



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 |
| 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 |

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