Target product profile (TPP) for readers of rapid diagnostic tests (RDT readers)

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Lateral-flow rapid diagnostic tests (RDTs) continue to play a vital role in global health in the management and diagnosis of infectious diseases including malaria, HIV, and COVID-19. Visually interpreted RDTs, more than any other class of diagnostics, fulfill WHO's ASSURED criteria[1], enabling their use at the lowest levels of healthcare and in self-testing[2]. Their utility, however, is compromised every time a test is not performed correctly or its result is not available in a timely manner for clinical decision making and surveillance.

Companion tools for RDTs such as readers could promote more consistent, accurate test performance and reporting, recognized in a follow-up about the ASSURED criteria[3] and in comparisons of manually and automatically reported positivity[4].

This TPP addresses a broad collection of types of RDT readers without prioritizing among types. A point-of-care reader in the form of a dedicated hardware **instrument** or an **app** operating on a general-purpose mobile device, that is, a tablet or phone, can fill this role, whether for **professional use** by a healthcare worker or other representative of a health program or for **lay use**, also known as self-testing and home testing. The reader can be offered by the RDT's manufacturer, or it can be provided independently for use with one or more RDT brands. Whether the reader shows its interpretation to the user, as an **in vitro diagnostic (IVD)** device does—or if it acts within the narrower bounds of a **medical device data system (MDDS)**[5], recording the user's interpretation as the clinical result and transmitting the reader's interpretation only for non-clinical uses—all readers should automatically transmit results and associated data to a **health program**, such as a disease control program or laboratory service of a ministry of health, enabling patient records, referral, treatment, and contact-tracing as well as quality control, quality assurance, evaluation, and surveillance.

[1] Mabey, D., Peeling, R., Ustianowski, A. *et al.* Diagnostics for the developing world. *Nat Rev Microbiol* 2, 231–240 (2004). https://doi.org/10.1038/nrmicro841

[2] https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1

[3] Land, K.J., Boeras, D.I., Chen, XS. *et al.* REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. *Nat Microbiol* 4**,** 46–54 (2019). https://doi.org/10.1038/s41564-018-0295-3

[4] Adah, P., Maduka, O., Obasi, O. *et al.* The role of the Deki Reader™ in malaria diagnosis, treatment and reporting: findings from an Africare pilot project in Nigeria. *Malar J* **17,** 221 (2018). https://doi.org/10.1186/s12936-018-2356-8

[5] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-data-systems

Where a statement in this TPP applies only to one type of reader, it is preceded by the name of that type, summarized in the table below:

Category	Types
Device architecture	• **Instrument**: dedicated hardware, as readers have traditionally been • **App**: software operating on general-purpose mobile devices
Use case	• **Professional use**: by a healthcare worker • **Lay use**: self-testing and similar use by the general public
Intended use	• **IVD**: In Vitro Diagnostic, showing its interpretation of the RDT to the user • **MDDS**: Medical Device Data System, not showing its interpretation to the user (Both send data to the health program)
Optical technology	• **Colorimetric**: detectable by a line's changed presence, intensity, or color when illuminated by white light; includes tests that can be visually read without an instrument • **Fluorescent**: detectable, typically in otherwise darkness, by a line's emission near one wavelength when excited near another wavelength • **Luminescent**: similar to fluorescent but without excitation

Within the category of device architecture, most readers fall into one type or the other, but a reader may have aspects of each. Examples:
• an app that relies on a physical accessory to hold the RDT in front of the camera
• an instrument that relies on an app on a wirelessly connected phone
Such hybrid readers are therefore subject to certain app-only characteristics as well as other instrument-only characteristics.

While all readers must be able to report results automatically, the complete set of data features specified by this TPP does not have to be implemented in the reader itself if those features are available in a digital health system with which the reader integrates. Features for management and analysis of the data generated by these readers are not in the scope of this TPP.

Each characteristic in the TPP has an optimal criterion that product developers should achieve if feasible and, in case the optimal is not feasible, a minimal criterion. Where the two columns are merged, the optimal and minimal criteria are the same.

Characteristic	Minimal	Optimal	Notes
General			
1. Intended use	MDDS: To collect user interpretations and other data from RDTs.	Same as minimal plus To support proper test performance.	If an MDDS, the reader does not show its interpretation to the clinical user. If an IVD, in most countries each combination of reader and test is subject to medical regulation.
	IVD: To interpret RDTs to aid clinical decisions and to collect other data from RDTs.		
	The reader may be used during screening, diagnosis, or management of disease. The reader will transmit test data, patient data entered by the user, and contextual data to the health program.		
2. Target use setting	All levels of healthcare as well as non-healthcare settings[6]		Examples of non-healthcare settings: homes, schools, workplaces, transportation hubs, high-traffic areas
3. Target operator	Professional use: Healthcare worker including community health worker with at least basic literacy and minimal training, or any healthcare worker with superior training Lay use: Person with at least basic literacy and without formal education in a relevant field of healthcare or medical discipline App: Person with access to a mobile device and basic app skills Operator may have accessibility requirements		Examples of lay users: self-testers, caretakers, workplace screeners, school screeners Accessibility: To design a reader appropriately, see Web Content Accessibility Guidelines[7] and characteristic 28.
4. Target population being tested	People wanting to know their status, being screened for active cases or surveillance, or presenting for healthcare		

[6] Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature 2015;528:S50-52. https://doi.org/10.1038/nature16038
[7] https://www.w3.org/TR/WCAG21/

Characteristic	Minimal	Optimal	Notes
Physical			
5. Number of tests performed at a time	Instrument: Operates with one test at a time	Instrument: Offered in two or more configurations: • Single-bay: operates with one test a time • Multi-bay: operates with multiple tests in parallel, with random access and the ability to test different analytes simultaneously	See characteristics 20 and 21 regarding timing of interpretation. Parallel, random-access testing: In "walk away" mode, while one test develops in the reader, a user can start additional tests for more analytes for the same patient or for other patients. A multi-bay instrument may therefore provide the throughput of multiple single-bay instruments at lower cost, space, or administration, though with less flexibility and more user interface complexity.
	App: Operates with one test at a time	App: Interprets one test at a time, and can track the timing of multiple tests running in parallel	
6. Size (instrument only)	Small, portable table-top device		Appropriate size may vary depending on the features of the instrument. The instrument should be designed to be moved easily and to withstand the drops and impacts associated with portable (not necessarily handheld) devices (see characteristic 28).
7. Additional physical components required for use (app only)	Acceptable if they are highly portable and nearly universal (not specific to a small number of models of mobile devices or RDTs)	None	Acceptable example for minimal: an optical calibration card. Dependence on such is not optimal because of costs, logistics, and (if not single-use) maintenance.

Characteristic	Minimal	Optimal	Notes
Operational			
8. Power requirement (instrument only)	Local 100–240 V AC, 50 or 60 Hz mains power	Same as minimal plus User-replaceable rechargeable battery sufficient for an 8-hour shift, or user-replaceable single-use batteries	The reader's documentation should explain the electrical interfaces, including power consumption, cord length, mains plug style, and single-use battery model, so that implementers can plan accordingly.
9. Lighting of the operating environment	Any setting in which the user can see well enough to run the test. Infrequently, the reader may tell the user that it cannot operate in the current lighting. The reader should then tell the user what to change about the lighting to enable operation.	Any setting in which the user can see well enough to run the test.	Example settings: • dim indoors without artificial lighting • window-less indoors with fluorescent lighting • mixed lighting • outdoors in direct sun • outdoors in dappled, moving shadows from a tree • outdoors in shade with indirect sunlight bounced off a red or blue wall
10. General operating environment (instrument only)	10–40°C and up to 90% non-condensing humidity at an altitude up to 2,500 meters; able to withstand dusty conditions and water splashes	5–45°C and up to 98% non-condensing humidity at an altitude up to 4,000 meters; able to withstand dusty conditions and water splashes	

Characteristic	Minimal	Optimal	Notes
11. Training for operation	Professional use: ≤ 2 hours with options for remote or self-training.	Professional use: ≤ 1 hour with options for remote and self-training. Support provided for training of trainers.	Assuming users already have experience with RDTs. Given the roles of professional users and the features of professional readers, these products typically do require training.
	Lay use: No training necessary. The user must be able to use the reader correctly when presented with it, including its instructions for use and any other labelling.	Lay use: Same plus the reader enables frequent users to perform tests in an abbreviated workflow appropriate for them (new users are expected to require more support)	Assuming users lack experience with RDTs and assuming the RDT is designed for lay use. Like self-test RDTs, a self-test reader must be designed and demonstrated to be usable without training. For both professional and lay use, see also characteristics 21 and 22.
12. Biosafety (instrument only)	Easy decontamination of surfaces with 70% isopropyl alcohol or a bleach solution with 0.5% chlorine		
13. Service and maintenance	Instrument: Weekly maintenance (including any software updates) by an operator of < 10 minutes; mean time to failure of ≥ 24 months; self-check alerting operator to instrument errors or warnings; operator-involved calibration check at set time intervals	Instrument: No maintenance required; software updated automatically or manually depending on administrator preference; mean time to failure of ≥ 36 months or 30,000 tests; self-check alerting operator to instrument errors or warnings; no operator-involved calibration check needed	
	App: Software updated automatically or manually depending on administrator preference, as needed to ensure compatibility with latest OS		

Characteristic	Minimal	Optimal	Notes
Compatible mobile devices and RDTs			
14. Compatible mobile devices (app only)	The app maker shall publish and maintain a list of Android mobile devices and OS versions, including low-priced devices and older versions, that have been determined compatible with the app. Devices using the app shall remain functional for other apps and uses.	Same as minimal plus Most Android (lay use: and iOS and iPadOS) mobile devices with a rear-facing camera that are readily available in LMICs. The app maker may provide an optical performance check allowing users to enable operation on any device passing the check.	Presently, the capability of a mobile device's camera for RDT analysis, particularly as an IVD, is difficult if not impossible to determine from its advertised specifications. The minimal may be adequate for health programs that provide mobile devices to their health care workers. The optimal is intended to support less-controlled scenarios, including "bring your own device" (BYOD). The optimal app shall not require a "dedicated device" or "lock task mode" as defined in Android.

Characteristic	Minimal	Optimal	Notes
15. Reader-oriented features of compatible RDTs	The reader's manufacturer shall publish and maintain a list of compatible RDT models. The reader shall be compatible with user markings on the RDT.	Same as minimal plus The reader shall be compatible with RDTs that were not necessarily designed for this reader. The reader shall be compatible with multiple brands and types of RDTs. The reader shall be compatible with RDTs having a plastic cassette or not ("dipsticks"). The reader shall utilize 1D and 2D barcodes, if present on the RDT, to identify the model, lot, expiration, or serial number.	User markings: It is common for users to write the name of the patient or another identifier on the RDT. No IVD reader is expected to be "universal" in the sense of reading all RDT models, since the reader's performance must be validated with each RDT model. Barcoded serial numbers can enable tracing of each test, verification of authenticity, and prevention of reuse, but they may remain rare in LMICs, partly because of the costs.
16. Compatible RDT types by result type	• Qualitative	• Qualitative • Semi-quantitative threshold, by comparison of intensity of a test line to a reference • Semi-quantitative levels, such as low, medium, or high • Quantitative	Semi-quantitative and quantitative tests may require design integration between reader and RDT beyond the scope of this document
17. Compatible RDT types by optical technology	Instrument: Colorimetric (visible) lateral flow assays	Instrument: Colorimetric (visible), fluorescent, and luminescent lateral flow assays	Fluorescent and luminescent tests may require design integration between reader and RDT beyond the scope of this document
	App: Same as instrument minimal		
18. Compatible RDT types by number of lines, including test and control	2 or 3	2, 3, 4, or more	Example of a 3-line test: a malaria test with a control line and lines for Pf and Pv.

Characteristic	Minimal	Optimal	Notes
Functional			
19. Language support	For each country where the reader is deployed, one popular language, such as the official language or de facto national language	Same as minimal plus additional languages that enable use by additional residents of that country	
20. Operating modes (instrument only)	The reader provides “read now” mode, in which the user presents the test to the reader and the reader promptly interprets the test	The reader provides “read now” mode (see minimal) and “walk away” mode, in which the user presents the test to the reader at the start of the development period and the reader controls when the test is interpreted	In “walk away” mode, the reader may be able to release a positive result before the development period has elapsed, if the RDT manufacturer provides for this.

Characteristic	Minimal	Optimal	Notes
21. Help provided by the reader on timing of RDT interpretation	None	In “read now” mode, the reader shall provide a countdown timer to prompt the user when the RDT is ready to be read and before expiration of the reading period. The reader shall set the times according to each RDT’s Quick Reference Instructions (QRI) or job aid. Whether the user can override the elapsed time limits shall be configurable by the health program. App: During the countdown, the user shall be able to use the mobile device for other tasks and still receive a prompt from this app when the RDT is ready to be read.	Regarding elapsed time data, see characteristics 23 and 29.

Characteristic	Minimal	Optimal	Notes
22. Help provided by the reader on other aspects of RDT instructions	None	The reader shall provide the user with access to RDT instructions equivalent to the QRI or job aid. The reader may provide enhanced instructions, such as videos, audio, and photographic examples of results.	Minimal: Users should follow regular instructions for use of the RDT, as they should without this reader. Optimal: If the reader provides enhanced instructions, their role in the test's regulatory authorization needs to be considered, and their usability for new users as well as frequent users needs consideration (see characteristic 11). Regardless of this characteristic, the reader will include instructions for use of the reader, such as how to place the RDT.
23. Quality control for each test	• Check of the RDT's control line • Instrument: Check of the optical system • App: Check of sufficient quality of the photo • Analysis of background to check sufficient clearance of the sample	Same as minimal plus • Check of elapsed time to reading of result • Check of sample applied to wrong well • Check of expiration by date • Professional use: Check of expected results when running quality control (QC) samples	Failures of these checks will result in warnings to the user and in the record
24. Help provided by the reader after determination of the result (lay use only)	The reader displays basic result terms like "positive", "negative", and "invalid"	The reader displays extended result messages from each test's QRI. Each health program can provide messages for each result type of each test, with referral and other resources	Extended result messages often explain the meaning and potential limitations of the result.

Characteristic	Minimal	Optimal	Notes
Performance			
25. Qualitative colorimetric RDTs: agreement of reader with expert visual interpretation	≥ 95%	≥ 98%	Expert visual interpretation typically employs a panel of skilled operators who directly view the RDT (not a photo of the RDT)
26. Qualitative colorimetric RDTs: sensitivity, specificity, and limit of detection	Close to that of expert visual interpretation	Equivalent to or better than that of expert visual interpretation	Minimal and optimal values will depend on the analyte. With colorimetric RDTs designed and manufactured for visual interpretation, a reader is unlikely to improve on expert visual interpretation
27. Other RDTs: performance	Equivalent to state-of-the-art readers		
Compliance			
28. Compliance with medical standards for design and manufacturing (IVD reader only)	• ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes • IEC 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment • Applicable standards associated with the above		

Characteristic	Minimal	Optimal	Notes
Data features within the reader			
29. Diagnostic data collected	• Brand and type of test as entered by the user • Underlying values and outcome of quality controls (e.g. elapsed time value and whether the time was in the expected range or not) • MDDS: Result as entered by the user • Result as calculated by the reader • Intermediate data used to calculate the result (e.g. intensities of test line and control line)	Replace first item in minimal with • Brand and type of test by photographing the test or its packaging Same as rest of minimal plus • Lot number and expiration date of the test (possibly by photographing the test and its packaging) • RDT instruction version • RDT photograph(s) used to calculate the result • Specimen type (e.g. whole blood, serum) • Other relevant diagnostic data entered by the user	Each health program should be able to choose whether to require their users to enter lot and expiration data. In recognition of limited connectivity and storage available in many settings, the reader should provide appropriate options for image resolution and crop. Multiple images may be appropriate: one cropped to the region of the control and test lines for evidence of the result, and another of the entire RDT for supervision of the type of test. Health programs may prefer to transmit images only for certain cases, such as faint lines and invalids, or during certain research programs. As noted in characteristic 15, images of the entire RDT may include patient-identifiable information.
30. Patient/case data collected	As determined by the health program and in compliance with local authorities (e.g. patient identification, location, consent, symptoms).		Data needs should be balanced with the data-entry burden on users. As noted in the preface, data features can be provided by integrating the reader with a digital health system that has those capabilities.

Characteristic	Minimal	Optimal	Notes
31. Contextual data collected	• User identification (lay use: if required by the health program) • Location of test as text entered manually, such as an address or facility name (if enabled by the health program) • Time and date of test • Manufacturer and model name of reader • Serial number of reader (instrument only) • Reader software/firmware version • Model of mobile device (app only) • OS version (app only)	Same as minimal plus • Location of test as an automatic geolocation (e.g. via GPS) (if enabled by the health program) • Reader operational data for administration, maintenance, and performance metrics (e.g. self-checks, calibration, quality control samples) • Other as determined by the health program	Almost all these data can and should be collected automatically rather than needing manual entry
32. Methods for data entry	• Typing	• Typing • Scanning 1D and 2D barcodes	The user can choose from these methods when entering the data types listed above. When possible, the reader should instead collect data automatically or enable the user to select from lists to avoid data-entry errors.

Characteristic	Minimal	Optimal	Notes
33. Memory and storage	Professional use: ≥ 200 patient results ≥ 20 QC results	Professional use: ≥ 1000 patient results ≥ 100 QC results	Reader memory is intended as a log of recent results and a buffer of results not yet sent to a server using the data connectivity features described later. At least certain images should be kept with these recent results. See characteristic 29 for considerations of image types. App: This assumes the mobile device has enough space.
	Lay use: ≥ 50 patient results		
34. User access rights (professional use only)	Provides access to specific data and reader features for users with different roles		Roles may include multiple levels of data manager (e.g. supervisor, site administrator, national manager) and RDT user (health care worker)
Data connectivity			
35. Data connectivity methods	Instrument: mobile network, Wi-Fi, USB, or Bluetooth	Instrument: mobile network and at least one of Wi-Fi, USB, Bluetooth, or Ethernet	Throughout this section, as noted in the preface, data features can be provided by integrating the reader with a digital health system that has those capabilities.
	App: mobile network or Wi-Fi as provided by the mobile device		
36. Handling of intermittent or low-bandwidth connections	The user shall be able to perform tests (IVD: and receive results) offline, in which case the reader shall transmit that data when back online	Same as minimal plus The reader shall transmit automatically (without user action) in the background when back online, prioritizing basic data elements before sending larger, secondary elements like images.	

Characteristic	Minimal	Optimal	Notes
37. Data exchange standards	The reader supports FHIR or JSON	The reader supports FHIR and JSON	For connections to systems such as LISs, DHIS2, EHRs, national registries, and surveillance systems
38. Data destination	The health program shall be able to choose the destination(s) of the reader's data		The reader's manufacturer would need permission from the health program to receive any data
39. Data ownership	The health program shall be able to set the ownership of the reader's data in compliance with local authorities and regulations		
40. Security and privacy	To facilitate use by health programs in accordance with the laws, regulations, and policies of their settings and best practices, the reader shall provide configurable features so that personal data can be (a) gathered transparently to users and patients, including consent (b) collected and processed only for purposes compatible with the health program's purposes (c) limited to what is relevant and necessary (d) collected accurately (e) stored in identifiable form no longer than necessary (f) secured for integrity and confidentiality, with encryption at rest and in transmission		(a)–(f) have been adapted from the EU General Data Protection Regulation 2016/679 (GDPR), article 5, sec. 1. Note that not all of the GDPR is relevant or appropriate to this reader in these settings.
Pricing and accessibility			
41. Pricing within the public sector in LMICs	The pricing structure should be adapted to LMICs, should be public, and should state all fees, including any for warranties, support, and software updates		