FIND
Diagnosis for all

TARGET PRODUCT PROFILES FOR NIPAH DIAGNOSTICS

MAY 2025

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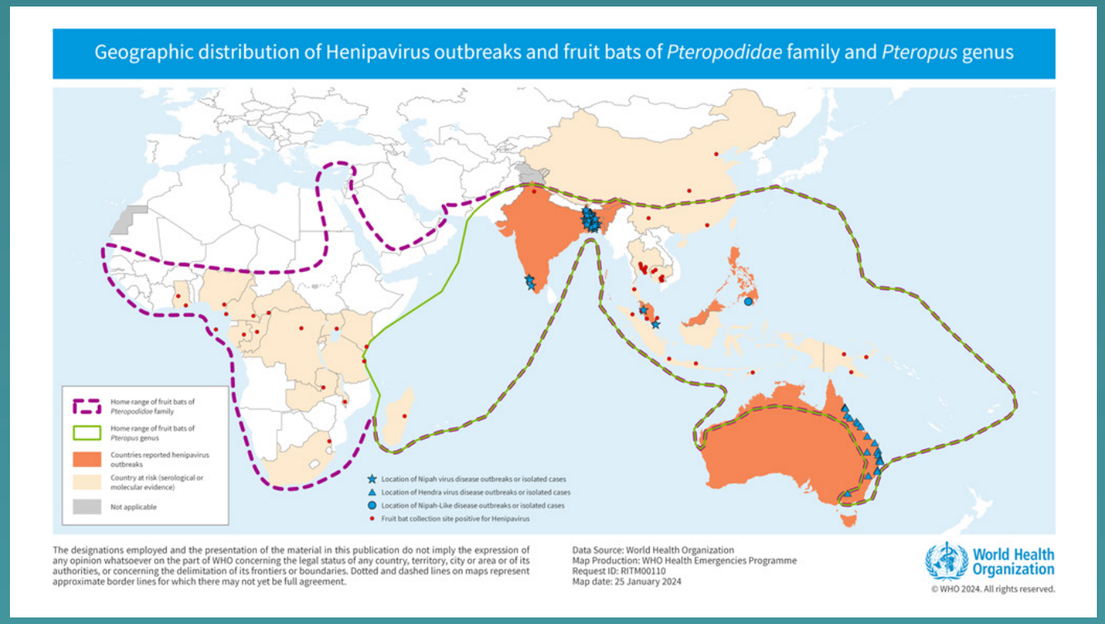
INTRODUCTION

Nipah virus (NiV) is an emerging zoonotic pathogen of significant global health concern due to its high case fatality rate, potential for human-to-human transmission, and lack of specific therapeutic or preventive measures [1]. First recognized in 1999 during an outbreak in Malaysia, NiV has since caused recurrent outbreaks in South and Southeast Asia, particularly in Bangladesh and India (Figure 1) [1, 2]. The virus, a member of the Henipavirus genus in the Paramyxoviridae family, is primarily transmitted from fruit bats (Pteropus spp.) to humans through direct or indirect contact, as well as through consumption of contaminated food [2, 3]. Human-to-human transmission has also been documented through contact with infected people and respiratory droplets [3].

FIGURE 1 **Geographic distribution of Henipavirus outbreaks and fruit bats of the Pteropodidae and Pteropus genus family [4].**



The historical outbreaks of NiV have highlighted its unpredictable nature and devastating impact on affected communities. The initial Malaysian outbreak, linked to pig farms, resulted in nearly 300 human cases and over 100 deaths, necessitating the culling of over a million pigs to contain the virus [2,5]. Since then, outbreaks in Bangladesh and India have demonstrated a different transmission pattern, predominantly involving direct bat-to-human or human-to-human spread, with case fatality rates often exceeding 70% [6]. The limited treatment options and lack of a licensed vaccine heighten concerns about its pandemic threat [7, 8].

Recognizing the urgent need for coordinated global action, the World Health Organization (WHO) included NiV in its Research and Development (R&D) Blueprint for priority pathogens [1, 9]. The R&D Blueprint aims to fast-track the development of medical countermeasures for high-risk emerging infectious diseases, including vaccines, therapeutics, and diagnostics.

The priority actions for Nipah virus under this framework focus on [10, 11]:

1. **Vaccine Development:**
   Accelerating the development of candidate vaccines, particularly those leveraging promising platforms such as viral vector and mRNA-based technologies.

2. **Therapeutics and Monoclonal Antibodies:**
   Advancing research into antiviral treatments and monoclonal antibodies that have shown preclinical efficacy.

3. **Diagnostics:**
   Enhancing laboratory capacity to develop rapid and reliable diagnostic tests to facilitate early detection and outbreak response.

4. **Epidemiological and Ecological Research:**
   Conducting in-depth studies on the virus's transmission dynamics, host reservoirs, and potential spillover risks.

5. **Public Health Preparedness:**
   Strengthening surveillance systems, response frameworks, and healthcare infrastructure in at-risk regions to mitigate future outbreaks.

Given the persistent threat NiV poses, concerted international efforts are crucial to developing and deploying effective countermeasures. This Target Product Profile (TPP) document outlines the essential characteristics and specifications for developing and implementing diagnostics to detect, respond to, and control NiV outbreaks.

LABORATORY DIAGNOSIS OF NIPAH VIRUS DISEASE

Diagnostics for Nipah virus rely on molecular and serological methods, each serving specific purposes in detecting and monitoring the disease.

Molecular techniques are preferred for detecting NiV due to their high sensitivity and specificity, particularly during the early stages of infection. Reverse transcription polymerase chain reaction (RT-PCR) is the most widely used molecular diagnostic method, targeting specific viral genes such as N, G, and P [12]. Real-time RT-PCR (qRT-PCR) enhances this approach by offering rapid and quantitative detection, which is crucial for early diagnosis [13]. Additionally, next-generation sequencing (NGS) plays a critical role in the surveillance of NiV by enabling whole-genome sequencing, which helps track viral evolution, genetic diversity, and outbreak dynamics [14]. There are few commercial molecular tests available, with one platform capable of near point-of-care testing [15].

Serological diagnostics are key in detecting past infections and understanding immune responses. Enzyme-linked immunosorbent assays (ELISA) are commonly used, with IgM-capture ELISA detecting recent infections and IgG ELISA providing insights into past exposure and seroprevalence [16]. Virus neutralization tests (VNT), including plaque reduction neutralization tests (PRNT) and pseudotyped virus neutralization assays, offer highly specific detection of neutralizing antibodies but require biosafety level-3 (BSL-3) or BSL-4 laboratories due to the hazardous nature of the virus [17]. Lateral flow assays (LFAs) provide a rapid, point-of-care alternative for serodiagnosis, particularly in low-resource settings, though they generally exhibit lower sensitivity than ELISA and VNT [18].

Despite the availability of molecular and serological diagnostic tools, significant gaps remain in the detection and management of Nipah virus infections:

1. **Limited Availability of Rapid Point-of-Care Tests:** The absence of widely available, field-deployable rapid tests hinders early case detection, particularly in rural and resource-limited settings where outbreaks often occur [19].

2. **Challenges in Differentiating from Other Febrile and Neurological Illnesses:** Nipah virus infection symptoms overlap with those of other viral encephalitis and respiratory infections, making clinical diagnosis difficult without confirmatory testing [1].

3. **Infrastructure Barriers for PCR Testing:** Many affected regions lack well-equipped laboratories, trained personnel, and reliable supply chains for PCR-based diagnostics, leading to delays in diagnosis and case confirmation [19].

4. **Need for More Accessible and Affordable Diagnostic Tools:** Current diagnostic methods are costly and often require centralized laboratory settings, making them impractical for widespread use in low-resource environments [20].

5. **Limited Surveillance and Early Warning Systems:** The lack of systematic surveillance programs and limited diagnostic coverage may contribute to underreporting and delayed outbreak detection, increasing the risk of larger outbreaks [21].

Investing in novel diagnostics, decentralized testing, and integrated surveillance systems is essential to address these gaps. Advancements in point-of-care testing and capacity building in affected regions will be critical in improving global preparedness and response to Nipah virus outbreaks.

PURPOSE OF THE TPP

Given the limited diagnostic landscape and high CFR of NiV, early presumptive diagnosis and laboratory confirmation were identified by stakeholders as the two highest priority use cases. The purpose of the TPPs is to support the development of new diagnostic tools for the following use cases:

- Point of care test for presumptive diagnosis of Nipah virus disease (TPP1)
- Confirmatory test for Nipah virus disease (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 NIPAH VIRUS DISEASE

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
SCOPE			
Goal	To provide the characteristics for a diagnostic test to detect Nipah virus (NiV) infection in a hospital setting, to initiate isolation and patient care during the same clinical encounter.	To provide the characteristics for a diagnostic test to detect Nipah virus (NiV) infection in peripheral settings, to initiate isolation, patient care, and timely referral to treatment centers.	
Target population	Adults and **children suspected** to have active NiV infection: • symptomatic patients, • contact with bats/palm sap, • endemic area/outbreak	Same as minimal and includes: close contacts of patients	Not for veterinary testing
Target user of test	Health care 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 sample	≤ $5 (Lateral flow assays)	≤ $3 (Lateral flow assays)	
	≤ $15 (Molecular diagnostics)	≤ $10 (Molecular diagnostics)	
Capital cost for the POC instrument	< US$ 2000	None required or compatible with existing platforms	
PERFORMANCE			
Test result	NiV detected/not detected	Quantitative output (Ct or viral load)	
Limit of detection (analytical sensitivity)	Equivalence to <10,000 copies/mL	Same as minimal	Copies/mL in clinical samples. May need to assess equivalent protein concentration for antigen/ antibody-based RDTs.
Linear range	None	None	
Inclusivity	NiV-B, NiV-I, NiV-M strains	Same as minimal and includes verification of Cambodian, Thai, and Philippine variants	
Cross-reactivity (analytical specificity)	No cross-reactivity with HeV other endemic febrile disease	No cross-reactivity with other endemic febrile diseases, including Japanese encephalitis	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
PERFORMANCE			
Diagnostic sensitivity	≥ 90%	≥ 95%	
Diagnostic specificity	≥ 90%	≥ 98%	
Non-actionable (indeterminate + invalid) results	< 5%	< 3%	
Multi-disease platform	No	Yes	
OPERATIONAL CHARACTERISTICS (1)			
Sample type	Plasma, serum, venous blood, oral fluid	Same as minimal and nasal swabs, fingerstick blood, urine	
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	This does not include the time for 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	Should require no more than current NiV assays at the peripheral level	Should require less than current rapid or molecular tests for NiV; reusable, recyclable, or non-plastic alternatives to disposable materials	
Waste disposal – infectious	Similar requirements for current NiV testing	Less than requirements for current NiV testing	
Third-party consumables	Separate kit(s) for sample acquisition, inactivation	None, all-inclusive kit	
Third-party instrumentation	Instrument for sample inactivation, centrifuge for plasma	None required	
Instrument	Fully automated instrument appropriate for POC	No instrument required	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (1)			
Size/weight	Benchtop/portable instrument, approx. 20cm x 20cm x 20cm; <10 kg	Disposable	
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. Routine calibration by trained operator using external pos/neg controls	No maintenance required; swap out or replace ancillary devices when needed 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 50°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	Same as minimal	
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 should not be required.		
Result documentation, data display	Visual readout – with an indicator for disease notification	Digital readout with ability to save, export results with prompt disease notification	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (2)			
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, 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. 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 NIV

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
SCOPE			
Goal	To provide the characteristics for a diagnostic test for confirmation of Nipah virus (NiV) infection at a reference laboratory.	To provide the characteristics for a diagnostic test for confirmation of Nipah virus (NiV) infection at a hospital laboratory.	
Target population	Patients suspected of having active NiV infection: Pre-screened population (e.g. positive NiV POC test)	Same as minimal and includes: • symptomatic patients • close contacts of patients	
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 sample	≤ $20	≤ $10	Can explore differential costs per region (e.g. high vs. low burden countries).
Capital cost for the instrument	< US$ 25,000 (automated platform)	< US$ 15,000 (automated platform)	Costs for new instrument.
	< US$ 5,000 (open source)	None (open source – existing platform)	
PERFORMANCE			
Test result	NiV detected/not detected with Ct	NiV quantitative copies/mL and Ct	
Limit of detection (analytical sensitivity)	< 1000 copies/mL	< 100 copies/mL	Based on clinical samples.
Linear range	10^3 to 10^6 copies/mL	10^2 to 10^9 copies/mL	
Inclusivity	NiV-B, NiV-I, and NiV-M strains	Same as minimal and includes verification of Cambodian, Thai, and Philippine variants, and other emerging variants	
Cross-reactivity (analytical specificity)	No cross-reactivity with other endemic febrile diseases.	No cross-reactivity with other henipaviruses, paramyxovirus, Japanese encephalitis virus, or other endemic febrile diseases	
Diagnostic sensitivity	≥ 95%	≥ 98%	
Diagnostic specificity	≥ 95%	≥ 98%	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
PERFORMANCE			
Non-actionable (indeterminate + invalid) results	< 5%	< 3%	
Multi-disease platform	No	Yes	
OPERATIONAL CHARACTERISTICS (1)			
Sample type	Plasma, serum, venous blood, oropharyngeal swab, nasal swabs, and oral fluid	Same as minimal and includes brain tissue 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	≥ 20 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 NiV tests at the reference lab level	Less than current NiV tests; reusable, recyclable, or non-plastic alternatives to disposable materials	
Waste disposal – infectious	Similar requirements for current NiV testing	Less than requirements for current NiV 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	
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	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (1)			
Maintenance and calibration	Preventative maintenance @1 year or >1000 samples; include maintenance alert. Daily external positive/negative calibration for quantitative result	No maintenance required; swap out or replace ancillary devices when needed 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 40°C, up to 70% humidity for up to 2 hours prior to use	Test components stable up to 50°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 6 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 **Sample ID and tracking**	Digital readout with ability to save and export results Software-enabled unique identifiers for assay and sample; accessory barcode scanner	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. Software includes unique identifiers for assay/cartridge and patient/sample with accessory or integrated barcode reader including barcode, RFID, or other.	

CHARACTERISTIC	MINIMAL	OPTIMAL	NOTES/COMMENTS
OPERATIONAL CHARACTERISTICS (2)			
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, 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 NiV 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	

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ANNEX 1. DEVELOPMENT OF THESE 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 NiV. At the same time, stakeholders with expertise in NiV 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 NiV 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 4 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.

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
Emily S. GURLEY	Johns Hopkins School of Public Health	United States of America
Dhamari NAIDOO	World Health Organization – Southeast Asia Regional Office	India
Emmanuel AGOGO	FIND	Nigeria
Harjyot KHOSA	ACT-A CS	India
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