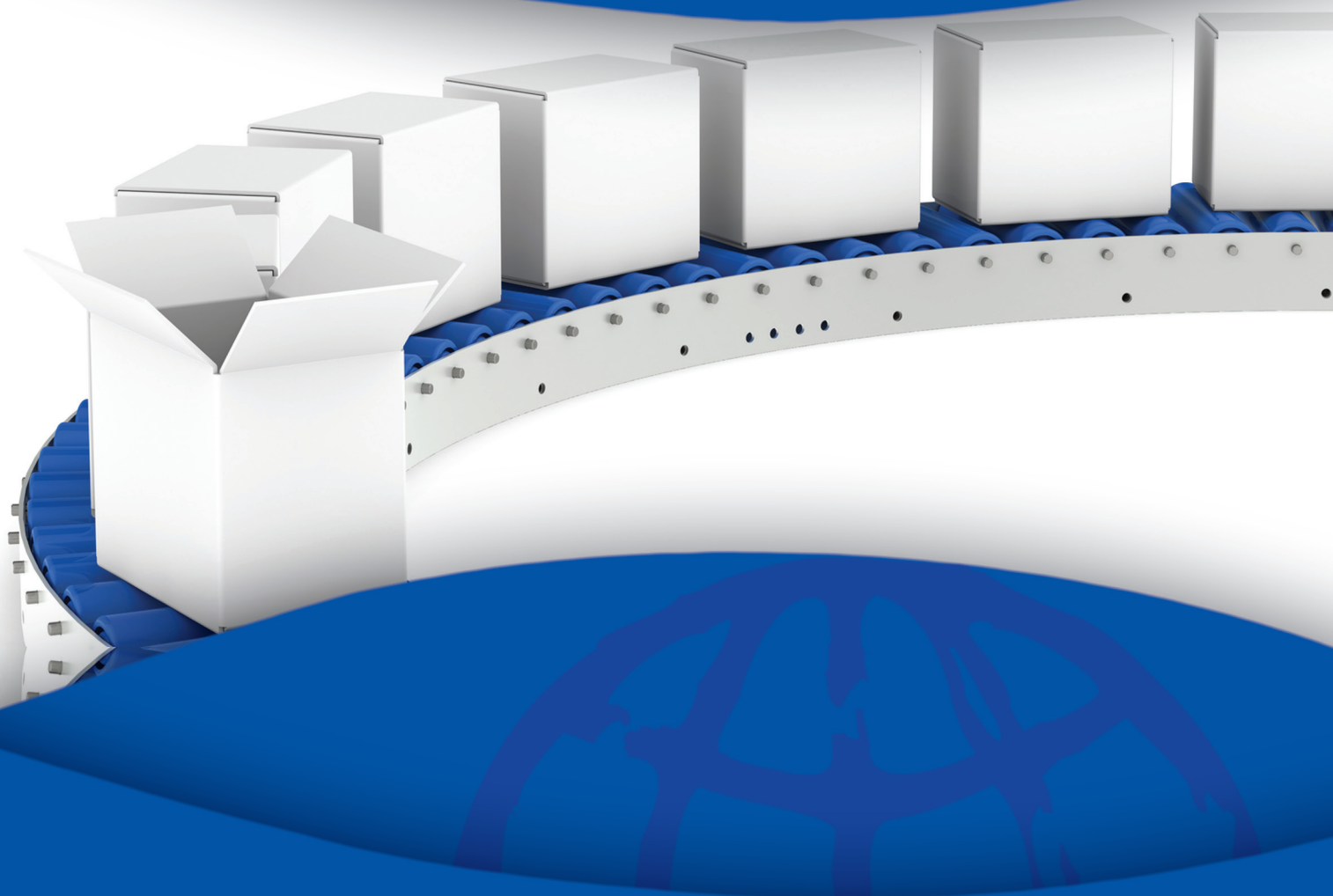


# **Guidance for procurement of in vitro diagnostics and related laboratory items and equipment**

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Guidance for procurement of in vitro diagnostics and related laboratory items and equipment  
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# ABBREVIATIONS

<b>CD4</b>	CD4 T-lymphocyte
<b>CFR</b>	cost and freight
<b>CIF</b>	cost insurance and freight
<b>CLIA</b>	chemiluminescence immunoassay
<b>CLSI</b>	Clinical and Laboratory Standards Institute
<b>ECL</b>	electrochemiluminescence immunoassay
<b>EIA</b>	enzyme immunoassay
<b>ELISA</b>	enzyme-linked immunosorbent assay
<b>EOI</b>	expression of interest
<b>EQA</b>	external quality assessment
<b>EQAS</b>	external quality assessment scheme
<b>FSCA</b>	field safety corrective action
<b>FSN</b>	field safety notice
<b>GAVI Alliance</b>	The Global Alliance for Vaccines and Immunization
<b>GFATM</b>	The Global Fund to fight AIDS, Tuberculosis and Malaria
<b>ICB</b>	international competitive bidding
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>INCOTERM</b>	International Commercial Terms
<b>ISO</b>	International Standards Organization
<b>ITB</b>	invitation to bid
<b>IVD</b>	in vitro diagnostic medical device
<b>LTA</b>	long term agreement
<b>NAT</b>	nucleic acid testing
<b>NGO</b>	nongovernmental organisation
<b>NRA</b>	national regulatory authority (for medical products)
<b>NRL</b>	national reference laboratory
<b>OD/CO</b>	optical density to cut-off
<b>OTIF</b>	on time and in full
<b>PEPFAR</b>	President's Emergency Plan for AIDS Relief
<b>PO</b>	purchase order
<b>POCT</b>	point of care testing
<b>PMI</b>	President's Malaria Initiative
<b>PMS</b>	post-market surveillance
<b>PSM</b>	procurement and supply management
<b>QA</b>	quality assurance
<b>QC</b>	quality control
<b>QMS</b>	quality management system
<b>RDT</b>	rapid diagnostic tests
<b>RFP</b>	request for proposal
<b>RFQ</b>	request for quote
<b>SOP</b>	standard operating procedure
<b>SOW</b>	scope of work
<b>TCO</b>	total cost of ownership
<b>TOR</b>	terms of reference
<b>UN</b>	United Nations
<b>WHO</b>	World Health Organization

# GLOSSARY

<b>Analyte</b>	A substance or chemical constituent that is analyzed (identified or measured) by the assay, e.g. polyclonal or monoclonal antibodies or antigen
<b>Analyser</b>	Equipment that consume reagents, consumables and produce a test result. Usually repaired and maintained by service contracts.
<b>Ancillary equipment</b>	Freezer, washers, readers, incubators, etc. Usually repaired and serviced by in-country biomedical engineers.
<b>Cleaning</b>	Process to remove any type of contamination, visible or not.
<b>Consumables</b>	Items that are used once during testing and are not reused e.g. gloves, pipette tips, etc.
<b>Decontamination</b>	Procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects.
<b>Disinfection</b>	Process to reduce the number of microorganisms but not usually of bacterial spores, without necessarily killing or removing all organisms, usually from non-living objects such as laboratory equipment or laboratory benches.
<b>Durables</b>	Items that can be reused for multiple tests such as glassware, plastic ware, etc.
<b>Equipment</b>	Items such as analysers that may be used for a range of specific assays and general laboratory equipment such as centrifuges, pipettes and incubators
<b>External quality assessment</b>	A programme designed to assess laboratory performance, i.e. assessment of the quality of the entire testing process from collection of specimen, the testing procedure, to the reporting of testing results. Usually composed of one or more of the following activities: site visits, participation in external quality assessment schemes/proficiency testing and inter-laboratory comparison.
<b>Hazardous waste</b>	Waste that is potentially harmful to human beings, property or the environment. E.g. used reagent strips contaminated with human blood, reagent solution containing sodium azide, decommissioned instruments containing heavy metals. Includes waste that is flammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious.
<b>In vitro diagnostic medical device (IVD)</b>	A medical device, used alone or in combination, intended by the manufacturer for the examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. For example, IVDs can be used for the following test purposes: diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status. IVDs also include reagents, calibrators, control materials and specimen receptacles.

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