FIND
Diagnosis for all

TARGET PRODUCT PROFILES FOR LASSA DIAGNOSTICS

MAY 2025

TABLE OF CONTENTS

INTRODUCTION

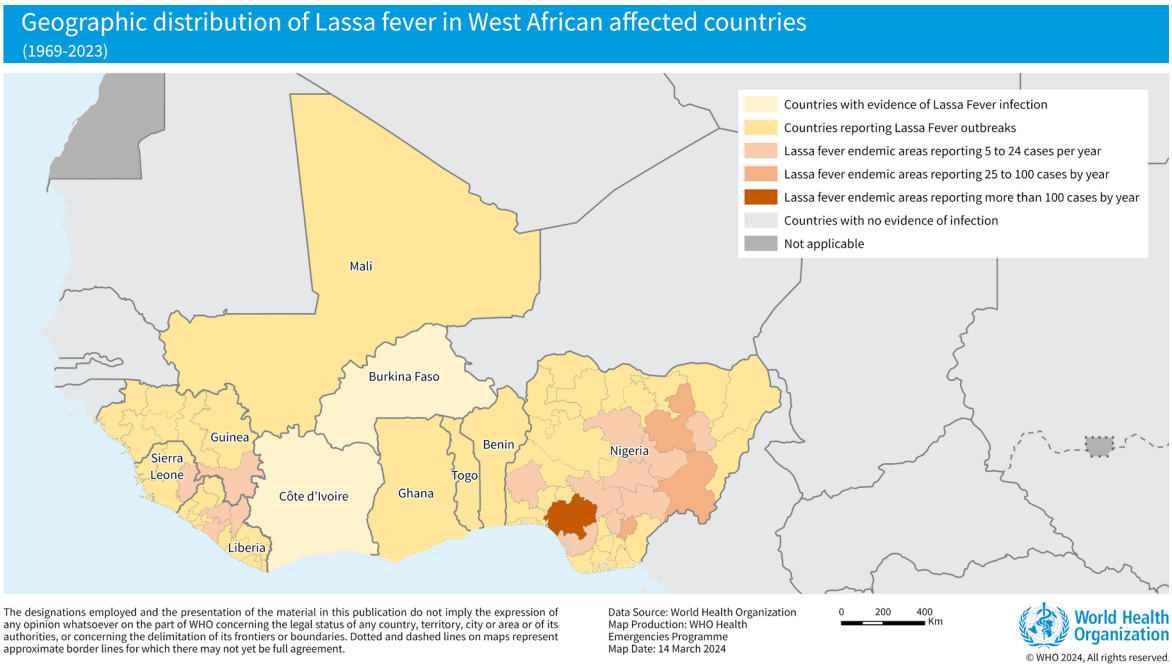
Lassa fever (Lf), a potentially life-threatening, acute viral hemorrhagic disease caused by the Lassa virus (LASV), is a significant public health concern, especially in West Africa [1]. The disease is endemic in several countries, including Benin, Ghana, Guinea, Liberia, Nigeria, Mali, Togo, and Sierra Leone, with possible existence in other West African Countries (Figure 1) [1], causing both sporadic and sometimes large-scale, prolonged outbreaks across the region [1, 2, 3, 4]. The disease burden is substantial, with an estimated 100,000 to 300,000 infections annually, resulting in approximately 5,000 deaths each year and recording case fatality rates up to 15% in individuals with severe disease [1].

The disease is primarily transmitted to humans through contact with food or household items contaminated by the urine or faeces of infected Mastomys rodents (Mastomys natalensis) [1,2]. Human-to-human transmission can also occur through direct contact with the bodily fluids of infected individuals, posing a substantial risk to healthcare workers, especially in settings with limited infection prevention and control practices in place [1, 2].

Despite its high burden, Lf remains a neglected disease, with underreporting and misdiagnosis exacerbating its impact [7, 8]. The limited availability of reliable and affordable diagnostic tools hampers surveillance, early detection, and disease containment efforts [9, 10].

Recognizing the growing threat of LASV and other arenaviruses, it has been consistently identified as a ‘priority disease’ under the World Health Organization (WHO) R&D Blueprint Initiative, which aims to fast-track research and development of medical countermeasures [5, 6].

FIGURE 1 Geographic distribution of Lassa fever in West African affected countries, 1969-2023 [1].



The priority actions have been identified to urgently enhance preparedness and response mechanisms to combat the disease effectively [5] and include:

1. **Strengthening Surveillance and Data Sharing:** Establishing robust surveillance systems to detect and monitor Lf cases in endemic and non-endemic regions. Improved data sharing and coordination among countries and global health organizations are essential for tracking disease trends and responding swiftly to outbreaks.

2. **Advancing Diagnostic Capabilities:** The development and deployment of rapid, affordable, and accurate point-of-care and confirmatory diagnostic tests are critical to improving case detection and timely treatment initiation. The Target Product Profile (TPP) outlined in this document serves as a guideline for developers to create diagnostics that meet the needs of healthcare settings at various levels.

3. **Enhancing Therapeutic and Vaccine Development:** While the efficacy of ribavirin is being studied in the treatment of Lf, there is a pressing need for novel antiviral treatments and supportive care strategies. In parallel, efforts to develop and evaluate Lf vaccines are ongoing, with several candidates in preclinical and clinical development.

4. **Capacity Building and Health System Strengthening:** Investing in laboratory infrastructure, training healthcare professionals, and improving infection prevention and control measures are key to reducing transmission and improving patient outcomes. Strengthening healthcare systems in endemic regions will enhance resilience against Lf and other emerging infectious diseases.

5. **Community Engagement and Risk Communication:** Raising awareness among at-risk populations about Lf transmission, prevention, and the importance of early medical intervention is vital. Engaging local communities in outbreak preparedness and response initiatives fosters trust and enhances compliance with public health measures.

Aligning research and development efforts with the priority actions within the R&D Blueprint framework towards enhancing diagnostic capacity would significantly contribute to the global strategy to mitigate Lf outbreaks and reduce morbidity and mortality.

Consequently, the development and implementation of standardized and effective diagnostic tools, as outlined in this Target Product Profile, will be instrumental in achieving these objectives and mitigating the impact of Lf in endemic regions and beyond.

LABORATORY DIAGNOSIS OF LASSA FEVER

Timely and accurate diagnosis for Lf is critical for patient management, outbreak response, and public health interventions. However, the diagnostic landscape of this disease remains primarily stagnant, with existing technologies facing considerable limitations in sensitivity, accessibility, and implementation within resource-limited settings [11, 12].

Molecular diagnostics, particularly real-time reverse transcription polymerase chain reaction (qRT-PCR), represent the gold standard for Lf confirmation due to their sensitivity and specificity [13]. This technique enables early detection by identifying Lassa virus RNA in blood and bodily fluid samples before seroconversion, making it indispensable for case confirmation, epidemiological surveillance, and outbreak response. Several RT-PCR assays are commercially available [14].

Serological diagnostics for Lf primarily detect host immune responses through IgM and IgG antibodies using enzyme-linked immunosorbent assay (ELISA). IgM ELISA facilitates the identification of recent or acute infections, as these antibodies emerge within days of infection and persist for weeks, while IgG ELISA serves as a marker of past exposure or convalescent-phase infections, supporting seroprevalence studies and epidemiological surveillance [10]. While IgM tests can detect active infection, not all patients have detectable IgM during the acute stage, and both IgM and IgG antibody responses may be suppressed in severe cases, further complicating diagnosis [15, 16]. In endemic settings, IgG is primarily utilized for surveillance rather than acute case detection, limiting its applicability for timely clinical management [17]. To address these limitations, antigen rapid diagnostic tests (Ag-RDTs) are emerging as promising alternatives, offering the potential for rapid, point-of-care detection of Lassa virus antigens during the acute phase of infection. While still undergoing validation, Ag-RDTs could substantially enhance early diagnosis, improve outbreak response efforts, and expand access to timely detection in decentralized healthcare settings [18, 19].

Several critical gaps continue to impede the timely and effective detection of Lf, ultimately hindering disease control efforts. One of the most pressing issues is the limited access to rapid and decentralized diagnostics. Currently, RT-PCR and ELISA-based testing are predominantly confined to national or regional reference laboratories, creating a significant diagnostic gap at lower-tier health facilities. The absence of robust point-of-care (POC) diagnostics capable of rapidly confirming Lf cases at peripheral healthcare centers exacerbates the challenge, leaving many suspected cases undiagnosed or misdiagnosed. This lack of decentralized testing capacity significantly hampers early detection and intervention, particularly in resource-constrained and rural settings [20].

Additionally, delayed diagnosis and clinical management challenges pose substantial risks to patient outcomes and infection control. The turnaround time for laboratory-confirmed diagnosis is often prolonged due to logistical barriers, including transporting samples from peripheral clinics to centralized laboratories. These delays result in suboptimal patient management, as timely therapeutic intervention is crucial in reducing Lf-associated morbidity and mortality. Furthermore, prolonged diagnostic timelines increase nosocomial transmission risks, particularly in healthcare facilities where suspected cases remain undiagnosed for extended periods [21].

Another major gap lies in the need for differential diagnostic tools. Lassa fever presents with non-specific febrile symptoms that closely resemble those of other endemic diseases such as malaria, typhoid fever, and other infectious diseases. This overlap frequently leads to misdiagnosis and inappropriate case management. The limited availability and restricted use of multiplex diagnostic platforms capable of simultaneously detecting Lassa virus alongside other regionally prevalent pathogens further complicate effective disease differentiation. Without such integrated diagnostic solutions, clinicians face significant challenges in accurately identifying and managing Lf cases [11, 22].

Furthermore, biosafety and laboratory infrastructure constraints present formidable barriers to effective disease detection. Molecular testing, particularly RT-PCR, necessitates biosafety-level containment, which remains inadequate or entirely absent in many endemic regions. Serological testing presents similar challenges. The shortage of well-trained personnel further exacerbates diagnostic bottlenecks, particularly in remote healthcare settings where laboratory expertise is often limited. These deficiencies impede accurate case detection and pose substantial occupational health risks to laboratory workers handling potentially infectious samples [23].

Finally, there is a critical need for cost-effective and sustainable diagnostic solutions. The high cost of existing diagnostic platforms limits their widespread implementation, particularly in low-resource settings where financial constraints are a persistent challenge. The urgent need for affordable, field-deployable diagnostic assays that maintain high accuracy and reliability in real-world conditions cannot be overstated. Addressing this gap would facilitate broader diagnostic coverage, enhance early case detection, and ultimately strengthen Lf surveillance and outbreak response efforts [12].

Bridging these diagnostic gaps requires a concerted effort to decentralize testing, develop rapid and accessible diagnostic tools, strengthen laboratory infrastructure, and invest in cost-effective solutions tailored for resource-limited settings.

PURPOSE OF THE TPP

The purpose of this TPP is to support the development of new diagnostic tools for the following use cases:

- **Point of care test for presumptive diagnosis of Lf (TPP1)**
- **Confirmatory test for Lf (TPP2)**

For each characteristic of the TPP, product developers are to achieve an optimal criterion if feasible and a minimal criterion if the optimal is not feasible. When two columns are merged, the optimal and minimal criteria are the same.

The development of this TPP is described in **Annex 1**.

TPP1: POINT OF CARE TEST FOR PRESUMPTIVE DIAGNOSIS OF LASSA FEVER

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
SCOPE			
Goal	To provide the characteristics for a diagnostic test to detect Lassa virus (LASV) at a hospital/clinic level, to initiate isolation, and to provide early optimized care.	To provide the characteristics for a diagnostic test to detect Lassa virus (LASV) in peripheral settings for immediate isolation, to initiate early patient care while awaiting patient referral for optimized care.	
Target population	Adults and children presumed to have active LASV infection, including symptomatic patients in an endemic area	Same as minimal and includes • symptomatic patients • close contacts of patients	This would be in endemic and non-endemic settings.
Target user of test	Healthcare workers with basic technical skills (non-precision pipetting, minimal sample processing)	Community health workers with minimal training	
Setting (level of the Healthcare system)	Primary health clinics: Level 1 (L1) - Primary Care Level 2 (L2) - District Hospital	Primary health clinics without labs: Level 0 (L0) - Community Level 1 (L1) - Primary Care Level 2 (L2) - District Hospital	
PRICING			
Cost per test	≤ $7 (Lateral flow assays)	≤ $3 (Lateral flow assays)	Contingent on test volume for procurement
	≤ $15 (Molecular diagnostics)	≤ $10 (Molecular diagnostics)	
Capital cost for the POC instrument	< US$ 500	None required or compatible with existing platforms	Cost of a new instrument. Ideally, new tests should be integrated into the current, existing infrastructures (e.g., available instruments in the laboratory).
PERFORMANCE			
Test result	LASV detected/not detected	Quantitative output (Ct or viral load)	
Limit of detection (analytical sensitivity)	Equivalence to <100,000 copies/mL	Equivalence to < 10,000 copies/mL	
Linear range	None		
Inclusivity	Pan-Lassa lineages I-VII		Based on known lineages at the time of writing.

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
PERFORMANCE			
Cross-reactivity (analytical specificity)	No cross-reactivity with other VHFs	No cross-reactivity with other VHFs and other non-pathogenic arenaviruses	
Diagnostic sensitivity	≥ 80%	≥ 90%	
Diagnostic specificity	≥ 85%	≥ 95%	
Non-actionable (Indeterminate + Invalid) results	≤ 5%	≤ 3%	
Multi-disease platform	No	Yes, panel should include diseases with similar symptoms, i.e. yellow fever, malaria, dengue, typhoid, and other VHFs	
OPERATIONAL CHARACTERISTICS (1)			
Sample type	Plasma, serum, venous blood	Same as minimal and includes capillary blood, urine, oral fluid	
Sample input	≤ 500 uL of specimen	≤ 50 uL of specimen	
Manual preparation of samples (steps needed after obtaining sample)	May require blood draw, serum or plasma separation; separate process for sample inactivation	Sample-in, results-out with 1-3 simple transfer steps; integrated sample inactivation	
Time to result	< 60 minutes	< 15 mins	Time does not include sample preparation.
Daily throughput	≥8 tests		
Sample capacity and throughput	Multiple samples should be able to be tested at the same time with multiple devices or random-access modules		
Walk-away operation	No more than 2 steps of operator intervention should be needed once the sample has been placed into or on the test/system	No operator intervention needed once the sample has been placed into or on the test/system	
Biosafety	Separate process for sample inactivation	Integrated process for sample inactivation	
Waste disposal – solid	Equivalent to current LASV tests at the peripheral level	Less than current LASV tests; reusable, recyclable, or non-plastic alternatives to disposable materials	
Waste disposal – infectious	Similar requirements for current LASV testing	Less than requirements for current LASV testing	
Third-party consumables	Separate kit(s) for sample acquisition, inactivation	None, all-inclusive kit	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (1)			
Third-party instrumentation	Instrument for sample inactivation, centrifuge for plasma	None required	
Instrument	Fully automated instrument appropriate for POC; Benchtop/ portable instrument, approx. 20cm x 20cm x 20cm; <3 kg	No instrument required	
Power requirements	Standard operating currents with built-in UPS for utilization in locations with variable power, preferably using battery-powered platforms, and/or other forms of renewable energy like solar power	No power required	
Maintenance and calibration	Preventative maintenance @1 year or >1000 samples; include maintenance alert.	No maintenance required; swap out or replace ancillary devices when needed	
	Routine calibration by a trained operator using external pos/neg controls	No user calibration required	
Regulatory requirements	ISO 13485:2016 compliant	ISO 13485:2016 certified; assay registered for in vitro diagnostic use	
Operating environment, temperature and humidity level	Test components stable up to 40°C, up to 70% humidity for up to 2 hours prior to use	Test components stable up to 40°C, up to 90% humidity for 2 hours prior to use	
Reagent kit – transport	Transport 2-8°C; do not freeze	No cold chain required; transport stress tolerance for at least 72 hours up to 50°C	
Reagent kit – storage and stability	Storage 2-8°C for up to 12 months	No cold chain required; device stability up 40°C, up to 70% humidity for up to 12 months	
Training and education	< 1 day for staff with the ability to perform low complexity assays		
Environmental impact	Minimize adverse impact on the environment	Tests and any associated instruments should minimize adverse environmental impact. This includes the potential to produce tests locally, minimize waste and maximize reusability and recycling of by-products, multi-use platforms, recycling of instruments at the end of their life, and low power consumption and radiation emissions.	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (2)			
Built-in analytics (for instrument-based tests)	Built-in analytics for instruments and test data; a PC should not be required.		
Result documentation, data display	Visual readout	Digital readout with ability to save and export results	
Sample ID and tracking	None (e.g. disposable LFA)	Software-enabled unique identifiers for assay and sample; accessory barcode scanner	
Connectivity	All test and device data can be securely transmitted via a standard cable connection interface (USB, ethernet) or wireless connection, including at least one of the following: Bluetooth, Wi-Fi, or mobile broadband modem (embedded or external). Data from the instruments should be compatible with different information systems at health facility levels using industry-standard formats/protocols.	For instrument-based tests, offline data storage should be available for data up to 3 months and should be interoperable over W/LAN and with information management systems. Non-device-based tests may have ancillary readers and other data capture apps	A lateral flow cartridge with a visual readout can be considered to meet the minimal characteristic.
Interoperability standards and format	Data, including device usage data, error rates, number of invalid tests, etc. can be exported in standard formats, including but not limited to: • XML • CSV • 3rd party instrument e.g. USB	Same as minimal plus transmitted data (including results) from devices should be encoded using health information exchange (HIE) standards including, Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR).	
Software/OS maintenance	As applicable, POC instrument should allow for routine software/operating system maintenance (automatically or manually)		
Data storage	The administrative institution (MoH or LASV programs) of sites where tests are deployed shall be able to specify or agree with the storage location of the device data without affecting the support and optimal use of the device.		
Data ownership	Test data, its management, and ownership must be in compliance with local regulations.		
Security and privacy	To facilitate use by health programmes in accordance with the laws, regulations, and policies in their settings and with best practices, the device shall provide configurable features so that personal data can be: • gathered transparently to users and people who are taking the tests, including consent, • collected and processed only for purposes compatible with the health programme's purposes, • limited to what is relevant and necessary, • collected accurately, • stored in an identifiable form no longer than necessary and • secured for integrity and confidentiality, with encryption at rest and in transmission.		
Language support	For each country in which the test is deployed, one popular language, such as the official language or de facto national language, and any language mandated by local regulatory or trade compliance requirements	Same as minimal plus additional languages that enable use by additional residents of the location of deployment	

TPP2: CONFIRMATORY TEST FOR LASSA FEVER

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
SCOPE			
Goal	To provide the characteristics for a diagnostic test for confirmation of Lassa virus (LASV) infection at a reference laboratory.	To provide the characteristics for a diagnostic test to confirm Lassa virus (LASV) infection at a hospital laboratory.	
Target population	Adults and children suspected to have active LASV infection: • Pre-screened population • Symptomatic patients	Same as minimal and includes: • asymptomatic patients • close contact with rodents	
Target user of test	Laboratorians with advanced technical skills	Laboratorians with basic technical skills (non-precision pipetting, minimal sample processing)	
Setting (level of the Healthcare system)	Level 4 (L4) – Reference/National Lab	Level 2 (L2) - District Hospital Lab Level 3 (L3) – Regional/Provincial Lab Level 4 (L4) – Reference/National Lab	
PRICING			
Cost per test	≤ $20	≤ $10	
Capital cost for the instrument	< US$ 20,000 (automated platform)	< US$ 10,000 (automated platform)	
	< US$ 5,000 (open source)	None (open source – existing platform)	
PERFORMANCE			
Test result	LASV detected/not detected with Ct	LASV quantitative copies/mL and Ct	
Limit of detection (analytical sensitivity)	< 1000 copies/mL	< 100 copies/mL	
Linear range	103 to 106 copies/mL	10^2 to 10^9 copies/mL	
Inclusivity	Pan-LASV lineages I-VII	Same as minimal	
Cross-reactivity (analytical specificity)	No cross-reactivity with other pathogens in circulation (filovirus, YF, CCHF, RVFV, LCMV, Dengue, Typhoid fever, leptospirosis)	Same as minimal including malaria	
Diagnostic sensitivity	≥ 95%	≥ 98%	Compared to the Altona LASV RT-PCR 2.0
Diagnostic specificity	≥ 95%	≥ 98%	Compared to the Altona LASV RT-PCR 2.0

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
PERFORMANCE			
Non-actionable (indeterminate + invalid) results	< 5%	< 3%	
Multi-disease platform	No	Yes. Panel should include diseases with similar symptoms, including yellow fever, malaria, dengue, typhoid, and other VHFs.	
OPERATIONAL CHARACTERISTICS (1)			
Sample type	Plasma, serum, venous blood	Same as minimal and capillary blood, urine, semen, oral fluid and CSF	
Sample input	≤ 1 mL of specimen	≤ 100 uL of specimen	
Manual preparation of samples (steps needed after obtaining sample)	May require separate process for sample extraction	Sample-in, results-out with 1-3 simple transfer steps	
Time to result	< 6 hours	< 2 hours	Including sample preparation
Daily throughput	≥8 tests		
Sample capacity and throughput	Multiple samples should be able to be tested at the same time; random access should be possible		
Walk-away operation	Manual processing for open-source platforms	No more than 2 steps of operator intervention should be needed once the sample has been placed into or on the test/system	
Biosafety	Manual process for sample inactivation (BSL-2 precautions)	Integrated process for sample inactivation	
Waste disposal – solid	Equivalent to current LASV tests at the reference lab level	Less than current LASV tests; reusable, recyclable, or non-plastic alternatives to disposable materials	
Waste disposal – infectious	Similar requirements for current LASV testing	Less than requirements for current LASV testing	
Third-party consumables	Standard laboratory consumables required (calibrated pipets, tubes, etc.)	Calibrated pipets, tips only	
Third-party instrumentation	Standard lab equipment required (centrifuge, thermocycler, etc.)	None required	
Instrument	Manual or semi-automated system	Fully automated system	
Size/weight	Benchtop instrument, approx. 60cm x 60cm x 60cm; < 60 kg	Portable instrument, approx. 30cm x 30cm x 30cm; < 20 kg	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (1)			
Power requirements	Standard mains operating currents with built-in UPS for utilization in locations with variable power	Battery powered platforms, and/or other forms of renewable energy like solar power	
Maintenance and calibration	Preventative maintenance @1 year or >1000 samples; include maintenance alert.	No maintenance required; swap out or replace ancillary devices when needed	
	Daily external positive/negative calibration for quantitative result	Weekly external linearity calibration for quantitative result	
Regulatory requirements	Manufacturing of the assay and system should comply with ISO13485 as well as ISO 14971 or higher standards or regulations, and comply with ISO IEC 62304 (Medical device software — Software life cycle processes); the manufacturing facility should be assessed at a high-risk classification and certified for use by one of the regulatory authorities of the founding members of the International Medical Device Regulators Forum (formerly known as Global Harmonization Task Force); the assay must be registered for in vitro diagnostic use		
Operating environment, temperature and humidity level	Test components stable up to 30°C, up to 70% humidity for up to 2 hours prior to use	Test components stable up to 40°C, up to 90% humidity for 2 hours prior to use	
Reagent kit – transport	2-8°C (or dry ice) for transport	No cold chain required; stress tolerance for at least 72 hours up to 50°C	
Reagent kit – storage and stability	Sealed kit stability 2-8°C for up to 12 months; -20°C for up to 12 months	No cold chain required; sealed kit stability up to 40°C, 70% humidity for up to 12 months	
Training and education	< 1 day for skilled laboratory technician	< 2 days for basic laboratory technician	
Environmental impact	Minimize adverse impact on the environment	Tests and any associated instruments should minimize adverse impact on the environment. This includes the potential to produce tests locally, minimizing waste and maximizing reusability and recycling of by-products, multi-use platforms, recycling of instruments at the end of their life, and low power consumption and radiation emissions	
OPERATIONAL CHARACTERISTICS (2)			
Built-in analytics (for instrument-based tests)	Built-in analytics for instrument and test data; a PC required.	Built-in analytics for instrument and test data; a PC should not be required.	
Result documentation, data display	Digital readout with ability to save and export results	Digital readout with ability to save and export results Access to assay details e.g. QR code on a test device or tests to digitally record and report data.	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (2)			
Sample ID and tracking	Software-enabled unique identifiers for assay and sample; accessory barcode scanner	Software includes unique identifiers for assay/cartridge and patient/sample with accessory or integrated barcode reader including barcode, RFID, or other	
Connectivity	All test and device data can be securely transmitted via a standard cable connection interface (USB, ethernet) or wireless connection, including at least one of the following: Bluetooth, Wi-fi, mobile broadband modem (embedded or external), Data from the instruments should be compatible with different information systems at health facility levels using industry standard formats/protocols.	For instrument-based tests, off-line data storage should be available for data up to 3 months and should be interoperable over W/LAN and with information management systems.	
Interoperability standards and format	Data, including device usage data, error rates, number of invalid tests, etc. can be exported in standard formats, including but not limited to: • XML • CSV • 3rd party instrument e.g. USB	Same as minimal plus transmitted data (including results) from devices should be encoded using health information exchange (HIE) standards including, HL7 FHIR.	
Software/OS maintenance	As applicable, POC instrument should allow for routine software/operating system maintenance (automatically or manually)		
Data storage	The administrative institution (MoH or LASV programs) of sites where tests are deployed shall be able to specify or agree with the storage location of the device data without affecting the support and optimal use of the device.		
Data ownership	Test data, its management, and ownership must be in compliance with local regulations.		
Security and privacy	To facilitate use by health programmes in accordance with the laws, regulations, and policies in their settings and with best practices, the device shall provide configurable features so that personal data can be: a. gathered transparently to users and people who are taking the tests, including consent, b. collected and processed only for purposes compatible with the health programme's purposes, c. limited to what is relevant and necessary, d. collected accurately, e. stored in an identifiable form no longer than necessary and f. secured for integrity and confidentiality, with encryption at rest and in transmission.		
Language support	For each country in which the test is deployed, one popular language, such as the official language or de facto national language, and any language mandated by local regulatory or trade compliance requirements	Same as minimal plus additional languages that enable use by additional residents of the location of deployment	

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ANNEX 1. DEVELOPMENT OF THE TARGET PRODUCT PROFILE

The TPP development process was led by FIND's Pandemic Threats Program (TPP Working Group: Devy M. Emperador, Hanesh Chi Fru, Fritz Fonkeng, Mikashmi Kohli, Laura Mazzola), with advice from CEPI (Solomon Yimer Abebe) and WHO (Anaïs Legand).

The TPP Working Group completed initial drafts of the two TPPs in June 2024 using available information on the diagnostic landscape and priorities identified by the WHO R&D Blueprint Roadmap on Lassa fever. At the same time, stakeholders with expertise in Lassa fever management and control were identified to make up the TPP Development Group (Table 1) to provide feedback on the draft TPPs.

An initial meeting was adjourned in July 2024, presenting the draft TPPs to the TPP Development Group, followed by a Delphi-like survey to obtain consensus and arrive at two final TPPs for Lassa fever testing. In the first survey round, stakeholders were surveyed electronically to obtain input on the two TPPs. Survey participants were asked to rank their level of agreement based on a Likert scale ranging from 1 to 5 (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree). Individuals were asked to comment when scoring a characteristic at 3 or lower. Consensus was pre-specified at >=75% of responders agreeing with the proposed characteristics. Responses were collated, and revisions were discussed by the TPP working group to address survey respondents' concerns about characteristics with lower levels of agreement.

On 6 March 2025, FIND hosted a virtual TPP consensus meeting with the TPP Working Group to discuss disagreements on specific characteristics and agree on updated wording. The updated TPPs were then shared with the TPP Working Group for final reviews before finalizing and publishing on FIND's website in May 2025.

TABLE 1 **Members of the TPP Development Group with no conflict of interest, by affiliation at time of participation.**

NAME	AFFILIATION(S)	COUNTRY OF RESIDENCE
Anaïs LEGAND	World Health Organization	Switzerland
Daniel G. BAUSCH	London School of Tropical Medicine and Hygiene	Switzerland
Dhamari NAIDOO	World Health Organization – Southeast Asia Regional Office	India
Donald S. GRANT	Kenema Government Hospital	Sierra Leone
Emmanuel AGOGO	FIND	Nigeria
Harjyot KHOSA	ACTA-CS	India
Ifedayo ADETIFA	Nigeria Center for Disease Control (former)	Nigeria
Joel MONTGOMERY	US Centers for Disease Control and Prevention	United States of America
John KLENA	US Centers for Disease Control and Prevention	United States of America
Pierre FORMENTY	World Health Organization	Switzerland
Robert GARRY	Tulane University	United States of America
Solomon A. YIMER	Coalition for Epidemic Preparedness Innovation	Norway
Sylvanus OKOGBENIN	Irrua Specialist Teaching Hospital (former)	Nigeria
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