Global **Malaria** Programme

Guidance on control materials for antigen detecting malaria RDTs

Tools for preparation and validation

GUIDANCE FOR PRODUCT DEVELOPERS AND MANUFACTURERS

World Health Organization

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ABBREVIATIONS

CLSI	Clinical and Laboratory Standards Institute
CRM	certified reference material
EIA	enzyme immunoassay
GMP	Good Manufacturing Practice
HBsAg	hepatitis B surface antigen
IFU	instructions for use
IS	international standard
ISO	International Organization for Standardization
LoD	limit of detection
PEI	Paul Ehrlich Institute
QA	quality assurance
QC	quality control
RDT	rapid diagnostic test
SOP	standard operating procedure
TSS	Technical Specification Series
WHO	World Health Organization

DEFINITIONS

calibrator	Reference material whose value is used for the independent variable in a calibration function Source: *(1) definition 3.7*
certified reference material (CRM)	Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes metrological traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence Source: *(1) definition 3.8*
commutability of a material	Closeness of agreement between the mathematical relationship of the measurement results obtained by two measurement procedures for a stated quantity in a given material, and the mathematical relationship obtained for the quantity in routine samples Source: *(1) definition 3.9*
control material	Substance, material or article used to verify the performance characteristics of an in vitro diagnostic medical device Source: *(2) definition 3.4*
international conventional calibrator	Calibrator whose value of a quantity is not metrologically traceable to the international system of units (SI) but is assigned by international agreement NOTE 1: The quantity is defined with respect to the intended clinical application NOTE 2: WHO international standards (IS) commonly fall within this category. Source: *(1) definition 3.11*
limit of detection	The lowest value of measurand that an examination procedure can report as present with a specified level of confidence Source: *(3) paragraph A.2.8*