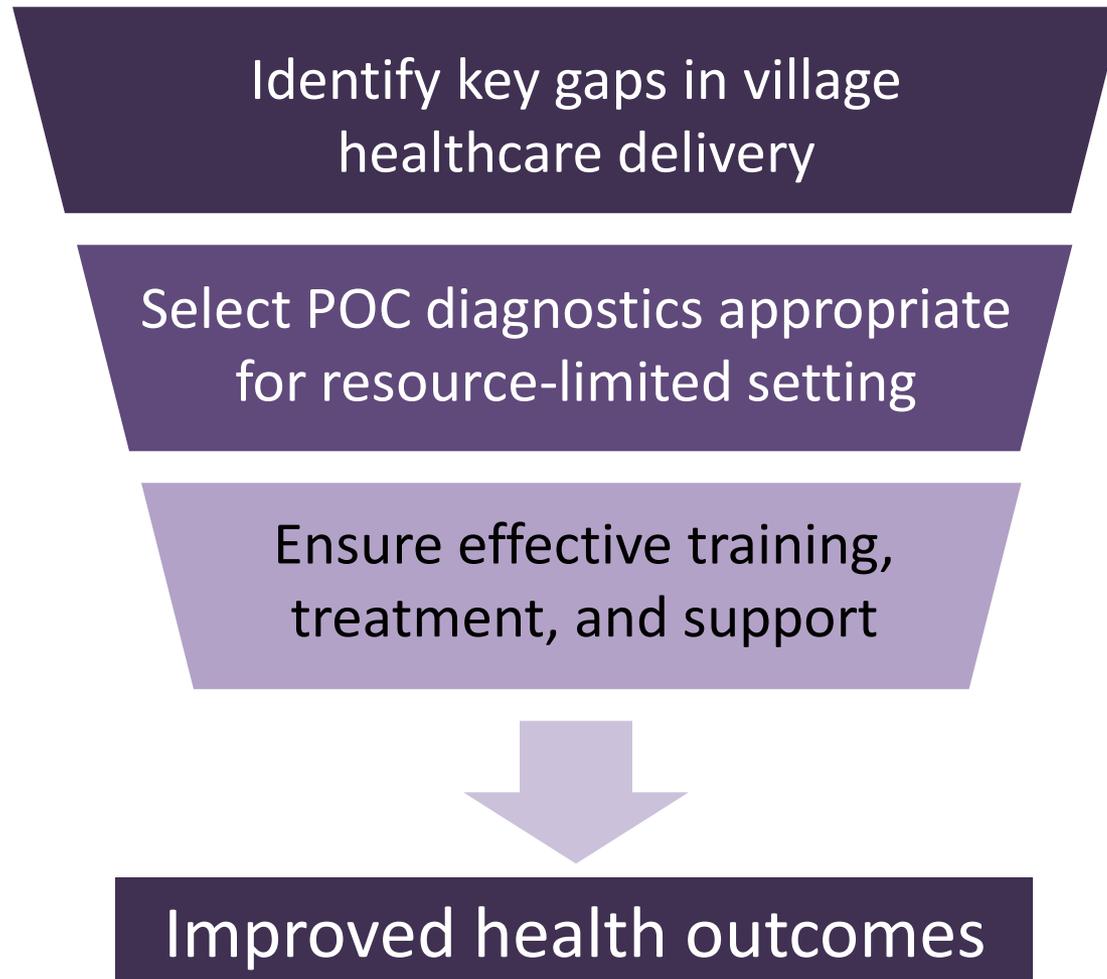
## Why do POC diagnostics improve healthcare delivery in resource-limited settings?

- **Improve scalability** of model by shifting health delivery more to local level
- **Reduce cost** of diagnosis and unnecessary travel to clinics
- **Improve early detection** by catching more illnesses
- **Improve access** to under-reached communities

# A framework for assessing point-of-care diagnostics

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*When selecting POC diagnostics, a healthcare delivery organization should pass through assessment steps that lead to choosing an appropriate and effective diagnostic tool.*



# Identify key gaps in healthcare delivery in community



- What are the primary health burdens of the community? Consider:
  - Prevalence
  - Morbidity
  - Mortality
  - Impact on standard of living
  - Risk of spread
  - Risk of development of resistant strains
- What are the gaps that currently exist for diagnosis and treatment in the community? Consider:
  - Current methods of diagnosis and treatment
  - Primary barriers to better methods of diagnosis and treatment:
    - Availability, access, and awareness barriers
    - Cost and supply chain barriers
    - Training and expertise barriers

# Select appropriate diagnostics for resource-limited settings



*Assess point-of-care diagnostics on these four criteria:*

<b>Robustness</b>	<b>Ease of use</b>	<b>Accuracy</b>	<b>Cost</b>
<p><i>Is it field suitable?</i></p> <ul style="list-style-type: none"><li>▪ Doesn't require electricity</li><li>▪ Doesn't require cold storage</li><li>▪ Rugged against dust and transport</li><li>▪ Portable</li><li>▪ Suitable for humid climates</li><li>▪ Doesn't require internet or strong cell phone signal</li><li>▪ Supply chain in place</li><li>▪ Long shelf life</li></ul>	<p><i>Can it be used by a community health worker?</i></p> <ul style="list-style-type: none"><li>▪ Requires minimal training (&lt; 1 hour)</li><li>▪ Doesn't require high levels of literacy or education</li><li>▪ Test conducted in &lt; 1 hour</li><li>▪ Procedure is &lt; 4 steps</li><li>▪ Requires minimal maintenance</li><li>▪ Requires minimal patient prep</li><li>▪ Meets regulations</li></ul>	<p><i>Is it "good enough"?</i></p> <ul style="list-style-type: none"><li>▪ Does it meet international standards?</li><li>▪ Will it improve diagnosis from current state?</li><li>▪ Does it meet specificity and sensitivity benchmarks for local prevalence levels?</li><li>▪ Are results clear and easy to understand?</li></ul>	<p><i>Is it affordable for BOP patients?</i></p> <ul style="list-style-type: none"><li>▪ Are patients willing to pay at cost?</li><li>▪ If not, are there ways to subsidize the cost?</li><li>▪ Will it save villagers money in other ways (e.g. lower transportation costs or treatment costs)</li><li>▪ Consider both variable and fixed costs and associated costs (e.g. maintenance)</li></ul>

# Color-coded categorization of POCs



*Use this categorization matrix, adapted to local setting, to assess a point-of-care diagnostic.*

Method	Status	Robustness	Ease of use	Accuracy	Cost
<b>Very good/acceptable</b>	For sale	No electricity Suitable for dusty, hot, humid climates Easy to maintain	Minimal training Minimal steps	WHO (or other reputable org) recommended as stand-alone test	< \$US 0.50 per test Low-medium fixed cost
<b>Not ideal, but suitable</b>	In R&D, close to commercialization (1-2 years)	May require batteries May requires moderate temperature control Easy to maintain	Some training Minimal steps	Moderate accuracy based on health standards for local prevalence	\$US 0.50 – 1.50 per test Low-medium fixed cost
<b>Outside range of acceptability</b>	In R&D, far from commercialization (3+ years)	May require electricity or internet May require high tech equip May require sensitive temp control	Significant training Significant steps	Accuracy below health standards for local prevalence	> \$US 1.50 per test

# Ensure effective training, treatment, and support



Are treatment, counseling, and follow-up available?

- What care exists for a person who tests positive?
- Is advice/counseling provided for patients?
- Can the health worker follow-up with patient and monitor progress?

What training and protocols are needed?

- Does the organization have the resources to provide the needed training?
- Can the organization develop a protocol for identifying when a test should be administered?

Is there a data management system in place?

- Is there a method to collect, store, and analyze test results and related data?

Is there the necessary infrastructure?

- If the test is best done in a private space, is that available?
- Is there an appropriate storage area for the diagnostics?
- Is a supply chain in place for all necessary items (reagents, cotton, etc)?

Is there the necessary tech support?

- Is there technical support in place if the health worker has a question or the diagnostic malfunctions?

Can the organization conduct proper quality control?

- Are there quality control measures in place to monitor tests and follow-up? Does the organization have the resources for this?
- Is there a method for calibrating tests to ensure accuracy?

Does the organization have the proper financing?

- Can the organization finance both the fixed and variable costs of the diagnostics as well as the indirect costs such as maintenance, treatment, training, etc?

# Appendix

Examples of POC diagnostic assessments

Selected Resources

# Malaria: Rapid Diagnostic Tests (RDTs)

## How it works

- Rapid Diagnostic Tests are one of the most common malaria diagnostics and involve applying a finger prick of blood to a test pad.

Status	Robustness	Ease of use	Accuracy	Cost
Currently in Use.	Field-suitable Cool chain required for transport and storage Need quality assurance	Takes about 15 minutes to achieve a result Basic health worker training required	Doesn't detect low levels of parasites Limited ability to determine species of malaria Accuracy varies by brand	\$0.65 to \$1.00 per test  More than 60 brands available on market

## Resources:

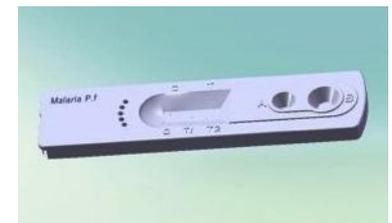
[http://www.cdc.gov/malaria/diagnosis\\_treatment/rdt.html](http://www.cdc.gov/malaria/diagnosis_treatment/rdt.html)

[http://www.wpro.who.int/sites/rdt/using\\_rdt/place\\_of\\_rdt\\_in+mal\\_programs.htm](http://www.wpro.who.int/sites/rdt/using_rdt/place_of_rdt_in+mal_programs.htm)

[http://www.wpro.who.int/NR/rdonlyres/63157C4B-A829-42C4-A460-67B884208B81/0/GuidelinesfortheTreatmentofMalaria\\_2ndEd\\_eng.pdf](http://www.wpro.who.int/NR/rdonlyres/63157C4B-A829-42C4-A460-67B884208B81/0/GuidelinesfortheTreatmentofMalaria_2ndEd_eng.pdf)

[http://www.finddiagnostics.org/programs/malaria/find\\_activities/new-improved-technologies/](http://www.finddiagnostics.org/programs/malaria/find_activities/new-improved-technologies/)

[http://whqlibdoc.who.int/publications/2009/9789241598088\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241598088_eng.pdf)



# Typhoid: Test-it™ Typhoid LFD

## How it works

- RDT performed by adding 5µL of serum to the sample pad of the assay device followed by the addition of 130 µL of sterile running fluid consisting of phosphate-buffered saline, pH 7.6, containing 1.67% bovine serum albumin and 3% Tween 20
- Test results are read after 10 min by visual inspection for staining of the antigen and control lines

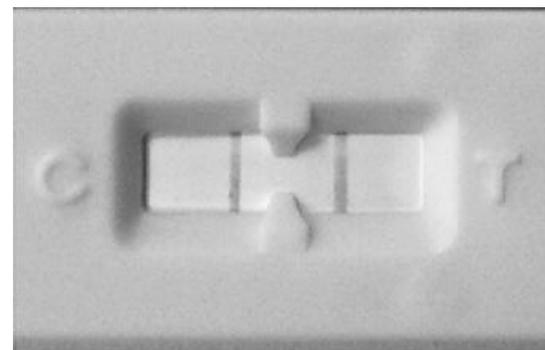
Status	Robustness	Ease of use	Accuracy	Cost
For sale by LifeAssay	Moderate - Sealed assay devices must be stored at 4 to 27°C	High – designed with rural healthcare workers in mind	Sensitivity 59.3%, Specificity 97.8%	\$2.8/test if bought in bulk (>2000 tests)

### Contact information:

LifeAssay Diagnostics  
Phone: +27 21 788 6989  
<https://www.lifeassay.com>  
[info@lifeassay.com](mailto:info@lifeassay.com)

### Physical Address:

Trojan House  
Gateway Close  
Capricorn Business and Technology Park  
7945 Cape Town, South Africa



# Selected Resources

## Major institutional players in R&D for POC diagnostics

Organization	Area of expertise	Contact Information
WHO Department of Essential Health Technologies	Capacity building, procurement, policy guidance on existing & new diagnostics	<a href="http://www.who.int/eht/en">www.who.int/eht/en</a>
PATH	Coordinating product development for diagnostics & vaccines	<a href="http://www.path.org">www.path.org</a>
Foundation for Innovative New Diagnostics (FIND)	Coordinating product development for diagnostics for Malaria & TB	<a href="http://www.finddiagnostics.org">www.finddiagnostics.org</a>

## Smaller organizations in R&D for POC diagnostics

Organization	Area of expertise	Contact Information
Beyond Traditional Borders (Rice University )	Diagnostics R&D; lab-in-a-backpack; hemocrit monitor	<a href="http://beyondtraditionalborders.rice.edu">beyondtraditionalborders.rice.edu</a>
Diagnostics for All	Non-profit diagnostic developer; malaria, TB, diabetes	<a href="http://www.dfa.org">www.dfa.org</a>

## Trade groups for POC diagnostic manufacturers

Organization	Area of expertise	Contact Information
Global Medical Technology Alliance	Trade group for companies that make diagnostics	<a href="http://www.globalmedicaltechnologyalliance.org">www.globalmedicaltechnologyalliance.org</a>
European Diagnostics Manufacturers Association	Trade group for companies that make in vitro diagnostics	<a href="http://www.edma-ivd.be">www.edma-ivd.be</a>