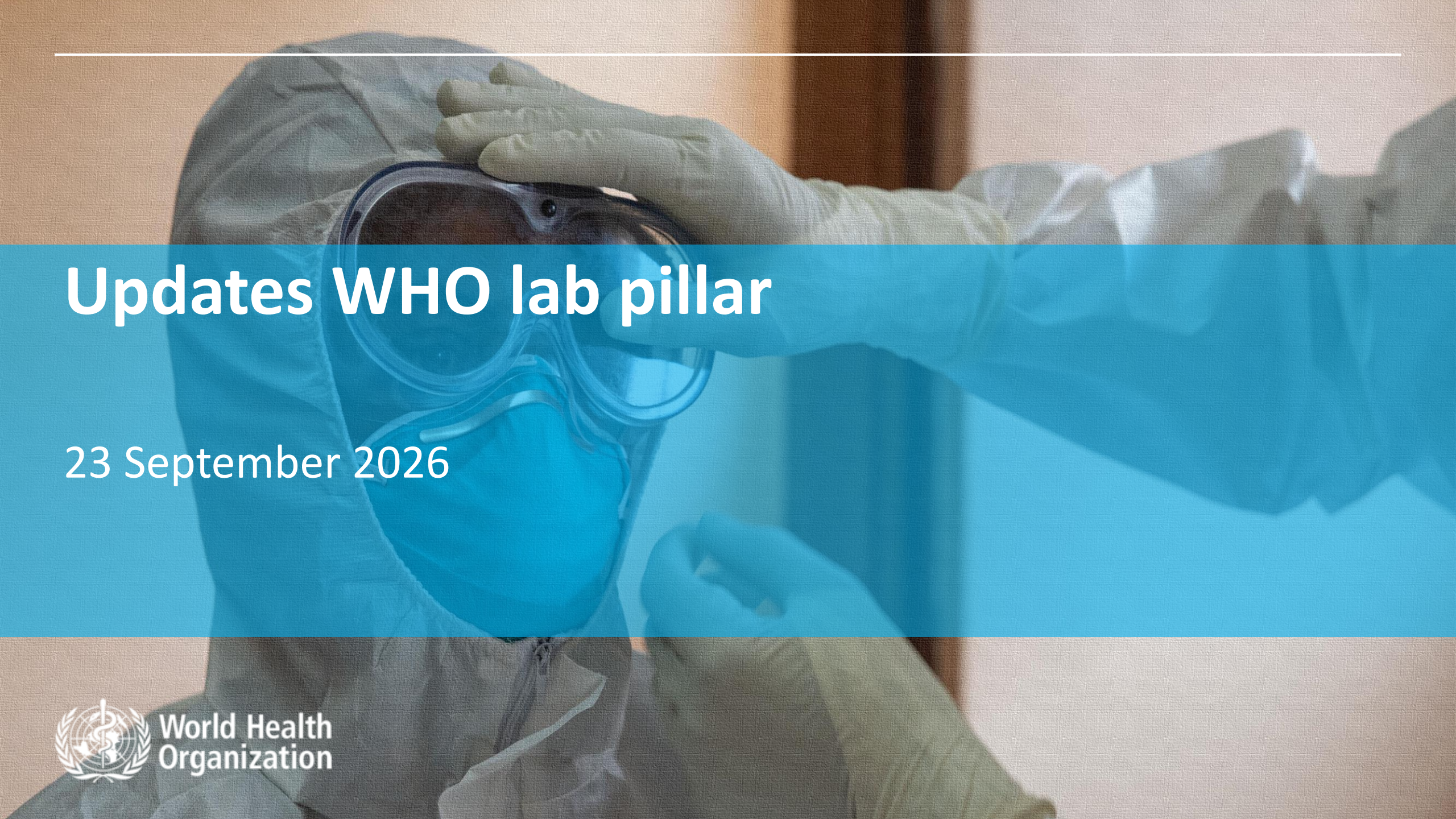


A person wearing a white protective suit and gloves is adjusting a blue respirator mask. The background is a light-colored wall.

Updates WHO lab pillar

23 September 2026

Laboratory scale up

26

testing sites in DRC (23 reporting)

>4 000

theoretical tests/day (3 700 in affected areas)

+10

additional testing sites expected

20

clinical laboratories planned



Democratic Republic of the Congo

- Capacity relies on labs with near-POC and/or open PCR platforms, with disparities across sites
- Decentralization continues; clinical testing scaling with beds (biochemistry and hematology analyzers)
- Genomic surveillance led by INRB, with sequences shared on public databases (Pathoplexus)



Uganda

- 4 testing sites
- Supplies and logistics support in place



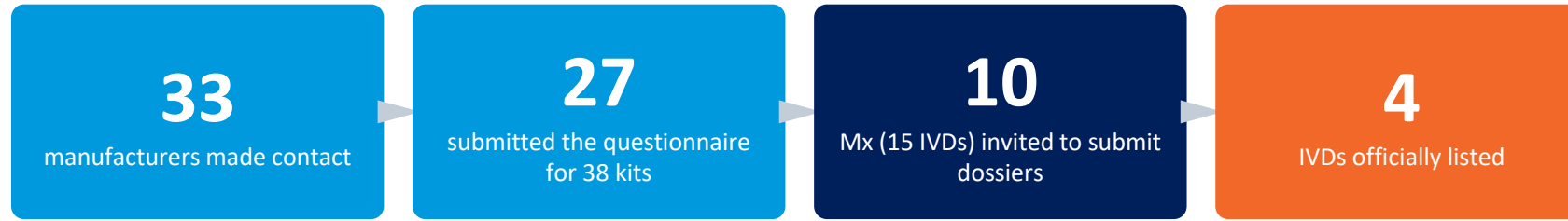
Neighbouring countries

- Readiness and preparedness activities ongoing in bordering countries

WHO Emergency Use Listing for BDBV nucleic acid detection

UPDATE September 09, 2026

Risk-based assessment on an essential set of quality, safety and performance data • EUL opened 26 May 2026 • 100% of pre-submission calls carried out



Four IVDs officially included in the EUL

- **Ebola Virus (EBOV) Real-Time RT-PCR Kit**
Shanghai ZJ Biotech
- **RealStar Filovirus Screen RT-PCR kit 1.0**
Altona Diagnostics GmbH
- **RADIONE Ebola/Marburg Detection Kit**
KH Medical
- **Xpert Hemorrhagic Fever Panel**
Cepheid

More information



World Health
Organization



HEALTH
FOR ALL

Partner coordination and global access

- Partner coordination efforts for diagnostics and supply, through i-MCM-Net diagnostics platform and continental IMST
 - Forecasting of Dx products needs
 - Online dashboard – partner support towards critical supplies
 - Market shaping of Dx products (led by CHAI)

Critical items overview by status

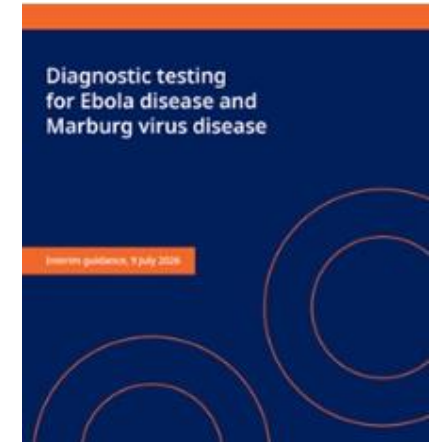
Category	Critical Item	00-Planned	01-Sourced	02-In transit	03-Arrived
Diagnostics, BVD	Extraction kit		18,964	4,000	2,500
	PCR Tests Ebola (BVD)	3,840	26,160		4,704
	Testing platform		7		
Lab supplies	Clinical Lab Supplies	26,000	10,682		1,868
	Lab equipment		14		3
	Sample transport	200	1,118	500	
	Sequencing		67		
	Swabs, dry transport		500		15,150
	Triple pack	173	306	15	850
	VTM + swab	3,000			7,375
	Zip bag, specimen				700

The expanding outbreak continues to increase demand for BVD diagnostic testing but also clinical testing, requiring further investments in specific equipment (eg. gloveboxes, biochemistry analyzers, hematology analyzers), consumables, trained and competent workforce, including biosafety officers who can provide oversight and support, and laboratory-clinical integration as well as a need for equipment to maintain electrical power access.

Normative guidance

Updated testing guidance

- Update of the WHO Diagnostic testing guidance for Ebola disease and Marburg virus disease, comprising recommendations on indications for testing, testing strategies, key considerations for quality, safe and secure testing, as well as decentralization and scale up of testing capacities.



5.4 Detection of viral antigen by rapid diagnostic test

Antigen rapid diagnostic tests (Ag-RDTs) may be available for some *Orthoebolavirus* species. They can be beneficial tools when used for post-mortem diagnosis during an ongoing outbreak, to detect cases and reduce burden on teams carrying out safe and dignified burials. Ag-RDTs are not currently recommended to confirm new outbreaks of orthoebolavirus or orthomarburgvirus infections, including in countries where there is not an ongoing outbreak, as this should be done by NAAT. Current data show lower sensitivity of Ag-RDTs compared with NAAT, with a risk of missing EBOD cases. For some tests there is a lack of data on their performance outside laboratory conditions. The performance of Ag-RDTs should be validated prior to use against the relevant *Orthoebolavirus* species and orthomarburgviruses. Results of Ag-RDTs should be interpreted with caution, considering clinical and epidemiological factors. At the time of publication of this guidance, no performance data were available for use of Ag-RDTs to test for *Orthoebolavirus bundibugyoense*.

Initiation implementation guidance to support testing decentralization

- Decentralization of testing continuum
- Key implementation considerations

Priorities

- Biosafety & inactivation
 - Validation of inactivation efficiency
 - Discussions on inactivation buffer composition and inactivation process – opportunities for standardization
 - Normative products
- TPPs
- EUL process expansion

Thank you

23_September_2026

Update on BRIDGE Access

Filovirus CORC Diagnostic Working Group meeting



AfricaCDC
Centres for Disease Control
and Prevention



BRIDGE-Access: ensuring equitable access to specimen for validation of BDBV Diagnostic Tools

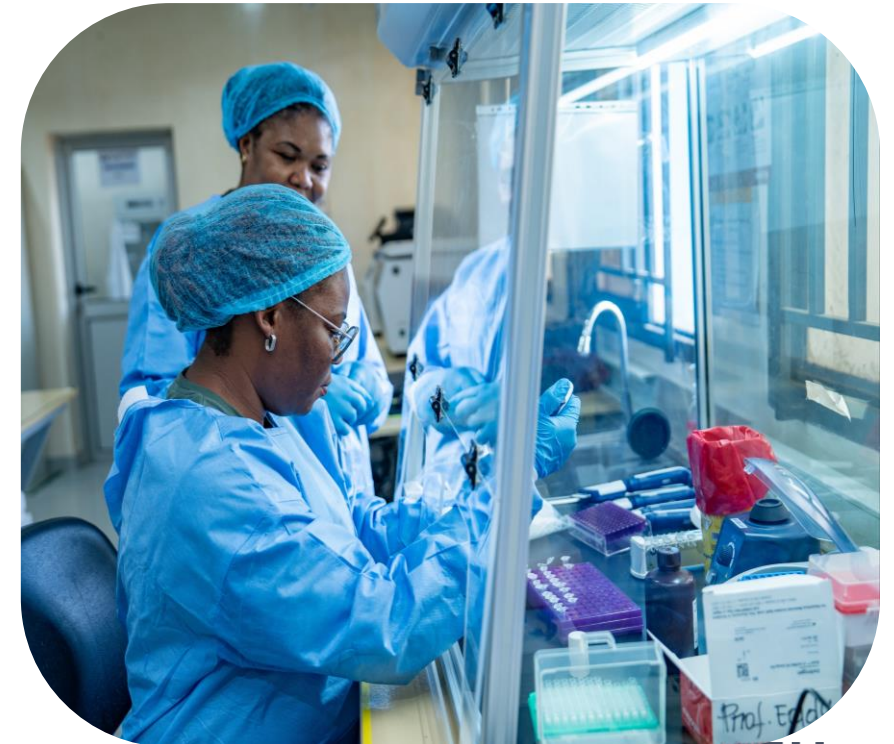


BRIDGE-Access

Bundibugyo Response for Improving
Diagnostic Global Equitable access

A pioneering partnership addressing validation equity directly in LMICs.

- **Strategic Consortium:** Lead by WHO, Africa CDC, and Unitaid, with partners, including PATH, CHAI and FIND have pooled resources to launch a vital Expression of Interest (EOI), now closed.
- **Operational Evaluation:** Inviting manufacturers of Ebola laboratory PCR kits, point-of-care molecular tests, and Ag-RDTs to validate (total of 66 submissions received, 7 near-POCTs and 11 AgRDTs and 21-based lab test shortlisted).
- **Equitable Access:** manufacturers signed an Access terms Commitments letter that ties participation to concrete, good-faith obligations: preferential access for affected countries, fair and transparent pricing amongst other terms



<https://africacdc.org/opportunity/seeking-manufacturers-of-ebola-laboratory-based-pcr-kits-pointof-care-molecular-tests-and-ag-rdts-to-participate-in-performance-evaluations-in-low-and-middle-income-countries/>

BRIDGE-Access: diagnostic evaluation update

Study Design for Initial Phase

- The initial phase of the BRIDGE-Access combines analytical testing, retrospective testing, and a planned prospective field study. These are taking place at various sites in DRC, Uganda, Germany, Switzerland, and the United Kingdom
 - **Analytical:** Charité, BNITM, UKHSA, Oxford, HUG, PATH
 - **Retrospective:** DRC (INRB Kinshasa) and Uganda (CPHL) sites
 - **Prospective:** DRC (INRB Bunia).

Retrospective study

- ERC approval granted on 26-August for start in DRC
 - Study launched in DRC on Monday, September 15th for the evaluation of the 7 near-POC/LC NAAT assays
- ERC approval for Uganda awaiting pending approval from local IRB

Analytical study & Prospective study

- Protocol being finalized for **analytical testing of Ag-RDTs and lab-based PCR kits** across the partner labs listed above.
- **Prospective study** protocol is in development in partnership with Professor Daniel Mukadi (Lab-pillar lead for the national IMST)

Next steps

- Continue procurement and shipment of assays to study sites (AgRDTs arrived/in process; lab-based kits procurement ongoing)
- Finalize the analytical study protocol.
- Continue development of protocol for prospective study.
- Will likely reopen EOI to collect information on additional products that have come to market since initial EOI



BRIDGE-Access: programme scope for Phase 1

Partners

WHO

Africa
CDC

Unitaid

CHAI

FIND

PATH

Aim: accelerate generation of performance data on selected Ebola diagnostic testing kits and products.

Products under evaluation

11

Ag-RDTs

7

Near-POC molecular

21

Lab-based PCR

Ag-RDTs: 5 clinical + analytical, 6 analytical-only.

Evaluation sites (additional sites may be added for prospective study)

Field

DRC: INRB

Uganda: CPHL

Analytical

HUG

Charité

PATH

UKHSA

BNITM

43

Submissions for LC NAAT/ nearPOCTs or AgRDTs reviewed

18

Submissions for LC NAAT/ nearPOCTs or AgRDTs selected

LC NAAT/ Near POCT

1. Cepheid (USA): **Xpert Hemorrhagic Fever Panel**
2. Coyote (China): **FlashDetect™ LyocartE Ebola virus Assay**
3. Molbio (India): **Truenat Ebola/Marburg**
4. SD Biosensor (South Korea): **Standard M10 Ebola/BDBV**
5. KH Medical (South Korea): **RADIONE Ebola/Marburg Detection Kit**
6. Abbott (USA): **mPIMA Filovirus Detect**
7. Mirai Genomics (Japan): **GenePad Smart BDBV**

AgRDTs (clinical + analytical)

1. SD Biosensor (South Korea): **Standard Q Antigen Test**
2. OraSure (USA): **OraQuick 2.0 Rapid Antigen Test**
3. Guangzhou Wondfo (China): **Wondfo Ebola Virus Antigen Test**
4. Diatropix (Senegal): **Ebola Antigen Test V6.1**
5. Naseni-Troment (Nigeria): **NCheckUp Ebola Rapid Antigen Test**

AgRDTs (analytical only)

6. BioSynchronicity (Canada): **C-Sync Pan-Ebola Antigen Test**
7. Zhejiang OrientGene (China): **Ebola Virus Ag Rapid Test**
8. Beijing Jinwufo (China): **JWF Ebola Antigen Rapid Test**
9. Intec (China): **Advanced Quality Ebola Antigen Rapid Test**
10. Chemtron Biotech (China): **Ebola Antigen Rapid Test Kit**
11. Shenzhen Reagent (China): **Ebola Virus Antigen Rapid Test Kit**

37

Submissions for lab-based PCR tests reviewed

21

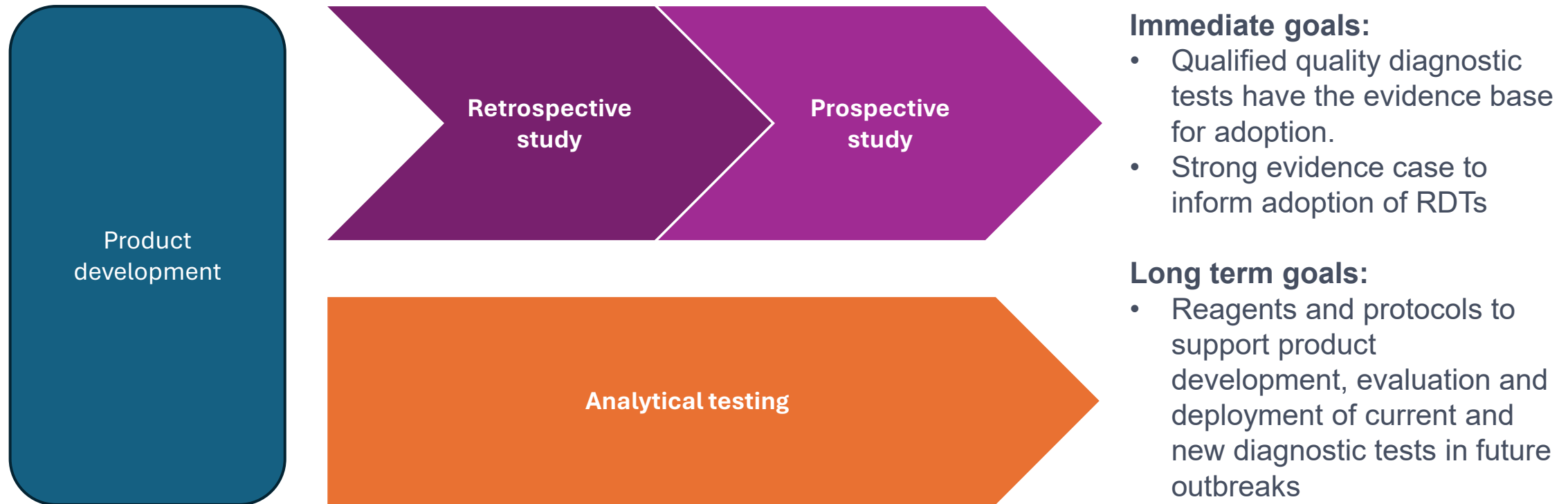
Submissions for lab-based PCR tests selected

1. Coyote Bioscience (China): **Pan Ebola & Marburg + Diff Ebola**
2. ZJ Bio-Tech / Liferiver (China): **Pan Ebola - no Diff**
3. BioGerm Medical Technology (China): **Pan Ebola – no Diff**
4. Tib Molbiol (Germany): **BDBV, Pan Ebola and typing**
5. Thermo Fisher Scientific (USA): **BDBV**
6. Orient Gene Biotech (China): **Pan Ebola – no Diff**
7. Zybio Inc (China): **Pan Ebola + Diff**
8. Altona Diagnostics (Germany): **BDBV**
9. KH Medical (South Korea): **Pan Ebola & Marburg – no Diff**
10. Fosun Diagnostics (China): **Pan Ebola + Diff BDBV**
11. HymonBio (China): **Pan Ebola – no Diff**

12. Sansure Biotech (China): **Pan Ebola + Diff**
13. Jiangsu BioPerfectus (China): **Pan Ebola + Diff BDBV**
14. Jiangsu Macro & Micro (China): **Pan Ebola + Diff**
15. Aldatu Biosciences (USA): **Pan Ebola – no Diff**
16. Primer Design (UK): **BDBV**
17. Naseni-Troment (Nigeria): **Pan Ebola - no Diff**
18. Capebio Technologies (South Africa): **Zaire, BDBV & Marburg + Diff**
19. Genes2me (India): **Pan Ebola - no Diff**
20. Huwel lifesciences (India): **Pan Ebola - no Diff**
21. Reme-D (Egypt): **Pan Ebola & Marburg + Diff Ebola vs. Marburg**

High level approach

Evaluation of near patient and point-of-care tests for BVBD/Ebola case detection



Prioritized near-patient and point-of-care tests for retrospective study

LC NAAT/ Near POCT

1. Cepheid (USA): **Xpert Hemorrhagic Fever Panel**
2. Coyote (China): **FlashDetect™ LyocartE Ebolavirus Assay**
3. Molbio (India): **Truenat Ebola/Marburg**
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Diagnostic performance evaluation on retrospective clinical specimens

Sites	Institut National de la Recherche Biomédicale (INRB)	Uganda Central Public Health Laboratory (CPHL)
Study PIs	INRB, CPHL, Africa CDC, WHO	
Study sponsor	PATH	
Number of specimens	50 confirmed PCR positive 75 confirmed PCR negative	30 confirmed PCR positive (from 20 patients) 100 confirmed PCR negative
Total	80 confirmed PCR positive specimens 175 confirmed PCR negative specimens	
Collection period	May, June 2026	May, June 2026 (last case identified June 16 th)
Origin of specimens	Bunia, Ituri Province	Specimens collected in Kampala
Specimen types available	Frozen whole blood (K2EDTA)	Frozen whole blood and match frozen plasma (/serum) (K2EDTA)
Reference test	RealStar® Filovirus Type RT-PCR Kit 2.0 (Altona Diagnostics GmbH, Hamburg, Germany)	

Diagnostic performance on prospectively collected specimens

Primary End points

1. Sensitivity and specificity of the index tests with 95% confidence intervals for the detection of BDBV compared to the reference standard (validated rRT-PCR) among symptomatic individuals with suspected BDV, stratified by specimen type (including **venous whole blood, capillary fingerstick, oral fluid, plasma, and/or serum, as applicable**).
2. Results agreement between specimen types for the reference assay and selected index tests, expressed as sensitivity, specificity, and overall percent agreement, with 95% confidence intervals.

Secondary End points

1. Sensitivity of Ag-RDTs stratified by viral burden with 95% confidence intervals.
2. Percent agreement of visually read Ag-RDT results between independent readers with 95% confidence intervals.
3. Invalid/error rates of index tests.
4. Operator-reported measures of ease of use and operational feasibility of index tests.

Study PI's: INRB, Africa CDC and WHO

Study sponsor: PATH

Funding: FCDO, UNITAID

PATH activities in analytical testing POC tests

1. Near-term Analytical evaluation of Ag-RDTs

- Sensitivity focus, detection of BDBV, and workflow/quality when used with human matrix

2. Support to clinical sites and reference testing

- Implement gold standard RT-PCR methods at PATH's lab to match partner labs to generate genome equivalence data on inactivated virus
- Establish antigen quantification to:
 - Link protein concentrations to genome equivalents
 - Link clinical RT-PCR data from clinical studies to tangible sensitivity targets and to guide test use
- Support coordination of these reference testing methods across labs

3. Identify gaps in reagents, direct resources towards those gaps to build accessible reagents for test developers and evaluators.

- Inactivated virus stocks, characterized by reference testing
- High sensitivity paired antibodies for protein detection
- Recombinant antigens from all species, high quality and structure/stability intact
- RNA-containing surrogates and other nucleic acid constructs to fully test specificity/inclusivity
- Current outbreak sequences represented

4. Analytical evaluation of rapid molecular diagnostics

- Sensitivity focus, detection of BDBV and other species, and replication of complete sample workflow
- Develop panels to quickly evaluate new rapid molecular assays, determine inclusivity across *Orthoebolavirus* species
 - Identify and fill reagent gaps