The diagnostic blind spot in the 2026 Bundibugyo Ebola disease outbreak: access gaps and priority actions

Introduction

The 2026 Ebola disease outbreak in eastern Democratic Republic of the Congo (DRC) and Uganda, caused by Bundibugyo virus (BDBV) — a species distinct from Ebola virus (EBOV, previously known as Zaire Ebola virus), which has dominated past responses — reveals a critical diagnostic blind spot in existing Ebola surveillance and testing systems. The decentralised test most widely deployed in past Ebola outbreaks, the Cepheid GeneXpert assay, detects only EBOV and does not identify BDBV.[1] In Bunia, the capital city of Ituri Province in the DRC, initial samples that tested negative on this assay were later confirmed positive by laboratory-based tests called reverse transcription polymerase chain reaction (RT-PCR) tests, which can detect a broader range of filovirus.[2] Experts believe that this gap between decentralised testing and circulating virus contributed to delays in detecting this outbreak.[3]

Since then, DRC authorities have expanded laboratory testing capacity for the diagnosis of BDBV. However, timely access to diagnostic remains a challenge. Most decentralised Ebola diagnostics, including lateral-flow rapid diagnostic tests (RDTs) used at community level and decentralised low-complexity closed platform molecular tests, were developed during or after outbreaks caused by EBOV, particularly the 2014–2016 West Africa epidemic. The World Health Organization (WHO) issued a target product profile (TPP) for Ebola diagnostics in 2015 and updated recommendations on Ebola and Marburg diagnostic in December 2024.[4,5,6] In practice, the available diagnostic tools remain disproportionately designed for EBOV, despite evidence highlighting the need for tests capable of detecting multiple Ebola viruses.[7,8]

Bundibugyo virus diagnostics: types and current availability

Diagnostics that could be used for BDBV virus operate across three main levels of the health system:

1. Rapid diagnostic tests (RDTs): Lateral-flow antigen-based RDTs can be used at community or field level, but only when appropriate biosafety measures are in place. No RDTs have been developed specifically for the BDBV. Existing tests designed for EBOV lack sufficient performance to reliably support surveillance or early clinical triage for other Ebola virus species.[9] In practice, their use in past EBOV outbreak responses has been largely limited to testing deceased patients to support safe and dignified burials while awaiting laboratory confirmation. All Ebola virus diagnostics, including RDTs, involve high-risk sample types and require full biosafety protective measures. This inherently limits the use of RDTs at community level compared to other outbreak contexts, such as COVID-19.

2. Decentralised molecular tests: Low-complexity nucleic acid amplification tests (LC-NAAT) and near point-of-care are two types of molecular assays that can be used in decentralised laboratory settings. These platforms typically require stable electricity and appropriate biosafety measures but are designed to be easier to use than conventional laboratory-based methods, often providing results through simplified "sample-in/result-out" systems. A few near point-of-care molecular platforms and several LC-NAAT platforms are developing tests capable of detecting BDBV.[10]

Decentralised diagnostics for BDBV in the DRC response

The LC-NAAT platform currently used in the DRC response is the RadiOne, developed by KH Medical Co., Ltd. (Republic of Korea), a medium-sized diagnostic company. RadiOne is a fully automated point-of-care molecular platform that integrates nucleic acid extraction, amplification and detection in a single instrument (RADIONE KM009).[11] The system was already installed and used in DRC following its evaluation for mpox. The RadiOne mpox test has received WHO Emergency Use Listing (EUL).[12]

Three qualitative tests capable of detecting BDBV are available on the RadiOne platform. All detect Ebola viruses — including EBOV, BDBV, Sudan virus (SUDV), Taï Forest virus (TAFV) and Reston virus (RESTV) — but differ in their ability to differentiate among different Ebola virus species and from Marburg virus.

The RADIONE Ebola Detection Kit (RP017) detects Ebola virus without distinguishing species, meaning a positive result confirms Ebola virus but does not identify the circulating species. The RADIONE Ebola/Marburg Detection Kit (RP033) detects Marburg and Ebola viruses and differentiates between the two. However, such as RP017, it does not distinguish Ebola species. Only the RADIONE Pan-Ebola Genotyping & Marburg Multiplex Kit (RP038) detects both Marburg and Ebola virus and enables Ebola species-level differentiation, identifying BDBV, SUDV and EBOV.

Given the limited availability of decentralised tests capable of detecting BDBV, the Africa Centres for Disease Control and Prevention (Africa CDC) and the Institut de Recherche Biomédicale (INRB) in Kinshasha, DRC, are currently conducting performance evaluations, comparing results from these tests to the results of RT-PCR tests while using RadiOne tests in clinical management.[13]

A few other LC-NAAT platforms are under development or nearing deployment but are not yet operational in the DRC.[14]

3. Centralised laboratory-based tests: Reverse transcription polymerase chain reaction (RT-PCR) assays are laboratory-based molecular tests used to detect RNA viruses by amplifying their genetic material. Several laboratory-based molecular tests capable of detecting BDBV are available in the region. These tests require high-level biosafety laboratories, specialised and reliable infrastructure, trained staff, and robust sample transport and systems for returning results. They often involve multiple instruments and processing steps and can process a higher number of tests during each run than the decentralised laboratory settings. The effectiveness of centralised laboratory-based tests depends on country-level logistics including distribution of testing materials to laboratories as well as laboratory capacity, sufficient trained personnel, and functioning sample referral and

result-return networks. Increasing kit availability alone does not resolve these operational constraints.

Global response and pipeline

The limited availability of diagnostics that detect BDBV at the start of the current outbreak has mobilised global and regional actors to accelerate the development and evaluation of tests capable of detecting multiple Ebola virus species. On 22 May 2026, Africa CDC recommended one decentralised LC-NAAT and three RT-PCR assays, developed using sequences from previous BDBV outbreaks.[15] On 26 May 2026, WHO re-opened an EUL, listing intended to be used primarily during public health emergencies of international concern or other public health emergencies, encouraging manufacturers to submit expressions of interest for assessing and listing of tests capable of detecting BDBV.[16]

To better understand the diagnostic landscape, the Foundation for Innovative New Diagnostics (FIND) launched an expression of interest (EOI) to update its DXConnect diagnostic directory.[17] As of 8 June 2026, over 90 manufacturers had responded, indicating that they have developed or are developing diagnostic tests to detect BDBV. However, most of these tests remain at early stages and require laboratory and clinical evaluation to independently assess their performance.[18]

To support the evaluation of new diagnostics, FIND, together with WHO, Africa CDC, Unitaid, and Program for Appropriate Technology in Health (PATH), issued a call for partners on 5 June 2026 to participate in laboratory and clinical evaluations of both molecular and antigen rapid diagnostic tests.[19] Africa CDC is coordinating these laboratory and clinical evaluations.

Diagnostic gaps in the Bundibugyo Ebola outbreak response

	Rapid diagnostic tests (RDTs) Antigen-based lateral flow	**Decentralised Molecular tests** Low-complexity NAAT/ Near point-of-care	**Laboratory-based molecular tests** RT-PCR molecular assays
Biosafety	Biosafety includes measures and materials (including Personal Protective Equipment (PPE), biosafety cabinets etc.) required to protect healthcare workers, community and environment from exposure to virus during sample collection, handling, testing and disposal.		
Centralisation	Decentralised		Centralised
Level	Community level	Decentralised laboratory facilities	National and regional reference laboratories
Use	• Safe and dignified burials	• Potentially quick results return closer to affected people • Confirmatory testing • Surveillance	• Confirmatory testing • Surveillance
Limitations	• Limited performance for surveillance and clinical triage for other Ebola species outbreak in the past • High biosafety risk severely limits community use	• Requires basic lab infrastructure, electricity, trained staff and biosafety • In high testing volume areas, decentralised testing may not be able to keep up with the demand.	• Require specialised labs with trained staff, biosafety, reliable electricity, functioning sample transport and result-return systems • Effectiveness depends on national laboratory capacity, logistics and referral networks, and not simple on kit supply.
BDBV Testing Availability	**CURRENTLY NO RDTS AVAILABLE**	**AVAILABLE**	**AVAILABLE**

Table: Comparison of Ebola diagnostic tests during the BDBV disease outbreak.

Critical diagnostic access gaps in the 2026 Ebola disease outbreak

Current diagnostic availability for BDBV reveals a diagnostic blind spot that has constrained timely detection and response to the outbreak. Widely deployed platforms at the outset of the response were not designed to detect BDBV and that led to severe delays in reaching out to affected people. This delay does not result from a single missing tool, but reflects a combination of factors, including a fragile laboratory system and infrastructure, a largely reactive R&D ecosystem and dependence on existing decentralised molecular closed platforms designed for EBOV and not adapted to BDBV.

Gap 1: Fragile laboratory system and infrastructure: Effective outbreak response requires a coordinated use of diagnostic tools across all levels of the health system, including tools for decentralised surveillance to enable rapid outbreak detection, decentralised molecular tests for clinical management and complex laboratory platforms for confirmation of results. However, the use of these tools requires a robust laboratory system. This includes sustained investment in infrastructure such as electricity, biosafety capacity, trained workforce, sample transport and effective systems for returning results. At present, investment in strengthening laboratory systems remains limited in comparison to investment in products and product development.

Capacity is further constrained by the limited number of laboratories with the highest biosafety level available to support the outbreak response and develop needed tests for viral haemorrhagic fever (VHF). There is no comprehensive global listing of biosafety level 4 (BSL-4) laboratories; however available evidence indicates that only three BSL-4 laboratories exist in Africa, located in Côte D'Ivoire, Gabon and South Africa.[20]

Gap 2: Reactive R&D ecosystem: A critical access gap for all outbreak diagnostics, including Ebola diagnostics, lies in the ecosystem surrounding research and development (R&D) for diagnostics. Funding remains largely reactive, increasing in response to outbreaks and declining once they are considered contained. This limits the time available for diagnostic development and results in incomplete development and performance validation of needed diagnostic tools. There is a lack of biobanks with the needed materials and equitable material-sharing provisions and of standardised protocols for analytical, laboratory and clinical evaluations that can be rapidly adapted for each response.[21,22] There is also no systemic inclusion of concrete access terms in contracts when public and philanthropic funding is used to support the R&D process.

Gap 3: Dependence on existing decentralised molecular closed platforms: The availability of decentralised molecular diagnostics is largely dependent on sample-in/result-out, closed platform systems. In these systems, only test kits manufactured and validated by the platform manufacturer can be used. This ties the availability of decentralised molecular testing to whether the manufacturer has developed, or is willing to develop, a test kit suitable for a specific pathogen. In the current response, the absence of a Cepheid GeneXpert test capable of detecting BDBV initially meant that widely deployed GeneXpert platforms could not be used for decentralised testing.

Although GeneXpert remains the most widely distributed decentralised sample-in/result-out closed molecular platform in the DRC and in Africa, there is an urgent need for greater investment in a diversified diagnostics system to avoid reliance on a single manufacturer and to respond swiftly to emerging future outbreaks.[23] New tests are under development for other decentralised closed systems that are less widely distributed than GeneXpert. However, these

require studies to understand their performance, and where the system is not already installed, additional time and effort is needed to procure, deploy and install machines, and train health staff to use them, delaying the ability to provide critically needed decentralised molecular testing.

A related limitation is the lack of decentralised molecular open platforms. These platforms would enable third-party development of diagnostic assays on systems already deployed in-country. This would reduce reliance on a specific diagnostic platform manufacturers and enable more rapid development of context-specific diagnostics.

Strategic access priorities to ensure sustainable access to diagnostics across time horizons

Immediate priorities

- Ensure availability of both critical testing materials and the systems required to use them, such as laboratory infrastructure (including biosafety measures), sufficient trained workforce, sample transport and effective systems for returning results.
- Prioritise the evaluation of additional antigen and molecular Ebola diagnostics capable of detecting BDBV during the current outbreak response. Publicly funded diagnostic evaluations should include clear access commitments to ensure tests are available and affordable for the current outbreak response and accessible for future outbreaks in the most affected countries.

Mid-term priorities

- Sustain the development pipeline for VHF diagnostics beyond the outbreak period through continued and dedicated funding to support longer-term preparedness.
- Adapt R&D funding approaches to align funding priorities with public health need, avoiding interruption of promising diagnostic development and ensuring tests developed during outbreaks are available in future for at-risk communities, regions and countries.
- Strengthen the enabling ecosystem for diagnostic development and early-stage validation for VHF beyond the outbreak phase, including coordinated efforts across national, regional and global stakeholders to establish biobanks and develop standardised protocols for analytical and clinical evaluations.

Long-term priorities

- Explore and support decentralised molecular open platforms that enable third-party development of diagnostic assays on systems already deployed in-country in order to reduce reliance on a single diagnostic platform manufacturer and enabling more rapid development of context-specific diagnostics.
- Clarify enabling conditions for open-platform models, including clear definitions, transparent contractual agreements between manufacturers and third-party developers, and evidence demonstrating system performance, such as sensitivity and specificity.

- Adapt regulatory systems at national, regional and global level to support open platform approaches, including by addressing limitations in current systems such as WHO Prequalification, which are currently not well suited to these models.

From reactive response to equitable access

The diagnostic blind spot identified in this brief reflects broader systemic challenges in ensuring timely and equitable access to medical tools needed for Ebola disease caused by BDBV. These challenges are closely linked to how research, development, and deployment are prioritised, financed and governed.

In our statement *Principles for equitable access to medical tools for Ebola disease caused by Bundibugyo virus*, MSF Access calls for a framework to strengthen access conditions and ensure preparedness is embedded throughout R&D and deployment processes.[24]

References

[1] International Pandemic Preparedness Secretariat. Ebola (Bundibugyo) Day 15: the status of diagnostics, investigational therapeutics and vaccines [Internet]. 2026 Jun 1 [cited 2026 Jun 17]. Available from: https://ippsecretariat.org/news/day-15-ebola-bdbv-2026/
[2] Mbala P. Initial genomes from May 2026 Bundibugyo virus disease outbreak in the Democratic Republic of the Congo and Uganda [Internet]. Virological.org; 2026 May 18 [cited 2026 Jun 17]. Available from: https://virological.org/t/initial-genomes-from-may-2026-bundibugyo-virus-disease-outbreak-in-the-democratic-republic-of-the-congo-and-uganda/1032
[3] Roundtable. Race to contain rare Ebola strain as cases explode in war-torn DRC: interview with Salim Abdool Karim (Special Advisor to WHO Director-General) and Ahmed Ogwell Ouma (CEO and President of VillageReach; former Deputy Director-General of Africa Centres for Disease Control) [Internet]. 2026 May 27 [cited 2026 Jun 17]. Available from: https://www.youtube.com/watch?v=AV5MJ9_hwjc
[4] Chua A C, Cunningham J, Moussy F, Perkins MD, Formenty P. The case for improved diagnostic tools to control Ebola virus disease in West Africa and how to get there. *PLoS Negl Trop Dis*. 2015;9(6):e0003734. Available from: https://www.who.int/tools/target-product-profile-database/item/the-case-for-improved-diagnostic-tools-to-control-ebola-virus-disease-in-west-africa-and-how-to-get-there-br-br--ebola-diagnostic-plos-neglected-tropical-diseases-7283
[5] Broadhurst MJ, Kelly JD, Miller A, Semper A, Bailey D, Groppelli E, et al. ReEBOV antigen rapid test kit for point-of-care and laboratory-based testing for Ebola virus disease: a field validation study. Lancet. 2015 Jun 25;386(9996):867–74. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)61042-X/fulltext
[6] World Health Organization. Diagnostic testing for Ebola and Marburg virus diseases: interim guidance, 20 December 2024 [Internet]. Geneva: World Health Organization; 2025 [cited 2026 Jun 17]. Available from: https://www.who.int/publications/i/item/B09221
[7] Bettini A, Lapa D, Garbuglia AR. Diagnostics of Ebola virus. Front Public Health. 2023;11:1123024. Available from: https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2023.1123024/full
[8] World Health Organization. Diagnostic testing for Ebola and Marburg virus diseases: interim guidance [Internet]. Geneva: World Health Organization; 2024 [cited 2026 Jun 17]. Available from: https://iris.who.int/server/api/core/bitstreams/e209d826-5f3
[9] Emperador DM, Kelly-Cirino C, Bausch DG, Eckerle I. Systematic review and meta-analysis of antigen rapid diagnostic tests to detect Zaire ebolavirus. *Diagn Microbiol Infect Dis*. 2024;111(1):116568. Available from: https://www.sciencedirect.com/science/article/pii/S0732889324003936
[10] Foundation for Innovative New Diagnostics (FIND). DxConnect test directory [Internet]. Geneva: FIND; [cited 2026 Jun 12]. Available from: https://www.finddx.org/tools-and-resources/dxconnect/test-directory/
[11] KH Medical. RADIONE (KM009) fully automated POCT-PCR [Internet]. Seoul: KH Medical; [cited 2026 Jun 12]. Available from: https://www.khmedical.co.kr/eng/products/detail/index.jsp?no=129
[12] World Health Organization. Mpox disease PHEIC – Emergency Use Listing procedure (EUL) for IVDs [Internet]. Geneva: WHO, 2026. Available from: https://extranet.who.int/prequal/vitro-diagnostics/mpox-disease-pheic-emergency-use-listing-procedure-eul-ivds
[13] Wawina-Bokalanga T, Amuri-Aziza A, Vercauteren K, Mukadi-Bamuleka D, Ngandu C, Kindrachuk J, et al. Diagnostic performance of RADIONE for diagnosis of BDBV. Lancet Infect Dis. 2026 Jun 17:S1473-3099(26)00321-X. Available from: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(26)00321-X/fulltext
[14] Foundation for Innovative New Diagnostics (FIND). DxConnect test directory [Internet]. Geneva: FIND; [cited 2026 Jun 12]. Available from: https://www.finddx.org/tools-and-resources/dxconnect/test-directory/
[15] Africa Centres for Disease Control and Prevention (Africa CDC). Molecular diagnostic tests (RT-PCR) for Ebola virus Bundibugyo strain [Internet]. Addis Ababa: Africa CDC; 2026 [cited 2026 Jun 18]. Available from: https://africacdc.org/download/molecular-diagnostic-tests-rt-pcr-for-ebola-virus-bundibugyo-strain/
[16] World Health Organization (WHO). EUL for IVDs – product questionnaire: Bundibugyo virus (BDBV) nucleic acid detection [Internet]. Geneva: WHO; 2026 May 26 [cited 2026 Jun 18]. Available from: https://extranet.who.int/prequal/news/eul-ivds-product-questionnaire-bundibugyo-virus-bdbv-nucleic-acid-detection
[17] Johnson M. WHO unveils official Ebola outbreak plan, including scale-up of point-of-care MDx system [Internet]. 360Dx (GenomeWeb); 2026 Jun 5 [cited 2026 Jun 12]. Available from: https://www.360dx.com/infectious-disease/who-unveils-official-ebola-outbreak-plan-including-scale-point-care-mdx-system
[18] Foundation for Innovative New Diagnostics (FIND). DxConnect test directory [Internet]. Geneva: FIND; [cited 2026 Jun 12]. Available from: https://www.finddx.org/tools-and-resources/dxconnect/test-directory/
[19] Foundation for Innovative New Diagnostics (FIND). Calls for partners [Internet]. Geneva: FIND; [cited 2026 Jun 12]. Available from: https://www.finddx.org/about-us/donors-and-partners/calls-for-partners/#ebola
[20] Muluneh AG, Moa AG, Lim S, MacIntyre CR. Mapping biosafety level 3 (BSL-3) and BSL-4 laboratories for public health threats reduction. *J Public Health (Berl)*. 2025. Available from: https://link.springer.com/article/10.1007/s10389-025-02492-3

[21] Broadhurst MJ, Kelly JD, Miller A, Semper A, Bailey D, Groppelli E, et al. ReEBOV Antigen Rapid Test kit for point-of-care and laboratory-based testing for Ebola virus disease: a field validation study. Lancet Infect Dis. 2015;15(9):1045–53. Available from: https://www.sciencedirect.com/science/article/pii/S1473309920304618
[22] Chaturvedi M, Köster D, Bossuyt PM, Gerke O, Jurke A, Kretzschmar ME, et al. A unified framework for diagnostic test development and evaluation during outbreaks of emerging infections. *Commun Med (Lond)*. 2024;4:263. Available from: https://www.nature.com/articles/s43856-024-00691-9
[23] Fletcher ER, Lustig S. New COVID-19 rapid diagnostic approved on 'GeneXpert' TB platform; could pave way for more testing in low- and middle-income countries [Internet]. Health Policy Watch; 2020 Mar 23 [cited 2026 Jun 12]. Available from: https://healthpolicy-watch.news/new-covid-19-rapid-test-approved-for-genexpert-tb-platform-could-pave-way-for-more-testing-in-low-middle-income-countries/
[24] Médecins Sans Frontières (MSF) Access. Principles for equitable access to medical tools for Ebola disease caused by Bundibugyo virus [Internet]. MSF Access; [cited 2026 Jun 12]. Available from: https://msfaccess.org/principles-equitable-access-medical-tools-ebola-disease-caused-bundibugyo-virus