

# WHO R&D Blueprint: Priority Diagnostics for Nipah

## Use Cases and Target Product Profiles

### Abstract

Documentation and coordination for diagnostic Target Product Profiles for Nipah as part of selected WHO R&D Blueprint and Roadmaps priority diseases in compliance with the WHO harmonized methodology



**This WHO TPP document should inform product developers, regulatory agencies, procurement agencies and funders on R&D and public health priorities, and is intended to facilitate the most expeditious development of products that address the greatest and most urgent public health need.**

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## 28 Abbreviations

Ag	Antigen
BSL	Biosafety level
CE	CE marking, Conformité Européene
CedV	Cedar virus
CO, S/CO	Cutoff, Sample vs. cutoff signal
EIA	Enzyme immunoassay (also, ELISA)
ELISA	Enzyme-linked immunosorbent assay
HeV	Hendra virus
IFA	Immunofluorescence assay
IgG	Immunoglobulin G (late immune response)
IgM	Immunoglobulin M (early immune response)
LAMP	Loop-mediated isothermal amplification
LAT	Latex agglutination test
LFA	Lateral flow assay
LMIC	Lower to middle income country
MCM	Medical countermeasure
mL	Milliliter
NAT	Nucleic acid test (also, nucleic acid amplification test)
NiV	Nipah virus
NPT	Near-patient (appropriate for hospital-adjacent laboratory)
NRA	National regulatory authority
POC	Point-of-care (appropriate for bedside and field testing)
RDT	Rapid diagnostic test (also, lateral flow assay)
RNA	Ribonucleic acid (viral nucleic acid)
RT-PCR	Reverse transcriptase polymerase chain reaction
TPP	Target product profile
uL	Microliter
USD	US dollar
WHO PQ	World Health Organization Pre-Qualification

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## WHO R&D Blueprint: Priority Diagnostics for Nipah

### Introduction

The WHO R&D Blueprint for Action to Prevent Epidemics establishes a platform for R&D preparedness that is intended to accelerate research and product development in advance of and during epidemics caused by the world's most significant infectious disease threats.<sup>1-4</sup> The R&D Roadmaps are intended to focus and catalyze international R&D effort to ensure the coordinated development of medical countermeasures (diagnostics, therapeutics, vaccines) thus reducing the time for new medical technologies and products to reach affected countries in a public health crisis. For diagnostics in particular, the emphasis of the R&D Roadmaps is toward acute and early detection of disease during outbreaks.

The Nipah Research and Development (R&D) Roadmap is the product of broad consultation with leading experts from Nipah-affected countries, international R&D diagnostic experts and other stakeholders for collaborative development of high priority medical countermeasures (MCMs) to prevent and control NiV outbreaks and disease in humans.<sup>5</sup> In 2018 and 2019, the Nipah R&D Roadmap was updated as a 5-year framework for identifying the vision, underpinning strategic goals, and prioritizing areas and activities for developing improved MCMs in diagnostics, therapeutics, and vaccines for NiV.<sup>6</sup> For diagnostics, the strategic goals were defined to reduce death and morbidity from NiV through interventions informed by rapid, reliable, and well-characterized tests, reagents and standards by 2020. The development and validation of *in vitro* diagnostic assays for NiV is a part of the collaborative development of high priority WHO R&D Roadmap MCMs to enable effective NiV infection prevention and control.

This NiV target product profile (TPP) document is intended to be a framework for facilitating the diagnostic development goals of the WHO R&D Roadmap for NiV, following the identification and prioritization of the diagnostic needs outlined in the R&D Roadmap. Use cases have been developed to define the critical functionality of diagnostic testing in the setting where it is most needed. The use case serves as a bridge to the TPP, a more detailed technical document for product development that describes the product's desired characteristics, features, and performance. High priority TPPs have been developed for the top priority NiV diagnostic test(s) and published to engage the diagnostic community for refinement and validation.

### R&D Roadmap: Strategic Goals and Milestones for NiV Diagnostics

The 2019 Nipah R&D Roadmap identified the primary challenges for NiV that can lead to delays in diagnosis, outbreak investigation, and response. For NiV, there is a need for diagnostic tests with high sensitivity and specificity for early detection of NiV infection in humans, particularly given its nonspecific (febrile) symptoms.<sup>7</sup> The Nipah R&D Roadmap identified the key priority actions needed to drive new NiV diagnostic test development, further developed below as use cases for how and where diagnostics should

be implemented, and target product profiles (TPPs) to define the specific performance characteristics for high priority NiV diagnostics:

- **Screening for active NiV infection.** Rapid screening is needed for suspected cases of active NiV infection, to support early outbreak detection and case management, and to ensure early implementation of infection control measures. There is a particular need for rapid first-line screening options, particularly in peripheral settings.
- **Confirmation of active NiV infection.** Rapid confirmatory testing is needed for active NiV infection, preferably with high sensitivity to all relevant NiV strains and specificity to differentiate from other febrile diseases, including henipaviruses, with rapid turnaround to initiate the appropriate medical countermeasures.

The R&D Roadmap set strategic goals thorough 2022 for the development of at least two point-of-care (POC) or near-patient (NPT) NiV diagnostics that are affordable, appropriately sensitive for first-line screening and for confirmation, and sufficiently robust for a range of peripheral settings.<sup>a</sup>

The Landmark milestones in the 2019 R&D Roadmap include (*in chronological order*):

- By **2019**, generate NiV diagnostic TPPs that identify the primary use cases and optimal and desirable characteristics to guide the development of promising NiV diagnostic assays.
- By **2019**, engage appropriate international and national regulatory authorities (NRAs) to inform commercialization pathways for NiV diagnostic assays.
- By **2021**, complete preclinical evaluation for at least two of the most promising NiV POC or NPT diagnostic assays that align with the TPP.
- By **2022**, complete field studies for at least two of the most promising NiV POC or NPT diagnostic assays that align with the TPP.

The NiV Roadmap also identified parallel efforts needed to support diagnostic test development and implementation, including 1) a specimen repository (held and maintained in the countries of origin) to assess and validate diagnostic tests, 2) international reference standards to calibrate diagnostic test performance, 3) validation of new diagnostics in endemic and at-risk geographic regions using defined performance and use criteria, 4) committed laboratory support for diagnostic test implementation, proficiency testing, and field monitoring (post-market surveillance), and 5) improved diagnostic preparedness in at-risk areas with appropriate deployment strategies for different geographic areas.

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<sup>a</sup> Decentralized diagnostics are often described as point-of-care (POC) tests if they can be used at the bedside or community setting, or as near-patient (NPT) tests if they are intended to be used in an adjacent hospital or clinic laboratory.

## NiV Diagnostics Overview

Nipah virus (NiV) is a highly pathogenic virus with potential for zoonotic and human transmission, with few options for treatment and prevention.<sup>8,9</sup> Early diagnosis of NiV infection is critical for containment of an outbreak and to facilitate appropriate patient care. NiV symptoms are similar to other febrile diseases including encephalitis with features of acute brain dysfunction.<sup>10,11</sup> NiV infection often occurs in rural locations with minimal laboratory facilities, however there are currently no tests appropriate for remote settings. Moreover, diagnostic laboratories in district level and tertiary hospitals lack the biosafety infrastructure required to handle highly fatal pathogens like NiV.

Diagnostic tests used to detect NiV include nucleic acid tests (NAT), enzyme-linked immunosorbent assay (ELISA), immunofluorescence assay (IFA), and virus isolation.<sup>12–14</sup> ELISA IgM or Ag have been used for first-line testing for active infection, followed by serum neutralization or PCR as a confirmatory test.<sup>5,17</sup> ELISA IgG is more useful in epidemiological and surveillance studies for retrospective diagnosis. Newer ELISAs enable pan-henipavirus (NiV and HeV) detection, as well as some differentiation between NiV and HeV.<sup>18,19</sup> Increasingly, PCR is used for first-line NiV testing where available. Virus isolation is not a first-line test in due to the challenges with containment and processing time.<sup>15,16</sup>

In general, ELISA tests can be run on the benchtop in a modest laboratory environment, while rapid diagnostic tests (RDTs) are simple enough to be used for rapid screening in field or community settings. Newer automated NAT platforms have been developed for decentralized testing, and have been successfully implemented in the field under outbreak conditions.<sup>20–23</sup>

**Standardization.** Currently there are few standardized or regulated tests for NiV. The majority of international labs use “in-house” assays rather than commercial kits, with significant variation in reagents, methods, and instrumentation.<sup>10,11</sup> Clinical validation of NiV assays and kits has also been a challenge due to a lack of NiV-positive specimens and reference reagents (including International Standards) for calibrating and harmonizing assays. Strain variation of NiV between and within countries is still an open question for diagnostic sensitivity.

**Containment.** Pathogen containment in the field is a major concern during a NiV outbreak. Henipaviruses (NiV and Hendra virus, HeV) are classified as a Biosafety Level-4 (BSL-4) pathogens which require the highest containment infrastructure of a reference laboratory.<sup>24,25</sup> Most NiV patients are identified in peripheral settings, which typically have modest-to-minimal support infrastructure. Peripheral testing would be better served by a minimal protocol for sample preparation under enhanced BSL-2 conditions. For field testing, a “best practices” approach could be served by providing infrastructure for viral inactivation prior to testing, e.g. patient samples aliquoted directly into lysis buffer or trizol, or heat inactivated prior to testing.<sup>12,14,24</sup>

## Use Cases for High Priority Nipah Diagnostics

Diagnostic use cases are helpful to identify the infrastructure and resources of the setting where tests are needed. Use cases typically identify the intended use, target patient population, personnel and skill level, and any limitations that may be imposed by the setting – characteristics which help identify the setting-appropriate diagnostic options. In this way, the use case serves as a bridge to the target product profile for the preferred diagnostic test's features and performance.

The Nipah R&D Roadmap recommended the development of diagnostics for rapid screening and confirmation of active NiV infection.<sup>b</sup> Use Case 1 describes the need for rapid detection of active NiV infection at a peripheral health center (highest priority setting), and Use Case 2 describes the need for standardized confirmatory testing performed at a central reference laboratory. These use cases are intended to highlight capacity and challenges for NiV testing during an outbreak. For example, decentralized or community-based testing can enable more rapid outbreak detection and intervention, however peripheral facilities often lack the infrastructure for higher complexity tests.

### Use Case 1: Rapid detection of active NiV at a peripheral health center or hospital

Use Case 1 describes the need for detection of active NiV infection at a peripheral setting during an outbreak, ideally for rapid screening of patients who meet the clinical definition of suspected NiV infection.<sup>25</sup> Diagnostic test results should be available within the same day for rapid case management, preferably while the patient is still present for triage.

Active NiV infection is generally screened by detection of NiV-specific IgM, NiV antigen (Ag), or NiV RNA. For peripheral settings, diagnostic options for screening can include ELISAs, lateral flow assays (LFAs), latex agglutination assays (LATs), and NPT/POC NAT platforms.

Use Case 1: Rapid detection of active NiV infection in a peripheral setting	
<b>Clinical Impact</b>	Rapid detection of active NiV infection to support early outbreak detection and case management, and to ensure early implementation of infection control measures Confirmation should identify NiV from other diseases including henipaviruses.
<b>Use Setting</b>	Primary care facility, near-patient hospital laboratory, community clinic Resources may be limited: benchtop, microcentrifuge, transfer pipets, refrigerator
<b>Target Population</b>	Patient meeting the clinical definition of suspect NiV, presenting to health care facility
<b>Test Demand (max)</b>	Up to 50 specimens per day at peak outbreak for screening Up to 20 specimens/day for confirmation

<sup>b</sup> Diagnostics for peripheral settings are often described as point-of-care (POC) tests if they can be used at the bedside or community setting, or as near-patient (NPT) tests if they are intended to be used in an adjacent hospital or clinic laboratory.

<b>Test Operator</b>	Laboratory technician (1-2 year certificate); doctor, nurse, healthcare worker
<b>Test Complexity</b>	Lab tech can reliably process moderate test complexity ( $\leq 3$ steps) but preferably minimal (sample addition only) processing Minimal to no capacity for manual sample preparation; preferably BSL-1 containment
<b>Turnaround Time</b>	Same-day or next-day test results (can be while-you-wait test)
<b>Appropriate Diagnostic Options</b>	Screening tests: RDT, ELISA, NPT/POC NAT Confirmatory tests: NPT/POC NAT

147 **Use Case 2: Confirmation of active NiV infection at a centralized reference laboratory**

148 Use Case 2 below describes the confirmation of active NiV infection in a centralized laboratory setting,  
 149 using specimens transported to the laboratory and processed in batch. Test results are generally available  
 150 within 1-2 days, though sample transport and return of test results from reference laboratory to clinic  
 151 often requires several days to weeks.

152 Active NiV infection can be confirmed by detection of NiV RNA or viral culture. For a reference laboratory  
 153 setting, diagnostic options for confirmation can include laboratory NAT, NPT/POC NAT assays, virus  
 154 isolation (if BSL-3/4 available), and serum neutralization assays. Typically virus isolation and neutralization  
 155 take days to weeks for processing.

Use Case 2: Confirmation of active NiV infection at a centralized reference laboratory	
<b>Clinical Impact</b>	Detection of NiV infection to support early outbreak detection and case management, and to ensure early implementation of infection control measures; may also be used for vaccine and therapeutic trials Quantitative result may indicate severity of infection
<b>Use Setting</b>	Reference laboratory (typically requires specimen transport) Resources typically include: biosafety hood, centrifuge, calibrated pipets, refrigerator, -20°C and -80°C freezers, network for specimen transport and storage BSL-3/4 containment not typical
<b>Target Population</b>	Patient meeting the clinical definition of suspect NiV, or screening-positive specimen transported from health care facility to reference lab Patient inclusion criteria for vaccine (NiV negative) or therapeutic (NiV positive) trials
<b>Test Demand (max)</b>	Up to 100 specimens per day at peak outbreak
<b>Test Operator</b>	Laboratory technician (2+ year certificate)
<b>Test Complexity</b>	Operators can reliably process high complexity ( $\leq 5$ steps) to moderate ( $\leq 3$ steps) process Capacity for manual sample preparation and processing in biosafety hood Capacity for daily/weekly external controls and calibration
<b>Turnaround Time</b>	Next-day test results (batch processing), may have 1-2 week turnaround to clinic



<b>Appropriate Diagnostic Options</b>	NPT/POC NAT, laboratory NAT, virus isolation, serum neutralization
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## Target Product Profiles for NiV Diagnostics

The target product profiles (TPPs) below present the highest priority diagnostic needs as identified in the R&D Roadmap: NPT/POC rapid screening for active NiV infection in a peripheral setting (**TPP 1**) and NPT/POC rapid confirmation of active NiV infection in a peripheral setting (**TPP 2**). TPPs provide highly detailed specifications for new diagnostic test development, within a range from minimal to optimal performance characteristics. A diagnostic test is acceptable as long as performance meets the minimal requirements, however the preferred diagnostic test is expected to meet most of the optimal performance specifications.

### TPP 1: NPT/POC test for rapid screening of active NiV infection

For peripheral settings, tests for first-line screening should require minimal infrastructure and training, and provide adequate precautions for safe specimen handling. ELISA tests can be implemented in some near-patient laboratories, though LFAs (specifically the cassette-based RDT format) better match the limitations for clinic or community-based screening. RDTs are commonly used for POC testing and are easy to use, but can be less sensitive than laboratory tests due to tradeoffs in simplicity. Presently there are no RDTs for NiV.

Henipaviruses have high homology across the G, N, and P proteins, making it difficult to differentiate between NiV, HeV, and Cedar (CedV) virus by antibody or antigen detection. A general henipavirus RDT could be useful, provided that confirmatory testing can provide greater test specificity.

Specification	Minimal Performance	Optimal Performance
<b>Intended Use</b>	Detection of NiV-specific IgM <u>or</u> NiV Ag in patients meeting clinical criteria for NiV infection	Detection of NiV-specific IgM <u>and</u> NiV Ag in patients meeting clinical criteria for NiV infection
<b>Kit Overview</b>	<b>ELISA kit</b> includes <u>most</u> assay components and consumables. User may supply some reagents (e.g. water or buffer) and some consumables for sample collection and preparation	<b>RDT kit</b> (single-use lateral flow immunoassay) includes <u>all</u> assay components and consumables required to test one patient in individually packaged, self-contained cartridge
<b>Analytes</b>	NiV-specific IgM <u>or</u> Ag capture using recombinant NiV proteins and antibodies, validated for NiV-B and NiV-M strains	NiV-specific IgM <u>and</u> Ag capture using recombinant NiV proteins and antibodies, validated for NiV-B, NiV-M strains along with Cambodian, Thai, and Philippine variants
<b>Time to Result</b>	≤ 4 hours	≤ 30 minutes
<b>Specimen Type</b>	Serum	Serum, plasma, whole blood or oral fluid

<b>Sample Input</b>	≤ 500 uL of specimen (serum)	≤ 50 uL of specimen (serum, plasma, blood, oral fluid)
<b>Sample Preparation</b>	Biosafe collection; Inactivation protocol for BSL-2 sample preparation (heat inactivation or lysis)	Biosafe collection; field Field-appropriate inactivation protocol (aliquot into lysis buffer or similar)
<b>Test Output</b>	Instrument readout: detected/not detected above threshold	Visual readout: detected/not detected visual readout compared to internal full process control line
<b>Limit of Detection</b>	Empirical cutoff (CO) threshold established for each assay run using positive control	NiV analyte signal detectable by human eye (empiric faint positive threshold)
<b>Linear Range</b>	Defined by “normal range” of positive specimen control dilution series	
<b>Clinical Sensitivity</b>	>90%	> 95%
<b>Clinical Specificity</b>	> 80% for NiV/henipavirus genus	> 90% for NiV/henipavirus genus
<b>Cross Reactivity</b>	Minimal but characterized cross-reactivity with other endemic or syndromic pathogens Anticipated cross-reactivity with other henipaviruses, henipah paramyxoviruses	
<b>Interfering Substances</b>	No interference for individual or mixtures of analytes, endogenous/exogenous substances	
<b>Assay Controls and Calibration</b>	External positive and negative controls	Full process internal control, external positive/negative controls (lyophilized, included in kit)
<b>Third-Party Consumables</b>	ELISA microwell plates, calibrated pipettors/tips	Timer, materials required for venepuncture or fingerstick
<b>Third-Party Instrumentation</b>	ELISA plate washer and reader	None
<b>Opened Kit Stability</b>	Test components stable at 18-30°C for 1 working day, reagents stable at 2-8°C until expired	Test components stable at 15-40°C for 1 working day
<b>Unopened Kit Storage, Shelf Life</b>	Kit reagent stability 2-8°C (or dry ice) for transport and up to 6 months storage	Test kit stability 2-30°C for transport and up to 12 months storage
<b>Biosafety/Disposal Requirements</b>	Biohazard disposal as appropriate for potentially infectious material	Specimens sealed within single-use disposable; biohazard disposal (as appropriate)
<b>Kit Certification</b>	ISO 13485:2016 certified	ISO 13485:2016 certified; approved by stringent regulatory authority (SRA)
<b>Price of Single Test</b>	≤\$10 USD at volume production	≤\$3 USD at volume production

174 **TPP 2: NPT/POC test for rapid confirmation of active NiV infection**

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Diagnostic tests are needed that can rapidly confirm active NiV infection in peripheral settings, with appropriate clinical validation and quality assurance of reproducibility. NPT/POC nucleic testing platforms have been implemented for confirmatory testing in decentralized settings, and employed for a more rapid turnaround in higher infrastructure settings. Presently there are no validated NPT/POC NAT tests for NiV. NAT assays can be used for tandem screening and confirmation, provided the assay targets two or more distinct genomic regions; distinct targets also reduce the risk of false negatives that can arise from genomic mutations. RT-PCR is the most common type of NAT test used for NiV detection,<sup>c</sup> and is used below (without limitation) as the NiV assay.

Specification	Minimal Performance	Optimal Performance
<b>Intended Use</b>	RT-PCR test for detection of NiV (main circulating strains) and differentiation from HeV	RT-qPCR test for detection and confirmation of NiV (main circulating strains) and differentiation from other henipaviruses, henipah paramyxovirus
<b>Platform Overview</b>	Semi-automated platform with manual sample preparation	Fully automated platform with integrated sample preparation
<b>Kit Overview</b>	Kit includes <u>most</u> assay components and reagents in an individually packaged, self-contained cartridge; user may supply some reagents and consumables for sample collection and preparation	Kit includes <u>all</u> components required to test one patient, and all assay reagents in an individually packaged, self-contained cartridge
<b>Throughput</b>	Up to 20 samples per 8-hour day	Up to 100 samples per 8-hour day, capacity for random access (spot testing)
<b>Analytes</b>	NiV RNA, validated for at least one genomic target for detection of NiV-B and NiV-M strains	NiV RNA, validated for at least 2 distinct genomic targets for detection of NiV-B, NiV-M strains along with the Cambodian, Thai, Philippine variants
<b>Time to Result</b>	<6 hours	<2 hours
<b>Specimen Type</b>	Plasma, serum	Blood, plasma, serum, /oral fluid, saliva, CSF, brain tissue
<b>Sample Input</b>	≤ 1 mL	≤ 100 uL
<b>Sample Preparation</b>	Manual or semi-automated (≤3 steps) sample prep for RNA extraction and purification; inactivation protocol for BSL-2 sample preparation (heat inactivation or lysis)	Automated sample prep (sample addition only); field-appropriate inactivation protocol (aliquot into lysis buffer or similar)

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<sup>c</sup> Loop-mediated isothermal amplification (LAMP) has also been recently developed for NiV<sup>26</sup>

<b>Test Output</b>	Qualitative: NiV detected/not detected above threshold	Quantitative: NiV copies/mL
<b>Limit of Detection</b>	1000 copies/mL	100 copies/mL
<b>Linear Range</b>	Qualitative only	10 <sup>2</sup> to 10 <sup>9</sup> copies/mL
<b>Clinical Sensitivity</b>	≥95%	≥98%%
<b>Clinical Specificity</b>	≥95%	≥98%
<b>Cross Reactivity</b>	No cross-reactivity with other endemic or syndromic pathogens (henipaviruses or henipah paramyxoviruses)	
<b>Interfering Substances</b>	No interference for individual or mixtures of analytes, endogenous/exogenous substances	
<b>Assay Process Controls</b>	Process may require external negative and positive control	Internal full process control integrated into assay to ensure sample integrity
<b>Assay Calibration</b>	Daily external positive/negative calibration for quantitative result	Weekly external positive/negative calibration for quantitative result
<b>Third-Party Instrumentation</b>	Centrifuge, calibrated pipettors, pipet tips, timer, miscellaneous lab consumables	Requires transfer pipettes only
<b>Opened Kit Stability</b>	2-8 °C for up to 3 hours prior to use	≤30 °C for up to 3 hours prior to use
<b>Unopened Kit Storage, Shelf Life</b>	-20°C (or dry ice) for transport, up to 6 months storage	No cold chain requirements for transport or storage: 12 months, 70% humidity from date of manufacture (based on stability studies) at up to 30°C
<b>Biosafety/Disposal Requirements</b>	Biohazard disposal as appropriate for potentially infectious material	Specimens deactivated and enclosed within cartridge; biohazard disposal (as appropriate)
<b>Dimensions</b>	Benchtop approx. 60 cm x 60 cm, <60 kg	Benchtop approx. 30 cm x 30 cm, <20 kg
<b>Power Requirements</b>	110-220 V AC, external/internal UPS	110-220 V AC
<b>Data Readout</b>	Visual readout via on-board or attached computer display	Same as minimal, including connectivity to data network for direct data transfer
<b>Training Required</b>	<2 days training for skilled laboratory technicians	<2 days for minimally skilled medical personnel (minimal laboratory training)
<b>Test Process Controls</b>	Process may require external negative and positive control	Internal full process control integrated into assay
<b>Calibration</b>	Daily external positive/negative calibration for quantitative result	Weekly external positive/negative calibration for quantitative result
<b>System Maintenance</b>	Daily preventative maintenance <30 min; Mean time between failures: 12 months or 10,000 tests	Weekly preventative maintenance <30 min; Automated alert for errors or warnings; Mean time between failures: 24 months or 20,000 tests

<b>System Calibration</b>	Annual service call for calibration	Remote calibration service
<b>Connectivity</b>	USB interface, Integrated Local Network (LAN) port, local printer port.	Same as minimal, also supports connectivity to data network with end-to-end encryption.
<b>Sample ID and Tracking</b>	None – manual sample identification and tracking	Software-enabled unique identifiers for assay and sample, with accessory barcode, RFID, or other reader
<b>Environmental Stability</b>	Operation within 15°C-30°C	Operation within 10°C-40°C
<b>Kit and Platform Certification</b>	ISO 13485:2016 certified	ISO 13485:2016 certified; WHO PQ or CE or FDA approved
<b>List Price of Platform</b>	<\$50,000 USD	<\$25,000 USD
<b>Price of Single Test</b>	≤\$30 USD at volume production	≤\$10 USD at volume production

## Conclusions

The WHO R&D Blueprint for Action to Prevent Epidemics and the R&D Roadmaps are intended to focus and catalyze international R&D effort for medical countermeasures, and reduce the time for new medical technologies and products to reach affected countries in a public health crisis. Following the initial work of identification and prioritization of the diagnostic needs outlined in the Nipah R&D Roadmap, the diagnostic development priorities for NiV have been further described in this document as Use Cases and Target Product Profiles.

The TPPs in this document are intended to catalyze the development and validation of diagnostic tests to detect active NiV infection, specifically for early detection of regional strains in the event of an outbreak. TPPs were developed for rapid screening and confirmation testing that could be implemented in decentralized settings, specifically for high quality and validated diagnostics appropriate for remote patient settings. Following internal WHO consultation and consensus, these top priority NiV diagnostic TPP(s) will be published to engage the diagnostic community for refinement and validation.

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