

# POSITIVE CONTROL WELLS FOR MALARIA RAPID DIAGNOSTIC TESTS

Pilot introduction in Kenya and Tanzania



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## About Positive Control Wells (PCWs)

Positive control wells (PCWs) are easy-to-use, point-of-care tools to assess the quality of malaria rapid diagnostic tests (RDTs), even in the most remote areas of endemic countries. PCWs are intended for use by health workers and laboratory supervisors, as well as transport and storage personnel monitoring RDT quality in the supply chain.

A PCW that can work with most commercially available RDTs has been developed by FIND in partnership with Microcoat Biotechnologie GmbH. The product is a single-use, disposable plastic tube containing small amounts of dried recombinant malaria parasite antigens, histidine-rich protein 2 (HRP2). When reconstituted with water and applied to an RDT, a positive reaction should result. If the test result is negative, it indicates that the RDT is of poor quality, or has deteriorated and is no longer functional.



PCW package and contents

## Use of PCWs by RDT QA supervisors

In April and June of 2016, a pilot introduction was carried out in Tanzania and Kenya with the aim of assessing the utility, perceptions and acceptability of PCWs. The pilot involved a half-day training of quality assurance supervisors who oversee private and public sector use of RDTs in different districts. Individual participants were assessed immediately after the training and again ten weeks later, using a standardized checklist for: a) performance of a PCW-RDT reaction, b) interpretation of the result, c) proposed subsequent action, and d) proper record-keeping of PCWs used. Additional qualitative data was gathered through post-training surveys.

The study indicated that proper PCW use can be effectively taught in a short session and that the rationale for their use was clear and well-received by participating quality assurance supervisors. Opinions of participants varied with regard to whether PCWs should be included with RDTs or packaged separately. Further research will be needed on this issue. Finally, the study implied that PCWs may help health workers trust RDT results and therefore may be useful in supporting appropriate treatment decisions.

# Findings from pilot introduction

## **Half-day trainings are effective**

After the training, most participants were able to correctly use and interpret PCWs, and they maintained these skills through to the follow-up assessment. Data from the follow-up indicated that PCWs were useful not only to check the quality of RDTs but also to assess the competence of the provider.

## **Varying opinions on packaging & distribution**

When surveyed about preferred packaging and distribution options for PCWs, some participants suggested that PCWs be supplied together with RDTs in order to reduce waste and ensure PCW availability with RDTs. Others expressed concern that if RDT quality were compromised in transportation or storage, co-packaged PCWs might also deteriorate in quality.

Participants recommended inclusion of standardized guidelines for using PCWs in order to remind health workers how to use them and to prevent wastage. Several supervisors also raised concerns about the quality of the PCWs and the need for a shelf life similar or longer than RDTs.

## **Consensus on rationale for PCWs**

There was a general consensus amongst participants that PCWs be used as a supervision tool through the routine malaria RDT quality assurance scheme. This study of supervisors' use and perceptions of PCWs indicates that they are considered: a valuable component of malaria RDT quality assurance; a quality control tool that can be used by front-line health workers; and a means of evaluating health worker competence and performance.



*FIND staff giving presentation on PCWs; QA supervisors during training; Malaria RDT being tested with PCW; Two trainees practicing use of PCW.*

## Implications: PCWs may help to reduce the likelihood that health workers disregard a negative RDT result

Until now, inspection of the expiry date, examination of the desiccant and observation of the control line on the cassette were the only formal means of checking the quality of RDTs. It has been observed that when doubts about RDT quality arise, often due to discrepancy between clinical symptoms and test results, or when health workers believe there have been 'too many' consecutive negative test results, non-adherence to results becomes more likely. Given that the only way to cross-check RDT results is microscopy, which is not consistently available in most settings, PCWs can play a valuable role in assuring RDT quality. The qualitative responses of QA supervisors trained in this pilot suggest that this means of RDT quality assurance could improve health worker adherence to test results.