World Health Organization

Draft Target Product Profiles on developing IVDs for low- and middle-income settings

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Introduction

The recent *Lancet Commission on Diagnostics* found that nearly 50% of the global population have little to no access to diagnostics. It was estimated that over 1 million premature deaths in low- and middle-income countries (LMICs) could be avoided by reducing the diagnostic gap for six priority conditions, all of which rely on diagnostics for prevention and/or treatment. *In vitro* diagnostic assays (IVDs) are essential tools across a number of communicable and non-communicable diseases, both across programmes as well as during emergency outbreak response. Because of this, the World Health Organization (WHO) engages with many manufacturers that have either developed products or have marketing strategies focused mainly on prioritizing users in high-income settings. As a result, these IVDs often require the infrastructure commonly expected in developed countries making it difficult to distribute in other settings and where they might be critically needed. This situation is not ideal for the wide range of needs from all the WHO Member States, including and especially resource-limited settings.

Rapid, more sensitive and accurate diagnostics that are used close to or at the point of care (POC) are a mainstay of modern medicine. In 2006, WHO introduced the ASSURED criteria for point- of-care tests: affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end users. Although notable progress has been made in developing diagnostic tests for a variety of diseases, there are still considerable gaps. Diagnostic tests that are more responsive to the evolving needs of patient-centred care are needed; such tools include tests that are intended to be deployed at the most decentralized levels of care, and that are affordable and accessible. At the same time, laboratory-based testing and diagnosis remains the cornerstone of many disease and public health systems, ensuring high volume, high quality testing can be sustained as well as surveillance of new and emerging pathogens. New innovations and technologies continue to lead to ever evolving opportunities for improved testing, diagnosis, and surveillance of diseases and pathogens, emergent and endemic.

WHO has developed a number of supportive and relevant documents, such as target product profiles (TPPs), Prequalification (PQ) technical specifications, procurement specifications, etc. However, specific elements or guidance on designing and developing an IVD for low- and middle-income settings, and their particular challenges, is often scattered across various documents or has become part of a disease-specific TPP. The lack of a clear and comprehensive guidance document oftentimes results in manufacturers relying on their proven development and market strategies and/or product design, leaving procuring countries to try to adapt their storage and supply chain managements to the products available in developed settings. This is the case both for endemic pathogens as well as and in particular emergency outbreaks or, as of recent, pandemics.

Purpose and audience

The proposed document aims to provide considerations and preferred characteristics for manufacturers to proactively develop or adapt their IVDs to LMIC markets. As specifics may differ depending on the

setting and disease in question, the document will contain a generic list of parameters, in addition to highlighting relevant documentation available for further guidance and reference on the topic. The document should, therefore, provide information that will help guide manufacturers at the design phase of their products and encourage innovation the field.

Furthermore, the document should support procurers in developing technical specifications for procurement; national and global programmes in developing diagnostics-related guidance; and regulatory or prequalification groups to develop technical specifications.

This document should be seen as a generic target product profile, with a list of characteristics that will affect the reliability and thereby the access of IVDs in LMIC settings, and help improve procurement processes, by easing the selection, procurement, shipment, and warehousing of IVDs, particularly in resource-limited settings.

Target product profiles

The following target product profiles provide the key minimal and optimal characteristics for IVDs:

- TPP 1: offered at health care facilities without clinical laboratories, levels 0 and 1: instrument-free disposable tests
- TPP 2: offered at health care facilities without clinical laboratories, levels 0 and 1: instrument-based point-of-care technologies
- TPP 3: offered at health care facilities with clinical laboratories, levels 2, 3, 4: immunoassays, laboratory-based nucleic acid technologies, etc.

These three distinct target product profiles were developed due to clear infrastructural differences in the separate settings within LMICs.

World Health Organization

TPP 1. Target product profile for IVDs offered at health care facilities without clinical laboratories, levels 0 and 1: **instrument-free disposable tests.**

Characteristic	Minimal	Optimal
Scope		
Target user	Health care worker, community health worker, lay provider	
Equipment	None required - instrument-free or disposable	Compatible with a reader
Operational requirements		
Sample preparation	Minimal, no more than 2 steps and no precision measurements required	Integrated; transfer directly to test
Additional 3rd party consumables	All included in kit, except sample collection kit	All included in kit, including sample collection kit
Cold chain requirements	None required	
Power requirements	None required	
Water requirements	None required	
Test kit stability	18 months at 10-40°C; ≤ 70% humidity	>24 months at 4-40°C; ≤ 75% humidity; conform to ASTM D4169-05 and ISO 11607-1:2019
Test kit stability, once opened	1 hour	> 2 hours
Reagents and consumables	Proprietary reagents and consumables	
Sample stability, pre-testing	30 minutes	1 hour
Reagents reconstitution	None required, reagents ready	
Operating conditions	15-35°C; ≤ 70% humidity; altitude up to 1000m; operable in low light settings	10-45°C; ≤ 75% humidity; altitude up to 3000m; operable in low light settings
Ease of use	≤ 3 user steps, 1 step requiring precision using a provided simplified pipette, 1 timed step	≤ 2 user steps, no steps requiring pipetting, 1 or no timed steps
Total time to test result	< 1 hour	< 20 minutes
Throughput	3-5 tests per hour	Capable of batching; > 5 tests per hour
Invalid/error rate	< 5%	< 2%
Multiplex capability	No	Yes
Test results		

Result interpretation	Visual manual or reader interpretation with minimal interpretation instructions	Direct result with no interpretation necessary
Result validity stability	30 minutes	1 hour
Result storage	Not applicable	Compatible with a reader; > 200 test results
Data requirements		
Connectivity	Not applicable	Compatible with a reader; integrated Wi-Fi 802.11b/g/n; USB 3.0 or 4.0; internally designatable static IP address; support for DHCP-issued IP addresses; support for HTTPs and SFTP protocols; integrated global positioning system (GPS); ability to update connectivity software stack via USB or LAN.
Data export	Not applicable	Compatible with a reader; secure data export end-to-end encryption; data export in CSV and Excel file formats; configurable destination IP and DNS addresses; user-initiated data export
Quality, safety, and regulatory requirements		
Training required	1 day with tools, instructions for use, job aids, etc. available as hard copy and online	≤ 1 day with tools, instructions for use, job aids, etc. available as hard copy and online
Biosafety precautions	No hazards when observing Universal Blood Safety/Body Fluid precautions and all materials are free of components with a GHS classification H (particularly H350, H340, H360)*	
Waste disposal requirements	Waste disposal in biosafety bin following standard guidelines, including sharps containers for disposal of lancets, capillary tubes, etc. Appropriate disposal method for excess specimens and processing consumables (e.g. latrine, incineration). Standard operating procedure provided.	Same as minimal, but consideration for reusable, recyclable, or compostable material or non-plastic alternatives; no cyanide and no chlorine

Service and maintenance	None required	
Calibration	None required	
Quality control	Internal procedural control(s), external quality assessment (EQA) material compatible	Internal procedural control(s), including sample adequacy, external quality assessment (EQA) material compatible; colorimetric or other indicator to identify excessive heat/humidity
Regulatory requirements	Manufactured under ISO 13485:2003 certified. WHO prequalified or authorized for use by a regulatory authority of the founding members of the IMDRF	
Pricing		
Target price for test	< US$ 2 per test	< US $1 per test

*Globally Harmonized System of Classification and Labelling of Chemicals; H350: may cause cancer; H340: may cause genetic defects; H360: may damage fertility of the unborn child.

World Health Organization

TPP 2. Target product profile for IVDs offered at health care facilities without clinical laboratories, levels 0 and 1: **instrument-based point-of-care tests.**

Characteristic	Minimal	Optimal
Scope		
Target user	Health care worker, community health worker, lay provider	
Equipment	Small benchtop instrument	Minimal, small, portable, handheld or small results reader
Operational requirements		
Sample preparation	Minimal, no more than 2-3 steps and no precision measurements required	Integrated; transfer directly to test
Additional 3rd party consumables	All included in kit, except sample collection kit	All included in kit, including sample collection kit
Cold chain requirements	Refrigeration (2-8°C) acceptable	None required
Power requirements	Battery or solar-power operated > 6 hours; if necessary, local 110-240 AC mains, plus uninterruptable power supply to complete current cycle (integrated)	Battery with/without solar-power operated >10 hours
Water requirements	None required	
Test kit stability	18 months at 10-40°C; ≤ 70% humidity	>24 months at 4-40°C; ≤ 75% humidity; conform to ASTM D4169-05 and ISO 11607-1:2019
Test kit stability, once opened	1 hour	> 2 hours
Reagents and consumables	Proprietary reagents and consumables	Reagents and consumables can be used on available, validated, common instruments
Sample stability, pre-testing	1 hour	3 hours
Reagents reconstitution	None required, reagents ready	
Operating conditions	15-35°C; ≤ 70% humidity; altitude up to 1000m; operable in low light settings	10-45°C; ≤ 75% humidity; altitude up to 3000m; operable in low light settings
Ease of use	≤ 3 user steps, 1 step requiring precision using a provided simplified pipette, 1 timed step	≤ 2 user steps, no steps requiring pipetting, 1 or no timed steps
Total time to test result	< 1 hour	< 20 minutes

Throughput	3-5 tests per hour	> 5 tests per hour
Invalid/error rate	< 8%	≤ 5%
Multiplex capability	No	Yes
Test results		
Result interpretation	Visual manual or reader interpretation with minimal interpretation instructions	Direct result with no interpretation necessary
Result validity stability	30 minutes	1 hour
Result storage	> 200 test results	> 1000 test results
Data requirements		
Connectivity	Integrated Wi-Fi 802.11b/g/n; USB 3.0 or 4.0; internally designatable static IP address; support for DHCP-issued IP addresses; support for HTTPs and SFTP protocols; integrated global positioning system (GPS); ability to update connectivity software stack via USB or LAN.	Same as minimal, plus: integrated local area network (LAN) port; multiband global system for mobile communications (GSM) chipset 2G, 3G, 4G, 5G, LTE; integrated Bluetooth 5.0; integrated Wi-Fi 802.11ac; bidirectional communication – ability to update connectivity software stack.
Data export	Export of all instrument and test data over integrated hardware; secure data export end-to-end encryption; data export in CSV and Excel file formats; configurable destination IP and DNS addresses; user-initiated data export; connectivity to external printer.	Same as minimal, plus: scheduled/automatic data export using interoperable standards via the GSM SMS.
Quality, safety, and regulatory requirements		
Training required	1 day with tools, instructions for use, job aids, etc. available as hard copy and online	≤ 1 day with tools, instructions for use, job aids, etc. available as hard copy and online
Biosafety precautions	Inactivation step or self-contained system; no hazards when observing Universal Blood Safety/Body Fluid precautions and all materials are free of components with a GHS classification H (particularly H350, H340, H360)*	

Waste disposal requirements	Waste disposal in biosafety bin following standard guidelines, including sharps containers for disposal of lancets, capillary tubes, etc. Appropriate disposal method for excess specimens and processing consumables (e.g. latrine, incineration). Standard operating procedure provided.	Same as minimal, but consideration for reusable, recyclable, or compostable material or non-plastic alternatives; no cyanide and no chlorine
Service and maintenance	Swap out or replace instrument or reader; remote software updates available and simple enough for end-user implementation	None required; remote software updates available and simple enough for end-user implementation
Calibration	Remote calibration available or none required	None required
Quality control	Internal procedural control(s), external quality assessment (EQA) material compatible	Internal procedural control(s), including sample adequacy, positive, and negative controls, external quality assessment (EQA) material compatible; colorimetric or other indicator to identify excessive heat/humidity
Regulatory requirements	Manufactured under ISO 13485:2003 certified. WHO prequalified or authorized for use by a regulatory authority of the founding members of the IMDRF	
Pricing		
Target price for test	< US$ 10 per test	< US $8 per test

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TPP 3. Target product profile for IVDs offered at health care facilities with clinical laboratories, levels 2, 3, 4.

Characteristic	Minimal	Optimal
Scope		
Target user	Laboratory professional	
Equipment	Proprietary equipment or compatible with equipment existing in laboratories at level 2 and above	Small, table-top, multi-modular, integrated proprietary instrument
Operational requirements		
Sample preparation	≤ 3 steps; ≤ 1 precision step; centrifugation and/or vortexing acceptable	Transfer of sample to processing tube with necessary buffer, then to instrument
Additional 3rd party consumables	Minimal required, besides sample collection kit and standard laboratory materials (eg. pipette tips, etc.)	None required, except sample collection kit
Cold chain requirements	-20°C or 2-8°C acceptable	None required
Power requirements	Local 110-240 AC mains, plus uninterruptable power supply to complete current cycle (integrated); with rechargeable battery	
Water requirements	Laboratory-grade water acceptable	None required. If water is required, provide in sealed, pre-measured containers
Test kit stability	12 months at 4-35°C; ≤ 70% humidity	24 months at 4-40°C; ≤ 75% humidity; conform to ASTM D4169-05 and ISO 11607-1:2019
Reagents and consumables	Proprietary reagents and consumables, besides standard laboratory materials (eg. pipette tips, etc.)	Reagents and consumables can be used on available, validated, common instruments
Test kit stability, once opened	30 days	60 days
Sample stability, pre-testing	≥ 24 hours	1 week
Reagents reconstitution	Ready or maximum 5 steps within 15 minutes	None required, reagents ready
Operating conditions	15-30°C; ≤ 70% humidity; direct sunlight/low light and dusty conditions possible	10-40°C; ≤ 75% humidity; direct sunlight or low light and dusty conditions possible
Ease of use	≤ 10 user steps, of which ≤ 5 are timed steps, 1-3 precision steps possible	Direct primary tube application to instrument

Total time to test result	< 8 hours	< 2 hours
Throughput	> 100 tests per 8-hour shift per instrument	> 500 tests per 8-hour shift per instrument
Invalid/error rate	≤ 3%	≤ 1%
Multiplex capability	No	Yes

Test results		
Result interpretation	Requires some laboratory skills	Minimal interpretation
Result validity stability	Stored and can be referred to when necessary	
Result storage	6 months of expected results	1 year of expected results

Data requirements		
Connectivity	Integrated local area network (LAN) port; integrated Wi-Fi 802.11b/g/n; USB 3.0 or 4.0; internally designatable static IP address; support for DHCP-issued IP addresses; support for HTTPs and SFTP protocols; integrated global positioning system (GPS); ability to update connectivity software stack via USB or LAN.	Same as minimal, plus: multiband global system for mobile communications (GSM) chipset 2G, 3G, 4G, 5G, LTE; integrated Bluetooth 5.0; integrated Wi-Fi 802.11ac; bidirectional communication – ability to update connectivity software stack.
Data export	Export of all instrument and test data over integrated hardware; secure data export end-to-end encryption; data export in CSV and Excel file formats; configurable destination IP and DNS addresses; user-initiated data export; connectivity to external printer.	Same as minimal, plus: scheduled/automatic data export using interoperable standards via the GSM SMS.

Quality, safety, and regulatory requirements		
Training required	< 1 week	≤ 3 days
Biosafety precautions	Inactivation step or self-contained system; no hazards when observing Universal Blood Safety/Body Fluid precautions and all materials are free of components with a GHS classification H (particularly H350, H340, H360)*	

Waste disposal requirements	Waste disposal in biosafety bin following standard guidelines, including sharps containers for disposal of lancets, capillary tubes, etc. Appropriate disposal method for excess specimens, liquid waste, and processing consumables (e.g. latrine, incineration). Standard operating procedure provided.	Same as minimal, but consideration for reusable, recyclable, or compostable material or non-plastic alternatives; no cyanide and no chlorine
Service and maintenance	Routine service and maintenance no more than once per year with self-check alerts as required	Routine service and maintenance no more than once per 2 years by national staff with self-check alerts as required
Calibration	On-site yearly by a trained local technician	Remote or no calibration necessary; no more than once per year
Quality control	Internal procedural control(s), external quality assessment (EQA) material compatible	Internal procedural control(s), including sample adequacy, positive, and negative controls, external quality assessment (EQA) material compatible; colorimetric or other indicator to identify excessive heat/humidity
Regulatory requirements	Manufactured under ISO 13485:2003 certified. WHO prequalified or authorized for use by a regulatory authority of the founding members of the IMDRF	

Pricing		
Target price for test	≤ US$ 15 per test	≤ US$ 10 per test

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