Global **Malaria** Programme

Malaria rapid diagnostic test products

Suggested use of terms, requirements and preferences for labelling and instructions for use

World Health Organization

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INTRODUCTION

Rapid diagnostic tests (RDTs) largely account for the scale-up of malaria diagnosis in endemic settings. However, diversity in terminology, labelling and the instructions for use (IFU) limits their interchangeability and userfriendliness. Uniform, easy to follow and consistent terminology and labelling, aligned with international standards and appropriate for the level of the end user's education and training, is crucial. This document is intended as a reference for malaria RDT manufacturers and follows on from the consensus building efforts of a 2014 Roll Back Malaria Partnership stakeholder consultation and special taskforce to harmonize terms and abbreviations as well as specifications for labelling of box, device packaging, cassettes, buffer bottle and accessories.[1] Specifically, this reference indicates if WHO considers these specifications are requirements based on international standards or preferences based on the outcome of consultations with country programme implementers, experts in RDT implementation, IVD regulatory experts and manufacturers. These requirements and preferences are aligned with those of the WHO Prequalification (PQ) of IVDs programme and compliance will be monitored through the dossier and laboratory evaluation components of the WHO PQ process.[2]

1 Jacobs et al. Malaria Journal 2014, 13:505.

2 http://www.who.int/malaria/publications/atoz/978924151268/en/

Suggested use of terms

PREFERRED TERM	ABBREV.	DESCRIPTION	SYNONYM (NOT SUGGESTED TERM)	COMMENTS	CATEGORY
Accessories		Articles intended and validated by the RDT manufacturer to be used with the RDT in order to achieve its intended purpose (i.e. specimen transfer device, lancet, alcohol swab)	Ancillary items	The accessories provided might be replaced by other items without compromising safe, accurate performance of the test, e.g. different lancets This possibility of substitution differentiates "accessories" from "components" (see 'Component').	
Alcohol swab		A pad saturated with alcohol that is used to clean and/or disinfect skin	Alcohol pad, alcohol wipe, alcohol pre-pad	There was consensus that "alcohol swab" is the term in broadest use, both in spoken language and in labelling.	
Buffer		A buffered solution to enable specimen flow and conditioning of specimens, to optimize sensitivity and minimize non-specific reactions.	Many synonyms are in use, e.g. "blood lysis buffer", "clearing buffer", "assay diluent", "sample diluent", "reagent"		
Buffer bottle		Plastic bottle, often with cap and nozzle, containing the buffer, intended to be used in multiple tests			
Buffer vial		Small vial containing a sufficient volume of buffer to perform a single RDT test. See "primary packaging"	"Buffer ampulla"		
Buffer well		Physical place in the test device in which the buffer is applied.	Some RDTs have a single well for both buffer and specimen.		
Cassette		This is the test format in which the nitrocellulose strip is encased in a plastic housing, presenting openings for the result window, for the specimen and buffer well(s) and in some cases for evaporation.	Commonly referred to as the "device"		
Combination rapid diagnostic test		Test for detecting multiple malaria species and which distinguishes *P. falciparum* from other malaria species	Commonly referred to as a "combo test"		
Component		Dedicated parts of a finished, packaged, labelled RDT kit that are specific to and necessary for performing the RDT. These include the test device, buffer bottle/vial and instructions for use.		Note: There can be no substitution for a kit component, whereas accessories such as a lancet or alcohol swab may be replaced by items that perform the same function or are purchased separately.	
Control line		Visible line on the nitrocellulose strip that generally only, indicates satisfactory migration of buffer[a]			
Desiccant		Drying agent used to protect the test device from humidity. These may change colour (self-indicating) to indicate humidity saturation. The beads are contained in a transparent, partially transparent or non-transparent fiber pouch.	Silica gel is the most commonly used desiccant for RDT products.		

DESCRIPTION	SYNONYM (NOT SUGGESTED TERM)	COMMENTS	CATEGORY
alone or in combination, intended by rer for in vitro examination of specimens ıe human body, solely or principally rmation for diagnosis, monitoring or hey include reagents, calibrators, control :imen receptacles, software, related apparatus or other articles (International es Regulators forum)	http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n045r12-in-vitro-diagnostic-classification-070209.pdf		**Required**
ovided by the manufacturer to the user ıded purpose and proper use of in vitro d any precautions to be taken (GHTF/SG1/	"Package insert", "instructions leaflet"		**Required**
cribing the essential materials to perform ocedure or interpretation) provided apart ither as a separate leaflet and/or printed ackaging or in/on the RDT box	"Quick guide", "pictogram testing procedure"	Refer to the "WHO generic job aids" for an example.	
ents and accessories packed together or using a specific RDT (test device, buffer en transfer device, lancet, alcohol swab, use) (definition adapted from ISO 18113-			**Required**
-like, sterile medical device used to o obtain blood (CLSI H04-A6) ıncets (packed in a single packages for ıncets (in plastic housing with a plastic cap) lancets (mounted in plastic housing that is natically when the plunger is pressed) ıble lancets (mounted in plastic housing ed automatically after puncture)			
nt of material with uniform properties that uced in one process or series of processes e expected to be homogeneous (ISO 18113-	"Batch"		**Required**