

Guidance on control materials for antigen detecting malaria RDTs

Tools for preparation and validation

GUIDANCE FOR PRODUCT DEVELOPERS AND MANUFACTURERS



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ABBREVIATIONS

CLSI Clinical and Laboratory Standards Institute

CRM certified reference material

EΙΑ enzyme immunoassay

GMP Good Manufacturing Practice

HBsAg hepatitis B surface antigen

IFU instructions for use

international standard IS

ISO International Organization for Standardization

limit of detection LoD

PEI Paul Ehrlich Institute

QΑ 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		

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