Prequalification of In Vitro Diagnostics

WHO Protocol for Performance evaluation of Malaria Rapid Diagnostic Tests.

PQDx_317. Version: 1.0
4. Introduction

4.1. Prequalification of in vitro diagnostics

The World Health Organization (WHO) Prequalification of In Vitro Diagnostics is coordinated through the Prequalification Team - Diagnostics Assessment. The aim is to promote and facilitate access to safe, appropriate and affordable in vitro diagnostics (IVDs) of good quality, including Point Of Care Tests (POCTs) in an equitable manner. Focus is placed on products intended for use in resource-limited settings.

The WHO prequalification of IVDs process is comprised of three components:

- review of product dossier;
- performance evaluation of the product;
- inspection of the manufacturing site(s).

This document pertains to the objectives and processes of the performance evaluation component of the prequalification assessment.

4.2. Malaria Rapid Diagnostic Tests

Malaria Rapid Diagnostic Tests (RDTs) are used increasingly for diagnosis of malaria, particularly in remote tropical areas where good microscopy-based diagnosis is impractical. RDTs must therefore be robust, simple and safe to use, and reliably demonstrate presence or absence of malaria parasitaemia. Malaria RDTs, as referred to in this performance evaluation protocol, are immunochromatographic lateral flow devices that detect parasite antigen. Capture of dye-labeled ‘signal’ antibody-antigen complex by a fixed ‘capture’ antibody produces a visible line on a nitrocellulose strip, signifying a positive test result. Different products target various antigens specific to plasmodia. Blood, product reagent and labeled antibody-antigen complex are drawn along the nitrocellulose-fiber strip by capillary action and flushing with a reagent /buffer solution.

Sensitivity of malaria RDTs is therefore dependent on several factors, including the rate of flow of blood up the nitrocellulose strip, the adherence of capture antibody (Ab) to the strip, ability of the Ab to bind antigen (Ag), and the integrity of the signal Ab-dye conjugate. All these factors are subject to deterioration in adverse transport and storage conditions, and rates of deterioration and their effect on outcomes can vary between products.

The relationship between antigen concentration and parasite density can vary with the degree of sequestration of parasites, the stage of parasite growth, inherent variation in antigen expression and the persistence of antigen after reduction or elimination of the parasite population. Testing described in this protocol is performed against a bank of culture-derived parasites, wild-type parasites and parasite-negative blood samples. Preparation of the wild-type samples is described elsewhere.

4.3. WHO performance evaluation of Malaria RDTs

The performance evaluation determines the accuracy of Malaria DTs to detect malaria antigens in comparison with an established reference methods. The evaluation characteristics includes: accuracy (sensitivity, specificity, negative and positive predictive values), lot to lot variation and invalid rates. In addition, a number of operational characteristics are assessed including the suitability for use in laboratories and/or testing settings with limited infrastructure.
Malaria RDTs submitted for performance evaluation is assessed at designated WHO evaluating Laboratory [Malaria Branch Laboratory, Centers for Disease Control and Prevention, Atlanta, USA] upon the instruction of WHO/PQT.

5. Study objectives

The overall objective is:

i. To verify the performance of Malaria RDTs submitted for WHO prequalification against established performance criteria.

5.1. Specific objectives

The specific objectives of the evaluation are:

i. To determine the Panel Detection Score of Malaria RDTs submitted for WHO prequalification against a panel of malaria positive samples.

ii. To determine the rate of false positivity by the submitted RDTs against a panel of malaria negative samples.

iii. To evaluate the operational characteristics of Malaria RDTs, including the following: ease of performance, specimen type, inter-reader variability, reaction endpoint stability, rate of invalid runs/devices, and suitability for use in countries with limited infrastructure (no/limited electricity, no/limited clean water, and available means of biosafety disposal).

5.2. Study Design

5.2.1. PQ Evaluating Laboratory

Malaria Branch Laboratory at the Centers for Disease Control and Prevention, Atlanta, USA has been identified as the WHO PQ Evaluating Laboratory for this performance evaluation. The Laboratory at the Centers for Disease Control and Prevention has performed the Malaria RDT Product Testing for the WHO for the past 10 years and performs testing under a strict Quality Management System based on Laboratory Quality Management Plan.

The Head of the Malaria Branch Laboratory at the Centers for Disease Control and Prevention, Atlanta, USA will act as the Principal Investigator (PI).

5.3. Training and supervision

The following issues are key to minimizing error and maximizing the value of this evaluation:

- The PI will be responsible for training the laboratory staff on the evaluation protocol and in the performance of each test undergoing evaluation;
- Only those laboratory staff who have received specific training for the specific assay will be involved in the assessment;
- Accurate record keeping is crucial to the success of the evaluation and the PI will be responsible for ensuring that all data required for the evaluation are recorded on the agreed data collection sheets, and they are accurate and up to date;
- It is important to plan work in advance and follow standard operating procedures as prepared and controlled by the WHO Evaluating Laboratory;
To reduce the risk of adding an incorrect specimen to a test device/well, before starting the test run, the operator will prepare worksheets and label all tubes, dilution vessels, test devices or plates with the specimen’s unique number;

Because objective, machine-generated, permanent results for subjectively read POC tests are not feasible, it is essential that the PI emphasizes to the operator performing the tests the need for accurate recording of results and record keeping;

To minimize the risk of error, it is recommended that the results are read and recorded independently by three trained staff members;

To allow immediate correction of erroneous recording of results (rather than differences in visual interpretation), the PI or designee should assess the results as soon as possible and within the recommended reading time to allow him/her to return to the original test device to investigate apparently discordant readings;

5.4. Safety
HIV, hepatitis B and hepatitis C and other viruses are transmissible by blood and body fluids. Therefore, all types of specimens must be handled as potentially infectious. Appropriate precautions to minimize infectious hazards must be taken at all stages from the collection of specimens to the disposal of used materials from the laboratory. The WHO Guidelines on HIV Safety Precautions, and Guidelines for the Safe Transport of Specimens (WHO/EMC/97.3)\(^2\) and the WHO Evaluating Laboratory guidelines on laboratory safety should be strictly adhered to by the laboratory staff.

5.5. Storage of POC tests
All reagents must be stored as indicated in the instructions for use. Some POC tests may not need refrigeration. If refrigerated storage space is inadequate to store the entire test kit, they may be divided such that labile reagents can be refrigerated separately from the non-labile supplies. Calibrated thermometers or other environmental monitoring devices are placed at each location where reagents and specimens are stored, i.e. ambient, refrigerator and freezer. Temperatures are recorded daily. The lot numbers of the test kits received/used and their expiry dates are recorded on the individual run worksheets.

Two separate production lots with different expiry dates will be requested for evaluation, according to the following definition of a lot: “The amount of material that is uniform in its properties and has been produced in one process or series of processes. The material can be either starting material, intermediate material or finished product.” Furthermore, lots must be sourced from a representative production run and not produced especially for the purpose of this evaluation. The manufacturer shall send the WHO full batch records for the two lots sent to the WHO Evaluating Laboratory before commencing of the evaluation.

6. Performance evaluation testing

6.1. Malaria antigen performance specimen reference panel

Product testing will take place under coordination of WHO in one laboratory. This laboratory will receive and store samples from collecting sites contracted by WHO, perform sample characterization, and test

\(^{1}\)ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
products submitted by manufacturers. Testing will be conducted using cultured and wild type malaria parasites.

For all isolates of cultured or wild-type *P. falciparum* HRP2, aldolase, and pLDH content will be quantitated by ELISA's (See SOP 5.1-5.4)\(^1\). For all isolates of Wild-Type *P. falciparum*: HRP2, aldolase, and pLDH content will be quantitated by ELISA's (See SOP 5.1-5.4), Nested PCR assay will be performed for species identification (See SOP 5.8)\(^1\). HRP2 structure may be characterized by PCR amplification and sequencing (see SOP 5.9)\(^1\). The absence of malaria parasites in parasite-Negative samples will be confirmed using PCR and confirmatory test for pathology (e.g. Rh F positive) as summarized in Table 1 below:

### Table 1. Summary of the testing panels which will be used in Malaria RDT evaluation\(^1\).

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultured <em>P. falciparum</em></td>
<td>20 isolates (mixture of HRP2 A, B, C)</td>
</tr>
<tr>
<td></td>
<td>200 parasite/μL equivalence, 2000</td>
</tr>
<tr>
<td>Wild-type <em>P. falciparum</em></td>
<td>200 parasite/μL and 2000(^a) parasite/μL dilution</td>
</tr>
<tr>
<td>Total 100 common <em>P. falciparum</em>,</td>
<td>Sites: Asia/Pacific, Africa, South and Central America</td>
</tr>
<tr>
<td>Optional addition of further HRP2 variants</td>
<td>Characterized by ELISA or Luminex (antigen concentration, PCR (plasmodium genus and species)</td>
</tr>
<tr>
<td>Wild-type <em>P. vivax</em></td>
<td>35 isolates 200 and 2000(^a) parasite/μL</td>
</tr>
<tr>
<td>Wild-type/</td>
<td>5+ isolates 200 and 2000(^a) parasite/μL</td>
</tr>
<tr>
<td>Wild-type/</td>
<td>5+ isolates 200 and 2000(^a) parasite/μL</td>
</tr>
<tr>
<td>Parasite-negative human blood</td>
<td>Anti-nuclear antibody (ANA) 5-10</td>
</tr>
<tr>
<td>Total 100</td>
<td>RPR positive 5-10</td>
</tr>
<tr>
<td></td>
<td>Rheumatoid factor positive (5-10 samples)</td>
</tr>
<tr>
<td></td>
<td>Heterophile antibody positive 5-10</td>
</tr>
<tr>
<td></td>
<td>Anti-mouse antibody positive 5-10</td>
</tr>
<tr>
<td></td>
<td>Clean negatives (none of above) 50</td>
</tr>
<tr>
<td></td>
<td>Other tropical diseases, including: Chagas, disease, dengue typhoid leishmaniasis schistosomias</td>
</tr>
</tbody>
</table>

\(^a\) rarely 5000 parasite/μL dilutions are used for some samples rather than 2000 parasite/μL dilutions

### 6.2. Laboratory testing

Each product under evaluation is used strictly in accordance with the instructions for use (IFU) issued by the manufacturer. The PQ Evaluating Laboratory will send a copy of the IFU to WHO/PQT upon delivery of the
test kits and prior to the commencement of the laboratory evaluation. The IFU must be reviewed against
the IFU submitted to WHO/PQT as part of the dossier assessment for the prequalification assessment. If
the IFU has been updated since dossier submission, a letter detailing changes made must be sent to
WHO/PQT prior to the laboratory evaluation commencing.

For the purpose of evaluating the single-use devices, a ‘test run’ is defined as a consecutive run of tests of
the same production lot performed during the same ‘session’. A ‘testing session’ might be considered to be
a morning or afternoon.

**Phase 1 testing.**

RDTs from both lots are tested against 20 culture derived *P. falciparum* culture and 20 clean parasite-negative panel. RDTs reaching adequate performance criteria (≥80% overall Panel Detection Score (PDS) in both lots against 2000 parasite/µL samples and ≤50% false positive rate against 20 clean-negative samples tested on 2 RDTs of each lot (ie.≤40 of 80 FP across both lots) will proceed to phase 2 testing.

**Phase 2 testing**

All RDTs that passed Phase 1 are tested against the full panel of wild-type and parasite-negative samples. Products that have previously reached WHO performance criteria in previous GMP Testing Rounds of product testing, are excluded from Phase 1 and pass direct to Phase 2 evaluation. Products that are not intended to detect *P. falciparum* are only tested against the Phase 1 negative panel, and progress to Phase 2 based on false positive rate only.

Clean-negative samples should be from afebrile patients, with no known infectious disease, blood
dyscrasia or immunological abnormality. Samples from endemic countries should be confirmed as
parasite-negative by PCR for *P. falciparum*, *P. vivax*, *P. ovale*, *P. malariae*, and *P. knowlesi*. Ratio of clean
negative samples from endemic and non-endemic countries should be maintained close to 1:1. The
performance criteria used in Phase 1 testing is summarized in Table 2 below.

In Phase 2 testing, the RDTs are tested using 100 *P. falciparum*, 35 *P. vivax* wild-type panel and 80 parasite-negative samples (as 20 clean negative samples have been used already during Phase 1):

**Table 2: Pass criteria for sensitivity/specificity testing against culture-derived panel.**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Pass Criteria</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture-derived <em>P. falciparum</em> samples</td>
<td>Detection of 16 of 20 samples (80%) at 2000 parasites/µL equivalence</td>
<td>Failures may go through limited further testing to elucidate performance against antigen variants</td>
</tr>
<tr>
<td>Clean-negative samples</td>
<td>Negative results on at least 40 of 80 RDTs tested (2 RDTs on 20 samples x 2 lots)</td>
<td></td>
</tr>
</tbody>
</table>

6.3. **Recording test results and interpretation of test results**

All test results are recorded on standardized test result worksheets and then entered in SOP_PQDX_316
PQT Report template for malaria simple/rapid assays for further data analysis as shown in Table 3 below.
Visual interpretation of results of subjectively read assays is made independently by operator and two
more readers (without the knowledge of the others’ sets of results) and entered into the data collection
sheets. When the three readers interpret the results differently from each other, the consensus is recorded as that interpretation which occurs two out of three times.

**Table 3 - Results legend for data collection sheets for subjectively read assays**

<table>
<thead>
<tr>
<th>Scoring index</th>
<th>RDT results</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Non-reactive</td>
</tr>
<tr>
<td>1</td>
<td>Reactive (Very weak band)</td>
</tr>
<tr>
<td>2</td>
<td>Reactive (Medium to Strong Band)</td>
</tr>
<tr>
<td>7</td>
<td>Debris/invalid</td>
</tr>
</tbody>
</table>

In addition, a technician’s appraisal is made of each assay under evaluation and is completed by the operator performing the testing as shown in Table 4 below. The following parameters will also be recorded:

- Results of control and test lines are recorded as negative or positive by each technician.
- Where control line is very weak (+1 on band intensity template), this should be recorded in notes section.
- Marked abnormalities or issues affecting interpretation, such as poor blood clearance, should be recorded in notes section.
- Absent Control Lines: If control line is recorded as absent by either technician (‘Invalid test result’), the test is recorded as invalid by that technician. (In such cases, the result is not included in calculation of detection rates during later analysis).

**Notes recorded during RDT testing**:  

<table>
<thead>
<tr>
<th>Description</th>
<th>Short ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red background</td>
<td>RB</td>
</tr>
<tr>
<td>Red background obscuring test line(s)</td>
<td>ORB</td>
</tr>
<tr>
<td>Incomplete clearing</td>
<td>IC</td>
</tr>
<tr>
<td>Incomplete migration</td>
<td>MI</td>
</tr>
<tr>
<td>Failed migration</td>
<td>FM</td>
</tr>
<tr>
<td>Strip misplaced in cassette (shift)</td>
<td>SM</td>
</tr>
<tr>
<td>Specimen pad not seen in sample window</td>
<td>PAD</td>
</tr>
<tr>
<td>Ghost test lines</td>
<td>GL</td>
</tr>
<tr>
<td>Diffuse test lines</td>
<td>DL</td>
</tr>
<tr>
<td>Patchy broken test line</td>
<td>PL</td>
</tr>
<tr>
<td>Buffer remains pooled in buffer well</td>
<td>BP</td>
</tr>
<tr>
<td>Other (opens a box for typing free text)</td>
<td>OT</td>
</tr>
</tbody>
</table>

Abnormalities associated with buffers should be indicated and dated in the ease of use description form. These results are compared by the scientist performing the test so that any mistakes discrepancies may be identified and rectified immediately. Should recording errors be identified, both the original and corrected result are recorded and initialed by the reader. When the three readers interpret the results differently from each other, the consensus is recorded as that interpretation which occurs two out of three times.
Other operational characteristics appraisal is completed by the scientist performing the test. It includes questions about the ease of the procedure, reading of results, clarity of IFU, as well as room to record any specific difficulties encountered during the evaluation.

**Ease of Use Description**

**Agreed assessment by both technicians involved in testing:**

- **Blood safety**
  - Mixing wells involved (Y=0/N=1)
  - Retractable needle (N = 0, Y = 1)
  - Strip exposed, not within card/cassette (Y 0, N 1)

- **Quality of the instructions**
  - Pictures of results = 1
  - Pictures showing methods and results = 2
  - No pictures = 0
  - Incorrect method description = -2
  - Incorrect pictures of methods or results = -2

- **Number of timed steps**
  - Steps requiring specific training #

- **Total time to obtain result**
  - From placement of blood, when instructions are followed (#)

- **Characteristics of packaging and labelling of device, box and accessories**

**Additional information**

- **Format**
  - (card, cassette, dipstick, cassette- dipstick hybrid)
- **Blood transfer method**
- **Items included in package**
  - (swab, lancet, blood collection device)
- **Language of instructions available**
- **Anomalies identified in preparation or interpretation of RDTs**

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Report on Ease of Use (Form 039)
6.4. Test kit controls
When available, manufacturer-supplied positive and negative test kit controls will be run as indicated in the IFU for all test formats at the commencement of each testing session. Where positive and negative test kit controls are not supplied by the manufacturer, as will be the case for many rapid diagnostic tests, the laboratory will provide an in-house quality weakly reacting (200 parasite/ml) control specimen.

6.5. Internal control lines for POCTs
Generally, most POCTs contain a control band, line or spot to determine that the test device is operating correctly. Most control bands/lines/spots will become visible with the addition of reagent (i.e. buffer). However, some POC tests will contain a control band/line/spot that becomes visible with addition of specimen. It is imperative that the exact nature of the control band/line/spot is ascertained and recorded in the report. An experiment using distilled water instead of specimen is performed to verify this point, if not explicitly mentioned in the IFU.

6.6. Proficiency panels
A proficiency panel must be run successfully for each assay by each operator before the evaluation commences. This may be the same panel as that used at the time of assay demonstration by the manufacturer or for training purposes.

6.7. Limits of acceptability
All results on test kit controls and QC specimens are entered on the data collection sheets. Should the test kit controls or the QC specimens not give the expected results, testing is suspended until the cause has been identified and a satisfactory solution identified. Such problems must be communicated immediately to WHO/PQT and recorded on the data sheets. The PI is responsible for carefully checking all data entry forms for legibility, accuracy and completeness.

6.8. Interpretation of results
The interpretation of results for each assay under evaluation is made strictly according to the manufacturers’ instructions as described in the IFU. Invalid test results are recorded on the data collection sheets including where the control line does not appear or in any other way the test result is invalid as defined by the IFU.

7. Analysis of data

7.1. Invalid runs/devices
The number of invalid POC devices is recorded as the number of invalid test results as a percentage of the total number of devices used for the entire evaluation using all specimens. Invalid results will include invalid test results as defined by the instructions for use where the control line/band/spot does not appear or invalid due to obviously defective test device or defective transfer pipette.

7.2. Inter-reader variability
The inter-reader variability is calculated when test readings must be performed without any objective reading instruments i.e. subjective read POC tests. Three persons independently interpret each test result.
The inter-reader variability is expressed as the percentage of specimens for which initial test results are differently interpreted (i.e. reactive or non-reactive or indeterminate) by the independent readers.

7.3. Test performance
The results of the test under evaluation will be compared to the reference results at different levels of malaria antigen followed by calculation of the Panel Detection Score (PDS) which is defined as the percentage of parasite-positive panel samples of a defined parasite density against which all RDTs of both lots showed a positive result.

Acceptance Performance Criteria
- For the detection of P. falciparum in all transmission settings the panel detection score against P. falciparum samples should be at least 75% at 200 parasites/μL or its equivalent antigen (HRP2, pLDH or aldolase) concentration.
- For the detection of P. vivax in all transmission settings the panel detection score against P. vivax samples should be at least 75% at 200 parasites/μL or its equivalent antigen (pLDH or aldolase) concentration.
- The false positive rate should be less than 10%.
- The invalid rate should be less than 5%.

7.4. Discrepant results between test under evaluation and reference results
Those specimens with results that are consistent with the reference results i.e. the characterized specimen results, undergo no further testing. Those specimens with results discrepant from the reference result are retested in duplicate in both by the same operator. The results that occur two out of three times are recorded as the final result. If the result is still discrepant from the reference results, the result is recorded as is.

An initial sensitivity and specificity are calculated based on the initial results obtained for the test under evaluation on both lots. The final sensitivity and specificity are calculated taking into consideration the results of repeat testing performed on both lots of the test under evaluation.

7.5. Technician’s appraisal
The technical aspects of the test under evaluation are assessed by the scientist who performed the testing. These assessments, along with other selected test characteristics, contribute to an overall appraisal of each test’s suitability for use in small laboratories. To enable comparison between POC tests, a scoring system is used to rate specified operational characteristics as shown Appendix 1.

7.6. Report preparation
The data analysis and report drafting is carried out by WHO Evaluating Laboratory and sent to WHO in a timely manner. WHO verifies the draft report and sends to the authorized contact designated by the manufacturer for comment. The company has one month right of reply. The final report is prepared after one month has elapsed. The WHO scientist ensures that the comments of the authorized contact are reviewed and any outstanding issues are resolved before final publication. The final report is prepared and disseminated by WHO. A copy of the final report is sent to the authorized contact designated by the manufacturer and to WHO PQ Evaluating Laboratory.
Materials and supplies

7.7. Data collection sheets
All data will be reported to WHO/PQT on the following forms:

- Report of evaluation using MSWord template provided by WHO/PQT
- Results (all data) using MS Excel template provided by WHO/PQT
- Technician’s appraisal worksheet provided by WHO/PQT
- Findings of supplementary testing on discrepant specimens

7.8. Supplies
The manufacturers of products will provide the products and any equipment necessary for the evaluation free of charge.

8. Roles and responsibilities

8.1. Responsibilities of Malaria Branch Laboratory, Centers for Disease Control and Prevention, Atlanta, USA.

1. Act as repository for the WHO malaria specimen reference panel and lot-to-lot variation panels;
2. Conducting the laboratory evaluation in accordance with internationally recognized best practice;
3. Preparation of QC specimens and proficiency panels;
4. Preparation of draft report on laboratory evaluation;
5. Advising WHO on operational characteristics of POC tests evaluated.

All source data, data analysis records and all correspondence are retained and archived for a period of at least 10 years.

8.2. Responsibilities of WHO/PQT

i. Technical advice to the PI;
ii. Technical and administrative management of the laboratory evaluation;
iii. Procurement and delivery of supplies;
iv. Ensure that the manufacturer delivers POC tests to the testing laboratory;
v. Verification of the draft report, seeking of comments from manufacturer;
vi. Preparation and dissemination of the final report;
vii. Formal contacts with authorized contacts of the manufacturers.

Any publication by WHO of the results of these evaluations and the WHO recommendations derived therefrom will, however, be accompanied by the following disclaimer:

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by the World Health Organization or the Centers for Disease Control and Prevention, in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

WHO and the Malaria Branch Laboratory, Centers for Disease Control and Prevention, do not warrant or represent that the evaluations conducted with the HIV test kits referred to in this document are accurate, complete and/or error-free. WHO and the Malaria Branch Laboratory, Centers for Disease Control and
Prevention, disclaim all responsibility for any use made of the data contained herein, and shall not be liable for any damages incurred as a result of its use. This document must not be used in conjunction with commercial or promotional purposes.

9. References


2) http://www.who.int/csr/resources/publications/biosafety/WHO_EMC_97_3_EN/en/


International Standards
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
ISO 17025 (General requirements for the competence of testing and calibration laboratories)
ISO15189 (Medical laboratories — Particular requirements for quality and competence)
Annex 1. **EASE OF USE ASSESSMENT SHEET**

<table>
<thead>
<tr>
<th>Date (dd/mm/yyyy):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer: Product:</td>
<td></td>
</tr>
<tr>
<td>Catalogue Number: Lot:</td>
<td></td>
</tr>
<tr>
<td>Technician/ Initials</td>
<td>1.</td>
</tr>
<tr>
<td></td>
<td>2.</td>
</tr>
<tr>
<td></td>
<td>3.</td>
</tr>
</tbody>
</table>

### Blood safety

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixing wells involved (Y=0/N=1)</td>
<td></td>
</tr>
<tr>
<td>Retractable needle (No retract. needle = 0, retract. needle =1)</td>
<td></td>
</tr>
<tr>
<td>Strip exposed: not within card/cassette (Exposed = 0/ Covered = 1)</td>
<td></td>
</tr>
</tbody>
</table>

**Sub-Total**

### Instruction quality

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pictures / diagrams = 0</td>
<td></td>
</tr>
<tr>
<td>Pictures/diagrams of results = 1</td>
<td></td>
</tr>
<tr>
<td>Pictures / diagrams of results and method = 2</td>
<td></td>
</tr>
<tr>
<td>Qualitative assessment (0 poor - 2 good)</td>
<td></td>
</tr>
<tr>
<td>Incorrect method description = -2</td>
<td></td>
</tr>
<tr>
<td>Incorrect pictures of methods or results = -2</td>
<td></td>
</tr>
</tbody>
</table>

**Subtotal**

**Total**

### Timed steps required

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time to result</td>
<td></td>
</tr>
</tbody>
</table>

**Blood transfer device**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Capillary tube, pipette, straw, loop, inverted cup, other (specify)</td>
<td></td>
</tr>
</tbody>
</table>

**Format:** Cassette, Dipstick, Card, Hybrid (Ca, D, Cd, H)
## Language(s) of instructions

### Items included in package

<table>
<thead>
<tr>
<th>Desiccant (color indicator yes/no)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, colour change indicating humidity exposure</td>
<td>Yes, often ; Yes, rare</td>
</tr>
</tbody>
</table>

### Buffer

- Buffer container does not puncture
- Buffer does not flow freely
- Insufficient buffer in bottle or vial
- Empty buffer bottle or vial
- Discoloured buffer

### Comments:

### 10. Other documents required

#### Master Templates

<table>
<thead>
<tr>
<th>PQDx document number</th>
<th>Title of template</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple/rapid POC tests</td>
<td>PQT MSWord report template for simple/rapid POC tests for detection of Malaria including MS Excel template for data</td>
</tr>
</tbody>
</table>